

# POLISH PRESIDENCY OF THE COUNCIL OF THE EUROPEAN UNION 2025

# WHITE PAPER

Healthcare Policy Recommendations

Warsaw 2025

White Paper: Presidency of the Council of the European Union 2025. Healthcare Policy Recommendations

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# Security, Europe!

## Lech Wałęsa

Nobel Peace Prize Laureate (1983), President of the Republic of Poland (1990–1995)

"Security, Europe!" - the motto of the Polish Presidency of the Council of the European Union is particularly fitting in this challenging period, marked by the need to adjust many EU policies and growing global instability. Europe is facing the consequences of Russia's armed aggression against Ukraine, yet it remains steadfast and continues to reform. While military security is the top priority today, the Polish Presidency, following the course of history, will support efforts to strengthen European security in all its dimensions: external, internal, economic, informational, energy, food, and health.

In 1980, when we fought in solidarity for people's rights to truth and freedom, and in 1983, when I received the Nobel Peace Prize as Chairman of Solidarity, we were fighting for great ideals. Yet, we never lost sight of the issues that mattered to each of us – personal security, the right to work, education, and proper healthcare. I was honoured for my unwavering commitment to resolving conflicts through negotiation and cooperation rather than violence. Our struggle ended in victory, but today, more than four decades after Solidarity's push for change, in a different reality, we must ensure that people's rights to freedom and peace remain unshakable. The European Union's policies must safeguard every aspect of well-being for its people and all those residing within its territory.

In the area of health security, every citizen of Poland and the European Union has the right to health, which means equal access to healthcare, clean air, and safe water and food. The right to health and work is fundamental to the functioning of a modern society and a prerequisite for economic development. During the Polish Presidency, we once again have the opportunity to reflect on the true meaning of solidarity in health – what we can achieve together, how we can help, and how we can act for the benefit of society. When asked when they feel secure and optimistic about the future, most people say that health is the most important factor – because everything else can be earned. A real crisis begins when health deteriorates to the point where work is no longer possible. Only with a healthy society can we ensure sustained economic growth for Poland and the European Union.

That is why I support prioritising preventive healthcare. Every doctor knows that prevention is better than treatment, and every economist knows that preventing a crisis costs far less than dealing with its consequences. We must work together to respond swiftly and effectively to health challenges that hinder the growth and holistic development of children and young people, particularly in the area of mental health disorders. Patients understand how crucial pharmaceutical security is – meaning reliable access to the medicines prescribed by their doctors. Speed is essential in implementing reforms and taking action, which is why another priority is digitisation in healthcare – ensuring that information can reach everyone, whether on their phone or via email.

I commend all the changes and reforms in health policy that have been implemented in Poland over the past two decades of our membership in the European Union. Thanks to advances in medicine, we are living longer and in better health. I speak from experience – thanks to outstanding doctors and following their recommendations, despite my age and many life challenges, I can continue to be active in public life.

I encourage you to read the White Paper Polish Presidency of the Council of the European Union 2025. Healthcare Policy Recommendations, which, thanks to the contributions of many authors, provides an excellent summary of the needs of both the Polish and EU health sectors on the path to ever-improving healthcare. Above all, I wish everyone good health, as it is the foundation of a fulfilling life in society, family, and work.

pro / Lech Wałęsa



# **Opening Remarks**

## Małgorzata Bogusz

President of the Board of the Institute for Social Policy Development, member of the European Economic and Social Committee, member of the Council of Non-Governmental Organisations for the Polish Presidency of the Council of the European Union

#### Dear Readers,

It is with great satisfaction that I present to you this White Paper, *Polish Presidency of the Council of the European Union 2025. Healthcare Policy Recommendations*, prepared by the Institute for Social Policy Development. This document brings together recommendations from over a hundred healthcare experts, formulated in the context of Poland's ongoing presidency of the Council of the European Union. It is the result of intensive effort and close collaboration among distinguished experts, public authorities, clinicians, representatives of the healthcare sector, and civil society stakeholders.

The Polish Presidency of the Council of the European Union marks a pivotal moment for the future of the EU, particularly in the area of health security. As a Member State, our role is to strengthen the position of healthcare within the EU and to improve the health and quality of life of its citizens.

Over the past decade, Poland has made significant progress in healthcare, introducing innovative organisational, financial, and technological solutions. However, we still face numerous challenges that require our attention and action, particularly in ensuring patient access to high-quality medical services, which urgently needs improvement.

This White Paper presents a comprehensive set of recommendations for Poland's health agenda during its presidency of the EU Council. It provides analyses and proposals in key areas, including preventive healthcare, challenges in child and adolescent psychiatry, digitisation in healthcare, women's health, securing the supply of medicines and expanding their production within the EU, the need to combat health-related disinformation, and the impact of environmental changes on the well-being of Europeans.

This document is the result of consultations and collaboration that began well before Poland assumed the presidency. Our recommendations are based on a thorough analysis of the current situation, trends, and needs in the field of public health within the European Union.

We believe that the proposals presented in the White Paper will contribute to shaping effective and innovative health policies at the European level. Our goal is for the Polish Presidency to serve as a catalyst for positive changes in the EU healthcare system, contributing to the development of a crisis-resilient system accessible to all EU citizens.

We emphasise that the success of our presidency will rely on close cooperation and dialogue with EU institutions, civil society, and other Member States. Therefore, we encourage all stakeholders to take an active part in the discussion and implementation of the presented recommendations.

I am confident that this White Paper provides a strong foundation for further efforts at the ministerial, governmental, and European levels. I hope it will provide valuable guidance and information to all stakeholders developing health policies at the EU level.

I would like to express my gratitude to everyone who contributed to this document and invite you to read it and work together towards a healthier and stronger European Union.

Mengal Day

Małgorzata Bogusz



# From Priorities to Conclusions: Preparing and Implementing the EU Council Presidency Based on the Experience of the 2011 Polish Presidency

# Prof. Bolesław Samoliński MD PhD

Chair of the Subcommittee on Health Priorities during the Polish Presidency of the Council of the European Union 2011, Head of the Department of Environmental Hazard Prevention, Allergology, and Immunology at the Medical University of Warsaw, Chair of the Council of the Discipline of Health Sciences, Medical University of Warsaw

In January 2025, Poland assumed its second Presidency of the Council of the European Union. It is worth reflecting on the experience we gained in 2011, when we held the Presidency for the first time.

Three years before the start of the Polish Presidency, a Presidency corps was established. As part of this corps, we received language training in specialist terminology, EU organisation and EU law. We also met with the staff of DG SANCO (Directorate General for Health and Consumer Protection) of the European Commission. This period was a valuable learning experience. Thanks to our meetings with the European Commission and with Denmark, the second country in our Presidency trio, we gained an understanding of how the EU priorities and the conclusions adopted based on them should be shaped.

In preparation for the presidency, we have begun to form a corps and conduct negotiations. Deputy Minister Adam Fronczak contacted me with a proposal to lead the Public Health Working Party at the European Commission. The Working Party is a body that brings together delegations from all EU countries to negotiate common positions on conclusions arising from the priorities presented by individual Presidencies. Each time, this Working Party is chaired by a representative of the country holding the Presidency of the EU. The conclusions adopted by this body represent a form of EU soft law. When accepted unanimously by the health ministers of the EU Member States, they set the directions for the work and tasks of the European Commission, as well as for the Member States themselves. They are not as binding as the directives adopted by the European Parliament, but they can still influence international policy and individual national policies. In our case, this concerned health policies, while in other ministries, it pertained to their respective sectoral policies.

The proposed responsibility for leading such a politically significant committee was difficult for me to accept. A person with a legal and political background, preferably accompanied by relevant experience, was a better fit for the role. Accordingly, I agreed to support the work of the Working Party as its vice-chair, serving as deputy to the chair, Agnieszka Czupryniak. It is worth noting, however, that this role only became meaningful after the presidency began.

During the preparatory period, the leadership of the Ministry of Health established a Presidency team along with a subcommittee dedicated to health priorities. The team was a body composed of experts and representatives from various departments involved in the Presidency. This team was led by Deputy Minister of Health Adam Frączak. The subcommittee on priorities was tasked with developing proposals for topics for the Presidency – specifically, priorities to be discussed by EU Member States during that period – and suggesting potential conclusions for the Council of the European Union. Therefore, it was composed primarily of experts. In this respect, the Polish approach to preparing for the Presidency differed from the organisation of Presidencies in other EU countries, as the leadership of the Ministry of Health entrusted the development of substantive foundations to leading experts in medicine and pharmacy. Only then did the policymakers make strategic decisions on specific issues included in the Presidency's agenda.



In the second year before the presidency, we started training courses in which international experts taught us the art of negotiating in English. After passing an exam, we received a certificate confirming our full membership of the Presidency Corps. The meticulous selection process for the Corps was executed with great attention to detail.

Each ministry has a team with specialised training, capable of conducting negotiations and understanding current events in the European Union. Thanks to our strong preparation, we are now on equal footing with major EU countries during our presidency.

Within the Ministry of Health, the roles within the Presidency team were divided as follows:

- The Foreign Cooperation Office handled administrative tasks, including preparing documents, drafting reports, conducting diplomatic correspondence, receiving delegations, etc.
- The Department of Public Health provided support to the subcommittee on priorities. The entire operation was managed on behalf of Minister Ewa Kopacz by Secretary of State Dr. Adam Fronczak.

Several months prior to taking office, the trio presidency, comprised of Poland, Denmark, and Cyprus, held meetings. The trio's agenda was developed in three meetings. It is the countries of the trio themselves that must initiate such meetings. It is customary for the first meeting to be arranged by the country in charge of the first presidency, which in this case is Poland.

By the time we attended the trio's meetings, we had already reached agreements with the European Commission. Initially, Poland focused on discussing healthcare systems and the issues within them. We intended to approach this Presidency by addressing the difficulties we face in the country. However, the European Commission warned us that during the Presidency, we must focus on international issues and general factors related to public health, such as prevention, which can be initiated, implemented, and promoted at the international level. Health policy-making is an independent competence of the Member States. On the other hand, health promotion policy – focused more broadly on prevention and disease avoidance – has an international or Community dimension, and these issues should be our priority.

The selection of priorities for a Presidency is a compromise between the country holding the Presidency and the European Commission. The European Commission often proposes that the Presidency address issues that have already been priorities for other Presidencies or are priorities of the Commission itself. The Presidency Trio also sets common priorities. However, they are general in nature and serve to unify the Trio. The other members of the Trio have no influence on our decisions – just as we have no influence on decisions regarding their priorities. The European Commission responds by indicating the extent to which it considers our topics appropriate and suggesting potential proposals. Our subcommittee was tasked with consolidating the proposals into a coherent whole so that the Minister of Health could make appropriate decisions in consultation with the Standing Committee of the Council of Ministers. Ultimately, the health priorities for the Polish Presidency of the Council of the European Union were presented only at the start of the Presidency.

Within the subcommittee on priorities, we met approximately once a month for a year and a half to discuss these priorities. Initially, there were 15.

The Presidency commenced with an informal meeting of health ministers in Sopot at the start of July. "Old age begins in childhood" was the motto of the Polish Presidency. It served as a unifying theme, bringing together many other topics and issues. It was also acceptable to the entire Trio.

The Presidency plays a significant role in promoting the country. Our preparations in this regard met the expectations of both national and international politicians. The priorities were not only carefully selected but also diligently implemented during the six months of our Presidency of the Council of the European Union.

During the launch of the Presidency, certain aspects of the priorities are presented, while other issues are also included on the agenda. In Sopot in 2011, a presentation on hearing disorders and the prevalence of hearing disorders in Poland and around the world was delivered, prepared by



Prof. Skarżyński. We showed that this is an important communication problem, an educational problem and one that has a major impact on the quality of life and development of the individual and society. In an adjoining areas of the conference venue, stands were set up where delegates could have their hearing tested, enhancing the overall appeal of the event.

The implementation of the priorities begins immediately after the Presidency's inauguration ceremony. Each priority entails a specific expert and political debate at the international level. Meetings with MEPs were also frequently organised. On this basis, agreements are often reached in the public health working party. We organised two conferences at the Medical University of Warsaw: one on chronic respiratory diseases in children and another on brain diseases. Both were connected to the priorities of the Polish Presidency. For the conference I organised, we invited leading experts from the European Union, representatives of the European Commission and the European Parliament, as well as a Secretary of State at the Ministry of Health. We outlined the problem, based on which we, as an expert team established in Poland, had already developed proposals for conclusions. We then brought the topic to the Public Health Working Party. The group convened in Brussels systematically, with an average of one meeting per week. Sometimes we have also invited certain experts to the meetings in order to convince the participants, i.e. the representatives of the individual health ministries of the Member States, to include certain comments in the conclusions.

We also had to go back and forth a bit between the delegations and negotiate. In this way, we prepared conclusions that were accepted by the working groups.

The meetings of the Public Health Working Party were centred around the participation of Member States' delegations at a shared table. Following preliminary agreements, delegations returned to their governments to obtain new guidance and possibly approve the agreements reached within the working party. Further negotiations, guided by these guidance, were conducted at subsequent meetings. This continued for several months until the conclusion of our Presidency.

The conclusions were adopted at the end of the Presidency. Every provision in the conclusions required the approval of all Member States.

The conclusions included a preamble outlining their subject matter. The next step was to present the problems and tasks for the Member States, the European Commission, and those shared by both the Member States and the European Commission.

At the last meeting of the EU Council at the end of the presidency, the EU health ministers voted in favour of these conclusions.

The impeccably prepared and executed Polish Presidency of the Council of the European Union was regarded as the best presidency since the adoption of the Lisbon Treaty.

For Poland's 2025 EU Presidency, when identifying possible priorities to be proposed, it is worth noting that each EU country monitors epidemiological phenomena differently. In my opinion, this is a fantastic topic to lead on after the pandemic. However, constant monitoring of certain phenomena is an essential necessity. All public statistics in the world are always inaccurate. That is why epidemiology research studies, for example, are carried out to determine the actual state of the epidemic or in relation to lifestyle or infectious diseases in individual regions. This could be an interesting topic to address at EU level.

When discussing digitisation as a priority, it would be beneficial to specify it further. We should strive to unify health IT systems across the Union to establish shared databases as a scientific foundation for analyses supporting health policy. The unification of information systems may also facilitate improved care for Union citizens, irrespective of their place of residence. Allergologists have already developed a system where, for example, a Ukrainian patient can visit any doctor in the European Union, open an app, complete a health questionnaire in their own language, and the doctor reads it in theirs. Such solutions could also be used in cardiology, gastrology, urology, neurology, and so on.



Another priority we could propose to Europe is the establishment of a care system for rare diseases. This is an ideal topic for international cooperation. Collecting data on a rare disease in a single centre enables the development of improved diagnostic and therapeutic models through centralised data collection. This makes it possible to identify specific characteristics that facilitate earlier diagnosis.

During a Presidency, there is often an effort to conclude topics that were initiated, but this is not always achievable. For example, the issue of cross-border healthcare has spanned multiple presidencies. This is why cooperation with the European Commission is crucial, as the EC Ensures the continuity of priorities.

It is important to remember that the Council of the European Union is chaired by the Prime Minister of a presidency country. He or she leads the presidency. However, each ministry has its own agenda, its own working parties and its own ministerial meetings in the EU Council. Accordingly, the Prime Minister approves the priorities of the various ministries, but each ministry works independently.

At a certain stage of the presidency, it also makes sense to start preparing a certain summary well in advance. This is a kind of performance review mechanism – so that what has been identified as a priority can be monitored and remembered later if a new funding opportunity arises – for example from Horizon Europe. In that way, we can see how the work done within the priorities is later reflected in concrete results – be it in the form of regulatory changes, the funding of some programmes or more generally in the shaping of European policy.



# Poland's Second Presidency of the Council of the European Union

# Adam Jarubas PhD (Social Sciences)

Member of the European Parliament, Chair of the Committee on Public Health (SANT)

The Polish Presidency of the EU Council in 2025 presents a challenge distinct from the one we faced in 2011. Stable governance since 2007 enabled us to effectively prepare priorities and flagship initiatives, secure funding, and plan ahead for the staff of Poland's first Presidency. Two years before 2011, those who were to work during the Presidency were aware of their likely responsibilities and actively preparing for them. Preparations for the 2025 Presidency de facto began following the change in government after the elections on 15 October, during a protracted transfer of power – effectively commencing in 2024. Consequently, we face the significant challenge of catching up to fully seize the opportunities presented by this critical period in the EU and to prepare for potential challenges.

What appears to work in our favour is the different context in which the EU, its institutions, and particularly the European Commission, will operate compared to 2011. In 2011, we assumed the Presidency of the Council of the EU at an advanced stage of ongoing legislative work, with tripartite negotiations underway and topics already initiated by the Commission in its third year, being implemented in both the Council and the European Parliament. This time, the electoral calendar, the formation of the 10th Parliament following the elections in Poland on 9 June, and in other EU countries starting as early as 6 June, along with the continued selection of the new European Commission's composition - which may extend until late autumn or early winter 2024 – mean that the 2025 Polish Presidency will effectively coincide with the launch of the new Commission. Therefore, in principle, it will not be a period when legal acts proposed by the Commission are already under consideration, let alone a time for trilogue negotiations seeking compromises between the positions of the European Parliament and the Member States in the Council, for which the Presidency is responsible. On the one hand, this may result in a reduced burden on the Presidency and provide an opportunity to focus on issues that are priorities from our perspective. On the other hand, it may also limit the chances of influencing legislative negotiations at critical moments.

At the same time, this period provides Poland with an opportunity to exert more or less formal influence on the new European Commission's setting of its goals and strategies for the next five years. As this will be the focus of the European Commission during this time, it is an opportunity that must be effectively utilised. For Poland, as well as the entire EU, amid today's security challenges stemming from Russia's aggression, the strengthening of European defence, the defence industry, deterrence capabilities, and NATO's European component will be crucial. This is particularly important given the risk of increased US isolationism in the event of a change in the White House or greater American engagement in the Indo-Pacific. However, beyond defence potential, security encompasses other aspects such as energy, raw materials, technology, and health. By improving the capacity and effectiveness of healthcare, we enhance our resilience: it was the level of resilience that, during the COVID-19 pandemic, determined and differentiated the incidence threshold at which countries were forced into lockdowns, impacting economies among other areas. On the other hand, conflicts in regions from which we import medicines or the substances used in their production, as well as disruptions to transport routes, directly threaten the health and lives of Europeans. For these reasons, and in my capacity as Chair of the Subcommittee on Public Health of the European Parliament, I will focus on what could potentially lie ahead for the Polish Presidency of the EU Council in this area.

In the area of health, the Polish Presidency should ensure, among other things, that the Commission builds on the achievements of the Beating Cancer Plan, which we successfully initiated in 2021,



by implementing similar holistic strategies. These strategies, which may partly overlap, should include a focus on prevention for cardiovascular diseases, the leading cause of death in the EU, related diabetic conditions, and neurodegenerative diseases, which should be addressed in light of imminent scientific breakthroughs that may enable better treatment. In all these areas, beyond the treatment itself, attention must also be directed to the socio-economic aspects of care, including long-term care and maintaining professional activity. This issue is strongly advocated by the Netherlands, among others. Netherlands. Our priority should also include the adoption of a European action plan for mental health, addressing the situation of children and young people, inequalities in access to care across the EU, and concerning trends such as the harmful impact of algorithms and online content.

In setting the agenda for the new Commission, it is essential to remember that the next term of office will coincide with the negotiation and adoption of the next multiannual financial perspective for 2028–2034. It will be crucial to build support not only for the preservation but also for the substantial strengthening of the EU4Health programme, established for the first time during the current seven-year period, alongside the ongoing integration within the Health Union. It will be equally important to secure adequate funding for the EU research programme Horizon Europe, including additional health missions alongside the cancer mission. It will also be crucial to design the Cohesion Funds in a way that facilitates the elimination of disparities in access to health services, both between and within EU Member States, particularly between urbanised areas, smaller towns, and rural regions. As I often say, health depends on DNA, but it should not depend on your postcode. In all these areas, and particularly in remote and less accessible regions, the use of digital health technologies, including e-health, will be crucial. This aligns with the Digital Decade and Digital Compass strategy for 2030, both in the context of research and in optimising the efficiency of healthcare system resources. To achieve this, the EU must continue its efforts by implementing the already adopted regulations, such as the European Chips Act for microprocessor production, the Gigabit Infrastructure Act for access to high-speed networks, the Data Act and the European Health Data Space for secure data exchange, the Artificial Intelligence Act for the safe use of AI in research and healthcare, and the Artificial Intelligence Liability Directive, to be completed in the next term.

Bearing all this in mind, it should be emphasised that the 2025 Polish Presidency of the EU Council will not be entirely "exempt" from legislative work, including trilogues, as legal acts initiated during the current term will remain on the table at various stages of progress.

Key instruments in the area of health will include the directive and regulation comprising the pharmaceuticals package, the most significant reform of the EU drug market in 20 years. We must recognise that there are currently more than 6,000 rare diseases in Europe, affecting up to 30 million Europeans, for which no cures are available. In many cases, therapies exist for adults, but there are no paediatric applications. Europe is grappling with drug shortages, and medicines available in some countries only become accessible in others after two or more years. According to estimates by the European Commission, patients in western and larger Member States have access to nearly 90% of newly approved medicines, whereas in eastern and smaller Member States, this figure is as low as 10%. Antibiotic resistance and the shortage of new antibiotics pose an increasing threat.

The Subcommittee on Public Health (SANT) of the European Parliament, which I chair, was among the bodies involved in working on the package. I also coordinated work on the package within the Polish delegation of the EPP Group, tabling amendments, organising conferences with stakeholders in Poland and Brussels, engaging in dialogue with rapporteurs, and recommending voting directions to secure a good, compromise negotiating mandate for the European Parliament. In this work, I sought to strike a balance between fostering innovation in new medicines by guaranteeing temporary exclusivity for their sale in the EU and facilitating the efficient entry of cheaper alternatives to reduce costs for patients and healthcare systems across EU Member States. This is particularly relevant in the case of existing but extremely expensive orphan drugs



for rare diseases, which remain difficult to access due to their high cost. Conditional extensions of exclusivity will depend on serving the public interest, such as providing medicines for unmet medical needs, paediatric medicines, or orphan drugs for rare diseases; offering more effective medicines; finding new applications for existing medicines; conducting research and development of medicines within the EU; and developing new antibiotics.

Despite the adoption of the European Parliament's negotiating position on the directive and regulation of the pharmaceuticals package during the penultimate plenary session, the Council has yet to adopt the general approach required to commence trilogue negotiations with the EP and bring the legislative process to a final conclusion. Although the development of such a position is among the priorities of the current Belgian Presidency, which concludes in June this year, trilogues can only commence after the formation of the new European Parliament and European Commission. Even if the process begins in December, the majority of the work will, in practice, be carried out in 2025 under the Polish Presidency of the Council of the EU. This would represent a kind of relay in the area of health, with the current Belgian Presidency, where health is a priority, passing the torch to the incoming Polish Presidency.

During this term, despite the adoption of the list of critical medicines and the launch of the Critical Medicines Alliance, the European Commission did not manage to present a legislative initiative for the Critical Medicines Act. By employing, among other measures, solutions similar to those in the Chips Act and allowing for a broader application of state aid by EU Member States, this regulation would aim to retain or restore EU-based production of medicines and essential substances used in their manufacture, such as active pharmaceutical ingredients (APIs), as well as other medical resources, where Europe is currently overly reliant on imports. Following the surge in demand and supply chain disruptions caused by the Covid-19 pandemic, and as we navigate turbulent times marked by international tensions, we must strengthen pharmaceutical sovereignty within the EU. At the same time, this could serve as an economic stimulus for countries such as Poland, which boasts a thriving pharmaceutical sector, a highly educated workforce, and competitiveness within the EU. Poland's position was highlighted in a study commissioned on my initiative by the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI), published in March 2023. In addition to Poland's cost competitiveness, the study emphasised the importance of automation and the use of AI in production within the framework of Industry 4.0 for facilitating the relocation of production from Asia. Both trends should be promoted within the EU, and Poland should benefit from both.

The Commission is currently consulting on the Critical Medicines Act, including through the Critical Medicines Alliance, and is conducting the required impact assessment. Just as the current Belgian Presidency, as part of its priorities, succeeded in persuading the Commission to launch the Critical Medicines Alliance, the Polish Presidency, in cooperation with the European Commission, could prioritise submitting a draft Critical Medicines Act, initiating work in the Council, and, in parallel, in the European Parliament, while making as much progress as possible on these efforts. What should be emphasised is that the Critical Medicines Act must not distort competition within the single market. This includes ensuring European Commission oversight and considering solutions such as those proposed in the Enrico Letta report to the Council in April this year on strengthening the competitiveness of the single market. For example, the report suggests establishing a common mechanism where a portion of national state aid funds would flow into a shared fund and be redistributed. This would counteract distortions in the single market caused by the "big can do more" phenomenon, while supporting key industries critical to the entire EU, such as the production of APIs and medicines more broadly. The work on the Critical Medicines Act could, therefore, serve as another example of a relay in the area of health between the Belgian Presidency and the Polish Presidency in 2025. In addition to prioritising these issues during its term, Belgium was the first to present a study to the Council in May 2023, highlighting to the European Commission the need for such legal solutions. This initiative received the support of 23 EU Member States, including Poland.



Although formally a Polish Presidency, it is a Presidency of the Council of the European Union, and in undertaking these actions, the government must not overlook the importance of cooperation with the European Parliament. Resolving many issues at the stage of work in the European Parliament leaves less to be negotiated in the Council and simplifies trilogues. In the European Parliament, a broader debate with stakeholders can be facilitated, and non-legislative positions supporting the Presidency's priorities can be initiated. Finally, the European Parliament is the ideal forum to remind Europe of our economic potential and to promote Poland as a brand. It is often stated in the European Parliament that such cooperation yielded positive results in 2011. Therefore, it is important to ensure that MEPs elected in the upcoming European Parliament elections are open to cooperation with the Polish Presidency.

Poland now faces its second experience with the Presidency of the Council of the EU-a significant challenge, but also a renewed opportunity to take responsibility for the future of the European community, to demonstrate that the EU is ours as well, and to reaffirm our return to the mainstream of decision-making on the continent after 15 October 2023. I am confident that we will make the most of this opportunity.

# **Health as a Security Priority**

## Magdalena Sobkowiak-Czarnecka

Undersecretary of State, European Union Affairs Unit, Chancellery of the Prime Minister

While health has not traditionally been considered a core aspect of the European Union's security policy, the COVID-19 pandemic has clearly demonstrated that health security is an integral part of overall security. That is why we have chosen the motto *Security, Europe!* as the main message of the Polish Presidency. It was evident to us that health security would be one of the pillars of this broader security. The pandemic acted as a magnifying glass, highlighting the importance of international cooperation in managing health crises. By holding the Presidency of the Council of the EU, Poland now has a real opportunity to underscore the significance of this area and propose concrete solutions to strengthen European health care systems.

One of the key priorities is to strengthen European cooperation in health crisis management. Joint actions at the EU level, such as the coordination of vaccine procurement and joint pandemic response strategies, have demonstrated that the Union can act effectively when its members work together. There is a clear need to develop a common European system for monitoring and responding to health threats. This is particularly important given the growing challenges posed by climate change, extreme weather events, hybrid threats, and cyberattacks, all of which have significant implications for public health.

#### Mental health of Children and Adolescents

Another key priority on the agenda of the Polish Presidency is the mental health of children and young people. The Covid-19 pandemic has affected not only physical health but also significantly worsened young people's mental well-being. Social isolation, remote learning, and uncertainty about the future have contributed to a rise in issues such as depression, anxiety, and eating disorders. Additionally, the rapid development of digital technologies and their overuse among young people are emerging as new challenges to their mental well-being.

As a country committed to ensuring the well-being of future generations, Poland places the mental health of children and adolescents among its priorities. During its Presidency, we will propose initiatives aimed at enhancing psychological support in schools, expanding access to specialist psychological care, and promoting mental health education programs. Cooperation with other EU countries in this area could bring significant benefits for the entire Union.



#### **Digital Transformation of Healthcare**

The Polish Presidency has the opportunity to accelerate the digital transformation of healthcare in the EU. The Covid-19 pandemic has highlighted the importance of implementing modern technologies in healthcare, including telemedicine, electronic health records, and artificial intelligence for diagnostics. Poland may propose initiatives to facilitate the exchange of best practices among Member States and boost investment in digital health solutions.

Ensuring pharmaceutical security is also crucial in the context of digitisation. During its Presidency, Poland will take steps to diversify drug supply chains and support pharmaceutical production within the EU. This is particularly important in an era of global crises that may disrupt the supply of medicines and medical equipment. Strengthening local drug production and enhancing the resilience of healthcare systems are priorities that can significantly contribute to the health security of EU citizens.

#### Cooperation with the Trio and the European Commission

Poland, as the holder of the Presidency of the Council of the EU, operates within the so-called Trio, alongside Denmark and Cyprus. This collaboration allows Poland to introduce initiatives that will be continued by the subsequent presidencies. In the context of health and security, Poland will make full use of this opportunity to propose long-term strategies that will shape the work of the EU Council in the years ahead.

Cooperation with the European Commission will be essential for the success of the Polish Presidency. Poland will aim to align its health and security priorities with the broader objectives of the European Union. Joint efforts to strengthen healthcare systems, enhance mental health, and improve health crisis management could become a lasting legacy of the Presidency.

#### For a Healthier Europe

Poland, presiding over the work of the Council of the European Union, has a unique opportunity to shape European policies in the areas of health and security. In the face of challenges such as the Covid-19 pandemic, the youth mental health crisis, and the need for the digital transformation of healthcare, Poland can take the lead in developing solutions that will have a tangible impact on the lives of Europeans. By making responsible use of this opportunity, Poland will contribute to building a stronger, healthier, and more secure Europe.

# A Stronger, Healthier, and More Resilient Europe

## Katarzyna Kacperczyk

#### **Undersecretary of State, Ministry of Health**

The Polish Presidency, which began in January 2025, is first and foremost an opportunity – an opportunity for Europe and for Poland. In these challenging times, we must focus on consistency, vision, and the ability to engage in dialogue to develop solutions that benefit Europe as a whole, its individual Member States, and Poland itself.

That is why I welcome the creation of this White Paper, which we will discuss today. This is a comprehensive document that highlights what is - and what should be - our most pressing priority.

Upon assuming the presidency of the Council of the EU in January 2025, Poland set out to strengthen cooperation and enhance health security across Europe. Our efforts focus on four key areas: health security, digitisation of healthcare, health promotion and disease prevention, and the mental health of children and adolescents.



Health security is the foundation of the European Union's stability and development. The Polish Presidency is committed to enhancing the EU's pharmaceutical independence by diversifying supply chains and strengthening domestic medicine production within Europe. In light of the COVID-19 pandemic and the war in Ukraine, health security also involves crisis management – strengthening healthcare systems and ensuring the continuous supply of essential medical products.

An equally important element is the revision of pharmaceutical legislation, aimed at boosting the competitiveness of the pharmaceutical sector while ensuring equitable patient access to medicines – both in terms of availability and affordability. We must find a balanced approach within the EU that allows for the growth of both innovative pharmaceutical companies and the generic medicines sector. As part of the Polish Presidency, we also plan to present a Critical Medicines Act, aimed at strengthening European pharmaceutical production capabilities and securing access to Active Pharmaceutical Ingredients (APIs) within EU Member States.

The digitisation of healthcare is another key priority of the Polish Presidency. The implementation of the European Health Data Space (EHDS) will facilitate the secure exchange of medical data across Member States, thereby improving healthcare quality. The Presidency is also working to bolster cybersecurity in medical technologies and to support the expansion of e-health and telemedicine. Digital transformation in healthcare also includes the development of modern diagnostic and therapeutic tools, which will enable more precise and effective treatment.

Preventive healthcare remains the most effective strategy for improving public health. Our focus is on promoting healthy lifestyles, with particular emphasis on tackling obesity, alcohol abuse, and smoking. Additionally, we are committed to evaluating the effectiveness of existing prevention programmes and identifying best practices that can be implemented at both the national and EU levels.

Mental health among children and adolescents is one of the most pressing priorities of the Polish Presidency. The COVID-19 pandemic has significantly deteriorated the mental well-being of young people, necessitating urgent action at the European level. The increasing dependence on digital technologies and social media presents an additional challenge. As part of our agenda, we plan to secure EU Council conclusions on this issue and to collaborate with the WHO on a comprehensive report assessing the impact of digital technologies on the mental health of children and adolescents.

"Security, Europe!" – this is the motto of the Polish Presidency of the Council of the European Union. Our mission is to strengthen health security for all patients and to deepen cooperation among EU Member States – all in pursuit of better quality of life for citizens across Europe. This White Paper is dedicated to that very goal.

Poland's first Presidency in 2011 was undoubtedly a success. In 2025, we continue this mission – facing new challenges while working towards even greater integration and cooperation in the field of healthcare. We are confident that by pursuing these priorities, we will contribute to the creation of a stronger, healthier, and more resilient Europe.



# The Health Priorities of the Polish Presidency of the EU Council – a Robust Package for Times of Uncertainty

## **Prof. Piotr Czauderna MD PhD**

Chair of the Healthcare Section of the National Development Council under the President of the Republic of Poland

The pandemic has provided us with conclusions that we can use to implement health policy in times of war and drug shortages. The priorities of the Polish Presidency are maintained in this spirit.

Modern healthcare systems in European countries face many problems. These include the growing gap between their financial means and the rising costs of therapies, particularly for rare diseases and cancer, as well as the challenges associated with the demographics of developed societies.

The ageing of Europe is a particularly important phenomenon. There are currently around 10 million people over the age of 60 living in Poland, and this figure is set to rise by around 50% in the coming years. Similar trends can be observed throughout Europe – by 2050, 30% of the population will be 65 or older. Therefore, the independence of the elderly population, community-based care and the availability of geriatricians should be emphasised. A separate problem, and not only in Poland, is the rapid increase in the prevalence of various mental health problems, especially among children and adolescents, largely caused by the COVID-19 pandemic.

Too little attention is paid to prevention, while at the same time too much emphasis is placed on restorative medicine, which is ultimately much more expensive and sometimes less effective. It is never enough to remember that prevention is the most cost-effective way to improve the health of the population. I am therefore pleased that the Polish Ministry of Health has initially selected three indeed important health priorities of the Polish Presidency: the digital transformation of the healthcare system, the promotion of prevention and the problem of healthcare provision in the context of demographic changes. Over time, these were gradually expanded, which was also a positive step forward, to include the following additions: health promotion, mental health of children and adolescents and pharmaceutical security. These topics were primarily addressed in the document published by the WHO in 2024 titled A Public debate on the Future Health Priorities of the European Union: Outcomes, Insights and Ideas for Action. This publication summarised the debate held by the European Observatory on Health Systems and Policies (Observatory), with over 1,000 participants from 48 countries. The discussion focused primarily on the so-called "three Ds": democratisation of healthcare (health in all and for all policies), demography (addressing both challenges and the integration and coordination of care and services), and digitisation (as a crucial tool for addressing these challenges).

On specific matters, the Ministry of Health (MoH) also proposed reviewing the regulations on tobacco products and alcohol, as well as creating a common European catalogue of best practices in prevention and health promotion. Undoubtedly, the regulation of innovative tobacco products is necessary, particularly given the diverse approaches of European countries in this regard. On the one hand, there are UK recommendations to encourage traditional smokers, who are unlikely to quit, to switch to electronic cigarettes, which are considered less harmful. On the other hand, there is a more restrictive approach in Poland, which argues that e-cigarettes or 'vaping', especially among young people, are an easy gateway to smoking addiction. Another pressing issue is the complete lack of standardisation of e-cigarettes and so-called 'liquids', whose composition is still not regulated and which may contain a range of harmful substances. Furthermore, there is the emergence of a new generation of tobacco products, such as 'heat-not-burn' products, alongside the substantial profits and lobbying power of the tobacco industry.



I am also pleased that there are plans to prepare a comprehensive report and recommendations on the impact of social media on the mental health of children and adolescents. An increasing number of countries worldwide are recognising their profoundly harmful effects on the development of children and adolescents and are beginning to implement restrictions in this regard. In this regard, Poland lags far behind.

Finally, the issue of pharmaceutical security. It is crucial that it has now been officially recognised. The significance of this matter was starkly highlighted during the COVID-19 pandemic, when supply chains were disrupted. The production of active pharmaceutical ingredients largely occurs outside Europe, in over 50% of cases, primarily in China and India. Emergency situations, such as wars, mass pandemics, and other humanitarian crises, demand proper preparation. Therefore, it is essential to develop a Polish list and modify the European list of critical medicines, following the example of the one created by the U.S. FDA, which focuses on national security in the event of disasters, warfare, or other threats. In contrast, the list drawn up by the European Medicines Agency follows a completely different philosophy – it emphasises the availability of medicines, their supply chains, and the possibility of substitution by other products. Furthermore, the current European list includes even orphan drugs.

Another key topic is the digital transformation of healthcare, an area where significant progress has already been made at the European level. However, the advancement of such technologies varies across EU countries (Poland is doing relatively well in this regard). Notable examples include the European initiative for integrating cancer data (UNCAN) and the ambitious European Health Data Space initiative, which facilitates the exchange of information between patients and healthcare professionals at a pan-European level. The analysis of complex molecular data, particularly that related to cancer or rare diseases, is not feasible without digitalisation, which in turn opens up new treatment possibilities and allows therapies to be optimally tailored to the individual needs of patients.

# The Structure and Methodology of the White Paper

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The methodology for the preparation of the White Paper, which was drawn up as part of the Polish Presidency of the Council of the EU in 2025, was intended to enable a comprehensive and interdisciplinary approach to the main challenges in the field of healthcare. This process was based on several pillars that ensured scientific rigour, broad stakeholder representation and alignment with the health priorities of the EU and Member States. Below you will find a detailed overview of the methodology that forms the basis for the document.

## **Expert Consultations and Participatory Approach**

One of the key elements of the methodology was to conduct extensive consultations with experts from various fields, including medicine, public health, technology, law, as well as representatives from patient organisations, public institutions, and the private sector. These consultations took place as part of the series of expert debates, *Road to the Presidency*, organised in 2023–2024 by the Institute for Social Policy Development. During these events, the health priorities of the Polish Presidency were discussed, and key challenges and recommendations were identified.

These debates were interdisciplinary and covered a wide range of thematic areas, including cardiology, oncology, mental health of children and adolescents, healthcare digitisation,

prevention, and pharmaceutical security. As a result of these meetings, specific conclusions and recommendations were formulated and incorporated into the White Paper.

#### Analysis of Data and Trends

The methodology was based on an in-depth analysis of statistical data, reports, and research findings related to public health, healthcare systems, and demographic and technological trends in Poland and the European Union. Data from national and international sources were utilised, including reports from the World Health Organisation (WHO), the European Observatory on Health Systems and Policies, and the European Medicines Agency (EMA).

This analysis identified key challenges such as population aging, rising treatment costs, inequalities in access to healthcare, and the need for the digital transformation of healthcare system. Particular attention was paid to the impact of the COVID-19 pandemic and the war in Ukraine on health systems and pharmaceutical security.

#### **Interdisciplinary Approach**

The process of developing the White Paper was characterised by an interdisciplinary approach that enabled the inclusion of different perspectives and experiences. Experts from various fields such as medicine, public health, law, economics, technology as well as representatives of non-governmental organisations and patient groups were involved in the work on the document. This collaboration made it possible to develop recommendations that are both scientifically grounded and practically feasible to implement.

#### **Prioritising Key Areas**

The methodology involved prioritising key health areas identified as the most important in the context of the Polish Presidency of the Council of the European Union. As a result of the analyses and consultations, four main priorities were defined:

- 1. **Digital transformation of healthcare** encompassing the implementation of the European Health Data Space (EHDS), the development of digital tools, and the provision of cybersecurity.
- 2. Mental health of children and adolescents with a focus on prevention, mental health promotion, and mitigating the negative effects of new technologies and social media.
- 3. **Promoting prevention and public health** including evaluating the effectiveness of prevention programmes and developing a catalogue of best practices.
- 4. **Pharmaceutical security** including the revision of pharmaceutical legislation, the development of the Critical Medicines Act and the strengthening of pharmaceutical production in the EU.

Each of these priorities has been analysed in detail in terms of challenges, opportunities and recommended actions.

#### **Evidence-based Approach**

The recommendations in the White Paper were developed based on scientific evidence and best practices from other European Union countries. This process took into account the results of scientific research, systemic analyses, and experiences from previous EU Council presidencies, including Poland's Presidency in 2011. Special attention was also given to key EU strategic documents, such as the Europe's Beating Cancer Plan, the European Health Union, and the European Green Deal.

#### **Considering the EU Context**

The methodology also considered the EU context, including the Union's competences in the field of health and current legislative and strategic initiatives. The document references initiatives such as the European Health Data Space (EHDS), the Europe's Beating Cancer Plan, as well as the activities of the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC). As a result, the White Paper aligns with the broader framework of the European Union's health policy.



#### **Iterative Process and Verification**

The development of the White Paper was an iterative process, meaning that the document was repeatedly reviewed and refined based on feedback and suggestions from experts and stakeholders. The process also incorporated insights from conferences and expert debates held as part of the Road to the Presidency series. Each version of the document underwent detailed analysis and evaluation, allowing for content refinement and ensuring a high level of substantive quality.

#### **International Cooperation**

The development of the White Paper also incorporated an international perspective through collaboration with experts from other EU countries and international organisations such as the WHO. As a result, the document reflects both Polish and European needs and priorities in the field of healthcare.

#### Summary

The methodology for developing the White Paper was founded on scientific rigor, broad stakeholder participation, and an interdisciplinary approach. As a result, the document is a comprehensive analysis that not only identifies key challenges in the field of healthcare but also proposes specific and practical solutions that can be implemented during Poland's Presidency of the Council of the European Union in 2025.



# **Part I.** A Presidency Uncovered

## Robert Hyżorek, Jan Karsznicki

**Institute for Social Policy Development** 

# The Council of the European Union – Position, Role, and Treaty Foundations

The Council of the European Union is one of the primary decision-making bodies of the European Union. It comprises ministers from the governments of the Member States responsible for specific policy areas. Together with the European Parliament, the Council adopts EU law. Depending on the matters under discussion, it may consist of the foreign ministers of each Member State (the General Affairs Council) or ministers from other departments. For example, the Committee on the Environment, Public Health and Food Safety (ENVI) is composed of ministers from all Member States who, within their respective countries, are responsible for environmental protection.

In addition to its legislative role, the Council of the European Union fulfils other important functions:

- 1. Budgetary: the Council, together with the European Parliament, is responsible for adopting the European Union's budget.
- 2. Coordination: The Council oversees the coordination of the economic and social policies of the Member States.
- 3. Foreign and Security Policy: The Council defines and implements the Union's foreign and security policy, following the guidelines set by the European Council.
- 4. International Cooperation: The Council negotiates and signs international agreements on behalf of the European Union.

The meetings of the Council are prepared by the Committee of Permanent Representatives (COREPER), which consists of ambassadors from Member States accredited to the European Union (Heads of Permanent Representations of Member States). COREPER often also drafts and adopts decisions, which are later formally approved at official Ministerial meetings. COREPER meets weekly or biweekly, while formal Council sessions in various configurations are held approximately 70 times a year.

The Council is chaired by a minister from the country holding the current presidency, with the exception of the Foreign Affairs Council, which is always chaired by the High Representative of the Union for Foreign Affairs and Security Policy.

## Presidency of the Council of the European Union

The institution of the Presidency has existed since the Treaty Establishing the European Coal and Steel Community in 1951. Initially, members held the Presidency of the Council for a period of three months. The Treaty of Rome (1957) extended the Presidency to a six-month term (TEC, 1957, Article 146), held successively by each Council member in alphabetical order. At that time, it was a simple technical function, primarily logistical in nature. The creation of European Political Cooperation (EPC) and the formal establishment of regular European Council meetings in 1975 increased both the workload and the prominence of the Presidency. In the 1970s, the issue of a lack of continuity in the Council's work was recognised, particularly in the area of foreign policy, which at that time was conducted strictly in an intergovernmental format, parallel to economic cooperation within the framework of the European Community. Attempts to improve the continuity of work in the Council were made in the 1980s, when the "troika" format – comprising the current, previous, and next presidencies – was introduced in the field of foreign policy (EPC). Under the leadership of Council Secretary General Niels Ersbøll, the Council Secretariat was also reformed and tasked with supporting the Presidency in fulfilling its duties.



The Maastricht Treaty, adopted in the early 1990s, reformed the EU legislative process by introducing the codecision procedure, which expanded the powers of the European Parliament as an equal partner to the Council. This also altered the responsibilities of the Presidency and required even greater coordination between successive Presidencies. In the 1990s, another issue related to the rotating Presidency was identified as the question emerged how it should operate following the 2004 enlargement.

These issues were addressed in two forums. First, in the conclusions adopted by the European Council in Helsinki (1999) and Seville (2002). Second, these issues were also discussed during the Convention that prepared the Constitutional Treaty (2002–2003) and at the subsequent Intergovernmental Conference working on the adoption of the Treaty of Lisbon (2007). Ultimately, an institutional balance was achieved through arrangements that combined the permanent presidencies (of the European Council and the Foreign Affairs Council) with the continuation of the rotating six-month Presidency of the Council, strengthened by measures now known as the "trio".

According to the Lisbon Treaty, the Presidency of the Council, with the exception of the Foreign Affairs configuration, is "held by pre-established groups of three Member States for a period of 18 months". The groups are "made up on a basis of equal rotation among the Member States, taking into account their diversity and geographical balance within the Union". Accordingly, the changes between the provisions of the Lisbon Treaty with those of the Constitutional Treaty were minor. The Lisbon Treaty added a provision that other members of the group "shall assist the Chair in all its responsibilities on the basis of a common programme". In addition, it was agreed that members of the team may agree on alternative solutions among themselves, which serves as the basis for the Trio to implement the "team presidency" system, originally proposed in the Constitutional Treaty. The Treaty of Lisbon introduced specific legal provisions, implementing the policy developed by the European Council after more than a decade of reflection on the role of the Presidency. The Council elaborated on the treaty provisions and adopted more detailed rules on the Presidency in its Rules of Procedure. In doing so, it confined itself to defining the process for developing an 18-month joint programme. Article 2(6) of the Rules of Procedure provides that "every 18 months, the pre-established group of three Member States holding the Presidency of the Council for that period ... shall prepare a draft programme of Council activities for that period. The draft shall be prepared with the President of the Foreign Affairs Council with regard to that configuration's activities during that period. The draft programme shall be prepared in close cooperation with the Commission and the President of the European Council, and after appropriate consultations".

The long-standing practice of holding the Presidency has resulted in the development of several models for conducting the Presidency.

**The Brussels Presidency** – this model assumes that the primary responsibility for managing the presidency from an administrative and managerial perspective lies with the Permanent Representation of the respective Member State. In this model, the government of the Member State sets only the general framework for the presidency, leaving its implementation to the Permanent Representation. The Brussels model is considered more technical than political and is most often chosen by smaller countries with limited human and financial resources.

**The Capital-Centred Presidency** – in this model, the entire policy, organisation and planning centre of the Presidency is located in the capital of the Member State holding the Presidency and the role of the Permanent Representation is limited only to providing information from Brussels. This model enables greater political control.

**The Mixed Model** – in this model, tasks are divided between the capital of the Member State and its Permanent Representation. This approach is the most common way for Member States to conduct Presidencies. Poland's first Presidency was also conducted using this model, and all indications suggest that the upcoming one will follow the same approach.

**The Centralised Presidency** – this model is used when a single main decision-making and coordination centre is established. Individual ministries and other central or federal bodies propose



only the key premises within their respective competences, while the main centre is responsible for approving them, assigning priorities, setting the agenda, and managing all communication. Currently, the Polish Presidency is being set to follow this approach. The Chancellery of the Council of Ministers is responsible for the majority of the work and the delegation of tasks.

The Decentralised Presidency – a presidency is considered decentralised when individual ministries have significant freedom in shaping their sectoral programmes. During the presidency, they also have autonomy in organising specific meetings, setting information policy, and making decisions on key issues within their respective areas.

# The Rotating System of the Presidency

The rotating Presidency of the Council of the EU was originally established as a primarily administrative institution, intended to distribute the burden of planning Council meetings among the six member states of the European Coal and Steel Community. However, as the number of Member States increased and the European Union expanded its competences, the Presidency took on additional responsibilities. The rotating Presidency is now a key mechanism for ensuring leadership, equality, and fairness within the EU, granting each Member State, regardless of its size or duration of EU membership, a six-month term to lead the work of the Council of the EU.

The main functions of the rotating Presidency include managing the Council's activities, organising and chairing Council meetings at all levels, both in Brussels and in the Member State, with the support of the General Secretariat of the Council (GSC). Second, the Presidency has limited capacity to shape the EU agenda by prioritising specific issues within its programme, in accordance with the predetermined agenda of the Presidency Trio developed by the three Member States and the European Commission. In addition, as the chair of most Council formations, from the ministerial level to working groups, the Presidency serves as a neutral intermediary and mediator between Member States. The Chair also represents the Council of the EU to the European Commission, the European Parliament, and other EU institutions.

The Treaty of Lisbon of 2009 reduced the scope of the Presidency by introducing a permanent President of the European Council and a High Representative for Foreign Affairs, who chair the relevant Council formations, providing greater continuity at the highest level of EU political leadership. The Treaty of Lisbon significantly reduced the visibility, but not necessarily the workload, of the rotating Presidency, as the Presidency relinquished control over only two Council formations.

In summary, instead of merely attending EU Council meetings, representatives of the Member State holding the Presidency must chair them, act as intermediaries between ministers, diplomats, and officials from the EU-28 at all levels of the Council, and represent the Council of the EU in trilogues with the European Parliament and the European Commission, steering the EU legislative process. In addition, the Presidency must organise informal ministerial meetings of the Council in the capital.

The Presidency of the Council of the European Union is a remarkable event in the realm of international cooperation, offering unparalleled exposure to EU affairs not only to the political elite but also to a wide group of civil servants. No other responsibilities in international or regional organisations, such as holding a seat on the UN Security Council, presiding over the Organisation for Economic Co-operation and Development, the Visegrad Group, Benelux, the Council of the Baltic Sea States, or others, can match the scope and intensity of the Presidency of the Council of the EU. Typically, a small group of diplomats in foreign ministries handles UN or OECD affairs, NATO summits last only a few days, whereas the Presidency of the Council of the EU demands the involvement of all national ministries and over a thousand officials for six months, preceded by more than a year of intensive preparations often described as more demanding than the Presidency itself.

According to officials from the "new" Member States, the only undertaking comparable to the Presidency of the Council was their accession to the EU in 2004.



## **Presidential Trio**

The Presidency of the Council of the European Union is not determined through elections. Since 2009, under the Treaty of Lisbon, Member States have held the Presidency of the Council of the European Union for six months in turn, working closely together in groups of three countries (trios). The presidency of each country therefore falls every thirteen and a half years. Poland held its first Presidency of the Council of the European Union from 1 July to 31 December 2011 and will hold the second Presidency from 1 January to 30 June 2025.<sup>1</sup> This approach ensures that, over time, the European Union consistently focuses on the issues that are most important and crucial for all its Member States.

Each trio sets long-term goals and prepares a common agenda of topics and issues that the Council will address for 18 months. Based on the common agenda, each of the three countries develops its own, more detailed programme for its six-month Presidency of the EU Council.<sup>2</sup> The presidency chairs most meetings of the Council, committees and working parties. One of the exceptions is the Foreign Affairs Council meeting, which is chaired by the High Representative of the Union for Foreign Affairs and Security Policy, who is elected for a five-year term.

The main task of the country holding the Presidency of the Council of the European Union is to ensure the smooth continuation of the Union's work after the previous Presidency. The presidency is to stimulate the Council's legislative activities while ensuring the continuity of the Union's agenda, efficient implementation of the legislative process and effective cooperation between Member States. Based on this agenda, each of the three countries develops its own more detailed plan for the six-month period of its Presidency. Although most of the activities during the presidency result from the agenda of the European Union, the country holding the presidency has the opportunity to define the presidency's priorities. In this way, the country holding the presidency can actively shape the agenda, taking into account the most important issues for its national interests, even if the Presidency is subject to the general work calendar.<sup>3</sup>

# Continuity of the Council of the European Union's Work

Since 1995, following the modification introduced by the 1992 Treaty on European Union, the Council itself determines the order of holding the presidency. Nevertheless, when deciding on this matter, the Council always ensures that the current cycle is completed before incorporating new Member States into the next cycle. In practice, the delegations of new Member States occupy a fixed seat at the Council table until the end of the cycle, assigned according to the alphabetical order of the States' names in their national languages. Meanwhile, the delegations of existing Member States shift one seat to the left every six months.

The presidency of the Council, supported by the General Secretariat, plays a key role in organising the Council's work, particularly in advancing the legislative process. Prior to the reform of the Council's Rules of Procedure in 2002, the presidency, in consultation with the General Secretariat and the European Commission, submitted its draft six-month programme along with the proposed dates for Council sessions a few months before assuming office. Since 2002, the incoming presidency, when preparing draft agendas for Council meetings with the assistance of the Secretariat, must consider both the Council's "multiannual strategic programme", which spans three years, and its "annual operational programme." The responsibility for developing both programmes rests primarily with the respective presidencies – six for the multiannual programme and two for the annual programme. In this process, the presidencies always act in consultation with the Commission. The multiannual strategic programme is adopted by the European Council based on a recommendation from the General Affairs and External Relations Council. The annual

<sup>1</sup> https://www.consilium.europa.eu/pl/council-eu/presidency-council-eu/.

<sup>2</sup> https://www.consilium.europa.eu/pl/council-eu/presidency-council-eu/timeline-presidencies-of-the-council-of-the-eu/.

<sup>3</sup> https://www.consilium.europa.eu/pl/council-eu/presidency-council-eu/.



operational programme is developed in line with the multiannual operational programme and discussions in the General Affairs and External Relations Council. Relevant factors arising from the dialogue initiated by the Commission on the annual policy priorities are taken into account, inter alia.

The Council meets at the request of its Chair. The latter, the minister of the Member State holding the presidency in a given semester, organises and chairs Council meetings and prepares the provisional agenda for each session. At meetings, the presidency ensures adherence to the Rules of Procedure and the smooth conduct of debates. It is also responsible for facilitating consensus within the Council. The presidency does not represent its national delegation and therefore occupies a separate seat at the conference table. The presidency sits at the head of the table, beside the General Secretariat and facing the European Commission.

In principle, the bodies responsible for preparing the Council's work (COREPER, committees, and working parties) are chaired by a representative or delegate of the Member State holding the presidency of the Council.

The presidency is supported by a representative of the Member State that will subsequently assume the presidency. This representative, acting at the request of the presidency and in accordance with its instructions, replaces the presidency when necessary, relieves it of certain administrative tasks where appropriate, and ensures the continuity of the Council's work.

The presidency plays a significant representative role in the Community's external relations, its interactions with other institutions – particularly the European Parliament – and in regularly informing the media about the Council's activities.

Within the framework of the Common Foreign and Security Policy (CFSP), the Council presidency represents the European Union in matters falling under this policy. The presidency is responsible for implementing decisions on these matters; in this role, it generally represents the Union's position in international organisations and at international conferences. Following the entry into force of the 1997 Treaty of Amsterdam, the presidency is supported in these tasks by the Secretary-General of the Council (High Representative for the CFSP) and, where necessary, by the Member State due to assume the next presidency. The Commission is fully committed to these tasks (Article 18 of the Treaty on European Union). The configuration known as the Troika, in which the Council presidency collaborated with the preceding and succeeding presidencies, has therefore been modified. The Council presidency is no longer supported by the Member State that held the prior presidency.

As part of the third pillar of the Union, the presidency is required to regularly report to the European Parliament on the activities conducted in the areas of police and judicial cooperation in criminal matters (Article 39 of the Treaty on European Union).

Pursuant to Article 48 of the Treaty on European Union, the President of the Council is responsible for convening a conference of representatives of the governments of the Member States to jointly determine amendments to the Treaties.

## **Preparing the Presidency**

The work programme of the individual presidencies of the Council of the Union is closely tied to the EU legislative cycle, which, in turn, depends on the date of the elections to the European Parliament and the formation of the European Commission, which holds the exclusive right of legislative initiative in the EU. As of 1 April 2024, there were approximately 190 open legislative dossiers in the EU institutions, which the new Parliament can revisit (as there is no principle of legislative discontinuity at the end of its term of office) during the Polish Presidency. And this will result in the resumption of negotiations between the European Parliament and the Council of the European Union. Barring significant delays in the formation of the new Commission, which began its term on 1 December five years ago, its first new initiatives may emerge during the Polish



Presidency. Extensive discussions will also take place on the first draft of the EU multiannual financial framework (for the period beyond 2027). It is expected to be submitted by the Commission around mid-2025, but it remains uncertain whether the draft will be finalised before the end of the Polish Presidency.

Each presidency of the Council of the European Union operates based on two programmes that are part of the EU legislative cycle, developed jointly with the General Secretariat of the Council and the European Commission. They are based on the agenda of the Council's deliberations in Brussels and Luxembourg, as well as the schedule of its informal meetings in the presidency's host country. The first, more detailed programme covers the six months of the rotating Presidency, while the second is the programme of the trio of presidencies (also called the "Trio"), which in Poland's case consists of Poland, Denmark, and Cyprus (as was similarly the case during the first Polish Presidency in 2011-2012). The Trio of presidencies consists of groups of countries that, in accordance with the EU treaties, are chosen to maintain "diversity and geographical balance" within the Union. The Trio was intended to serve as a forum for close cooperation among its three rotating presidencies, but this concept has not proven effective so far – cooperation within Trios is typically very limited and primarily procedural.

During its first Presidency, Polish diplomacy valued certain political discussions with the Danes within the context of its Trio, for instance on climate policy, but had no significant additional contacts with the Cypriots arising from their membership in the Trio. However, as the first country in the Trio in chronological order, Poland is responsible for taking the initiative and bearing the primary administrative responsibility for drafting and securing the approval of the one-and-a-half-year programme of the Trio of presidencies by the Union's General Affairs Council (GAC) in the final weeks of 2024. Its aim is to ensure a coherent continuation of legislative work, which, on average, takes the Council of the European Union more than 20 months per project.

In addition, each presidency adopts its own political priorities, which it seeks to promote while steering the work of the Council of the European Union and, to some extent – insofar as the role of a "neutral intermediary" permits – by shaping the Council's work agenda. Their actual significance for the presidency is usually limited, but they can be important for the communication and political presentation of the presidency. In November 2023, the Mateusz Morawiecki Government adopted the *List of Priorities for the Work of the EU Council under Poland's Chairmanship*, which are as follows:

- Strengthening EU cooperation with the USA,
- Enlargement of the EU to include new Member States,
- The EU's involvement in the reconstruction of Ukraine,
- Ensuring the EU's energy security while adhering to the principles of
- Just Energy Transition.

On the other hand, the government of Donald Tusk has signalled its intention to modify the list of Presidency priorities by November 2024.

In Poland, the requirement itself to consult the priorities of the presidency of the Council of the European Union with the President of Poland is controversial. This requirement stems from the "Competence Law" of September 2023, which grants the President authority in EU affairs – a provision the current government interprets as being contrary to the Polish Constitution. Similarly, the same law establishes the principle that during the Polish Presidency of the Council of the European Union, the President "shall participate in meetings of the European Council and in international meetings involving the EU, where the presence of Heads of State or Government of the Member States is stipulated". This could become a point of contention, as the Polish Constitutional Court ruled in 2009 that the President may attend European Council summits but must cooperate with the Prime Minister, who leads the delegation. However, the Constitutional Court's ruling was issued before the formalisation of the European Council's role under the Treaty of Lisbon, which established that Member States in the European Council are represented by a single individual



(either the head of government or the president). In exceptional cases, the Council may decide to allow each leader to be accompanied by one minister. According to the Treaty of Lisbon, the Prime Minister and the President cannot attend the European Council at the same time, although the Member State has the discretion to decide who represents it at the EU summit.

The Permanent Representation to the EU, often informally referred to as the Embassy to the EU, plays a key role in selecting the presidency's priorities and, in particular, in properly planning the formal and informal work of the Council of the European Union. It is effectively a delegation of a Member State in Brussels, where, among others, officials seconded from various ministries are employed. This "embassy" maintains the closest contact with the European Commission and the General Secretariat of the Council of the European Union, as well as continuous insight into the state of affairs under discussion in the EU institutions.

### Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) and Informal Meetings of Health Ministers

The EPSCO Council comprises ministers responsible for employment, social affairs, health, and consumer policy from all EU Member States. The relevant European Commissioners also attend the meetings.

Typically, the EPSCO Council holds four meetings per year. Two of these meetings are usually devoted exclusively to employment and social policy issues.

The Employment, Social Policy, Health and Consumer Affairs Council was established through the merger of the Employment Council, Social Policy Council, and Health Council in June 2002. Since the merger, this Council's configuration has also overseen consumer protection issues, which were originally part of the Internal Market, Consumer, and Tourism Council. While Member States retain full responsibility for defining their health policies and for organising and delivering healthcare, the Council, together with the European Parliament, adopts regulations on the quality and safety of human organs and blood, patients' rights in cross-border healthcare, and the quality and safety of medicines and medical devices.

## Programme of the Polish Presidency of the Council of the European Union

In December 2024, the Council of Ministers adopted the programme of the Polish Presidency of the Council of the European Union, which commenced on 1 January 2025. The document outlines Poland's Presidency priorities, focusing on security in its broadest sense across seven dimensions: military, internal, economic, energy, informational, food, and health security.<sup>4</sup> In the context of the ongoing war in Ukraine and rising geopolitical tensions, the programme addresses challenges related to the erosion of the international legal order and the intensification of hybrid attacks that destabilise Europe's democratic institutions and security architecture.

#### **Defence and Security**

In the area of defence, the programme aims to enhance the European Union's defence capabilities by increasing military spending and developing the defence industry. Particular emphasis is placed on strategic infrastructure, including projects such as East Shield and the Baltic Defence Line. A key aspect of these efforts is also the deepening of cooperation with NATO to ensure greater coordination of defence activities in the region.

#### **Border Protection and Migration**

In the area of external border protection, including Poland's eastern border, the programme provides for the implementation of new solutions for migration management. The key priorities include

<sup>4</sup> https://www.gov.pl/web/premier/program-polskiej-prezydencji-w-radzie-ue.



reducing irregular migration, increasing the effectiveness of return procedures, and enhancing cooperation with third countries. These measures will be complemented by initiatives aimed at countering hybrid threats and dismantling international organised crime networks.

#### **Resilience to Disinformation and Cyber Threats**

One of the programme's key priorities is to strengthen the European Union's resilience to external interference, including disinformation and information manipulation. The plan includes improving coordination efforts in this area and enhancing the EU's capacity to counter hostile activities in cyberspace. The expansion of secure and modern digital services is also a key focus.

#### **Economy and Internal Market**

In the economic sphere, the Polish Presidency is committed to deepening the integration of the EU single market and removing barriers to cross-border activities, particularly in the services sector. An important objective is to restore fair competition for European industry in the face of global challenges. The programme also includes discussions on the future of cohesion policy, which plays a vital role in sustainable socio-economic development, as well as initiatives to reduce bureaucratic burdens across the EU.

#### **Energy Transformation**

The programme's energy agenda focuses on completely phasing out imports of energy resources from Russia, lowering energy prices within the EU, and reviewing the energy security framework. A key goal is to reduce reliance on imported technologies and critical raw materials, thereby increasing the Union's energy autonomy.

#### **Agriculture and Food Security**

In the field of agriculture, the programme calls for strengthening the Common Agricultural Policy to support farmers and promote the development of rural areas. These efforts will be directed toward encouraging environmentally sustainable agricultural practices and mitigating the effects of climate change. Ensuring food security, defined as access to high-quality products, remains a fundamental priority of the Polish Presidency.

#### **Public Health**

The Presidency's health agenda focuses on the digital transformation of healthcare, the mental health of children and adolescents, and disease prevention. Special emphasis is placed on enhancing the EU's pharmaceutical security, including diversifying supply chains and supporting pharmaceutical production within Europe.

The programme of the Polish Presidency of the Council of the European Union encompasses a broad range of initiatives aimed at enhancing the security, stability, and competitiveness of the European Union. In light of today's geopolitical and economic challenges, these priorities seek to bolster the EU's capacity to respond to crises and build long-term resilience across key areas of its functioning.

## The Course of the Presidency – Managing Work of the Council of the European Union's Work

The primary task of the rotating Presidency of the Council of the European Union is to take, with the assistance of its General Secretariat of the Council of the European Union, all necessary steps to ensure the smooth conduct of work. This includes chairing proceedings at the ministerial level, at the level of ambassadors to the EU (the "permanent representatives" and their deputies) within COREPER, and at the level of working groups, as well as negotiating compromises and managing voting processes. In addition, the Presidency represents the Council of the European Union in sessions of the European Parliament. The political expectation for each Presidency of the Council of the European Union is to act as an honest broker, operating beyond the interests of



its own country, and even abstaining from decisions that could tip the balance in favour of either supporters or opponents of the proposed project. However, this is an aspirational principle rooted in good practice rather than codified rules, and it is not always upheld by all rotating Presidencies. A significant challenge to the role of a neutral intermediary was the proposed Nature Restoration Regulation. Although Sweden opposed it, the country – holding the Presidency of the Council of the European Union – developed a compromise proposal and submitted it for a preliminary vote in June 2023. Sweden voted against it, which threatened the failure of the proposal, but ultimately, it was passed by a single vote. However, the Belgian Presidency in the first half of 2024 spent several months building a majority in the Council of the European Union for a revised version of this regulation agreed upon with the Parliament.

In the ordinary legislative procedure, which applies to about 80% of EU law, the task of the Presidency is to negotiate the position of the Council of the European Union on a specific proposal. In practice, this is most often achieved before the formal first reading of the proposal in the Council of the European Union by adopting the Council's "general approach", supported by the required majority of EU Member States. The Presidency is then tasked with negotiating a compromise version of the draft with the European Parliament (with the mediation of the Commission) through continuous consultations with the members of the Council of the European Union regarding the permissible limits of concessions. Finally, it must secure the official and legally binding approval of this compromise. A part of this process – usually concerning the "general approach" – is conducted at the ministerial level. For instance, the Minister of Agriculture chairs meetings of the Agriculture and Fisheries (AGRIFISH) Council configuration. Another part is handled at the COREPER level, with its decisions subsequently confirmed by ministers during their Council sessions - in some cases, through a written procedure. In the EU's everyday practice, the COREPER level is where the negotiating machinery – and therefore the Presidency – operates at full capacity. The Committee's work in areas such as financial and economic matters (COREPER II) is chaired by the ambassador (permanent representative) of the country holding the Presidency, while matters such as agriculture, energy, or transport (COREPER I) are overseen by the deputy ambassador of the country holding the Presidency of the Council of the European Union.

The presidency plays a special role in the General Affairs Council (GAC), where EU Ministers meet. This council, which falls under the responsibility of COREPER II ambassadors, is – together with the Commission – responsible for ensuring the coherence and continuity of the EU's work. In addition, the permanent President of the European Council briefs the GAC on the planned agenda of EU summits, which, to some extent, involves the rotating Presidency in the preparation of these summits. In addition, the prime minister or president of the country holding the Presidency is occasionally asked during EU summits to report on progress (and particularly on difficult issues) in specific legislative work.

The presidency presents a draft agenda for each thematic configuration of the Council of the European Union (except for the FAC), allowing it to influence the topics discussed and the pace of work on individual proposals. The internal regulations of EU institutions impose certain temporal constraints on legislative work, shaping the role of the presidency, although no final timelines exist for the first reading of the European Commission's proposals. In the event of persistent obstruction of individual topics by any government holding the presidency, a procedural vote can be conducted in the Council of the European Union to introduce an item for discussion or voting, even against the intentions of the presidency. However, this does not occur, and the presidency of the Council of the European Union – despite being significantly weakened by the Treaty of Lisbon – is not confined to merely administering negotiations. On the contrary, the presidency of the Council of the European Union has retained some influence over shaping the EU's work agenda by introducing new issues for discussion, structuring the agenda (order and time allocated for discussion), or delaying or excluding topics from the agenda. The presidency also exerts its influence by organising additional meetings of the Council of the European Union dedicated to topics that are particularly controversial, challenging, or urgent. In addition, discussions on



a topic of particular interest to the presidency are sometimes initiated as a result of a legal opinion commissioned by the Council of the European Union's Legal Service and distributed among EU Member States.

The fate of specific compromises in the Council of the European Union depends not only on the technical efficiency of the presidency's negotiating skills but also, to some extent, on its own objectives in identifying key negotiating issues and determining a common denominator in the Council's negotiations. These talks are conducted not only in Brussels and Luxembourg but also – in the case of key projects – directly between capitals or even at the level of prime ministers or presidents of major countries with particularly conflicting or pronounced interests in the negotiated field.

A review of the rotating presidencies' activities over the past several years highlights the influence of geographical location, GDP size, the ruling political faction, and the prominence of EU issues in domestic debates on the official priorities of the Presidency. This, to some extent, translates into the agenda of the Council of the European Union and, at the very least, into the communication framework accompanying the six-month leadership of this EU institution's work. Left-wing governments typically place greater emphasis on social and environmental issues, while right-wing governments focus more on economic policy and security. Countries that are net beneficiaries of the EU budget have also, during their tenure as Presidency of the Council of the European Union, placed greater emphasis on the EU's redistributive policy. The countries of Central and Eastern Europe placed greater emphasis on security policy (including before the war in Ukraine), while the wealthy countries of North-Western Europe focused more on the rule of law, civil rights, environmental protection, and trade liberalisation. Presidencies of the Council of the European Union held by states where Eurosceptic parties are in power (even as government coalition partners) typically emphasise the principle of subsidiarity in their programmes – enshrined in the EU treaties - which advocates for the non-intervention of EU institutions in matters that can be resolved at the national level.

The influence of the country holding the presidency of the Council of the European Union on the agenda and the course of EU negotiations depends on the size, efficiency, and training of its diplomatic and administrative apparatus – both in Brussels and within the ministries responsible for individual thematic configurations of the Council of the European Union. If a presidency is unable to address the topics it is meant to negotiate with sufficient expertise and political acumen, the General Secretariat of the Council of the European Union takes full control. In some cases, the Commission, participating in trilateral negotiations with the Council and the European Parliament, also assumes an informal role. On the other hand, large countries, as well as those with administrations highly familiar with EU matters, can achieve greater influence in Brussels by fulfilling the duties of the presidency, compared to what would be expected based on the formal limitations of the presidency of the Council of the European Union.

Six-month presidencies often serve as a period of political mobilisation for EU countries, during which their governments use the opportunity to promote their message, priorities, and objectives both in domestic politics and in relations with other countries at the EU level, and even beyond the EU. The authorities strive to achieve, at least symbolically, a tangible success or a significant increase in influence over EU decisions by the end of their presidency. The meetings of the European Council are held in Brussels, but in recent years, countries holding the presidency of the Council of the European Union have occasionally hosted extraordinary or informal meetings of the European Council ("informal EU summits"), sometimes organised alongside other international gatherings involving all EU Member States (e.g., the European Political Community Summit in Prague). Such out-of-Brussels summits, co-organised in practice by the rotating presidency and the permanent President of the European Council, help to promote EU topics to their domestic public, shape the agenda of leaders' meetings, and thereby advance issues of particular interest to the country holding the presidency.



## **Part II.** The Context of the Polish Presidency of the Council of the European Union in the Field of Healthcare

### The Polish Presidency of the Council of the European Union in 2011 in the Field of Healthcare: Progress, Achievements and Reflections

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On 1 July 2011, Poland assumed the presidency of the Council of the European Union (EU). This was Poland's first presidency. For six months, Poland presided over the work of the EU Council as the first country in the trio comprising of the Republic of Poland, the Kingdom of Denmark, and the Republic of Cyprus.

Holding the presidency of the European Union was a natural consequence of Poland's accession to the EU in 2004 and a unique obligation arising from its status as a Member State. This obligation was established by the 1957 Treaty of Rome, which established the European Community. The Polish Presidency took place in the second half of 2011, in accordance with the order established by a unanimous decision of the Council of the European Union. The order of the presidencies was established by the Council Decision of 1 January 2007 determining the order in which the office of President of the Council shall be held (2007/5/EC, Euratom).

The logo of the Polish Presidency featured six colourful upward-facing arrows and the Polish flag. The logo was accompanied by the inscription "PL2011.eu". The logo symbolically references the Solidarity movement.

The country holding the presidency is responsible for the following tasks:

- The most important task is to preside over the work of the Council of the EU and its subsidiary bodies (committees and working parties) and to chair meetings of the European Council. The implementation of this task requires the substantive and logistical organisation of numerous meetings, varying in nature, location, and level;
- Representing the Council before other EU institutions, particularly the European Commission and the European Parliament;
- Representing the Union in relations with third countries and international organisations, in collaboration with the High Representative for Foreign Affairs and Security Policy.

#### Government Plenipotentiary for Poland's EU Presidency

To coordinate tasks related to preparations for the presidency, on 15 July 2008, the Council of Ministers appointed a Government Plenipotentiary for the Preparation of Government Administration Bodies and the Holding of the Presidency of the Council of the European Union by the Republic of Poland. This role was held by Mikołaj Dowgielewicz, Secretary of the Committee for European Integration, Secretary of State in the Office of the Committee for European Integration, and Vice-Chair of the European Committee of the Council of Ministers.

One of the 14 priorities of the Polish Presidency focused on health – **Reducing Disparities in the Health of European Societies.** 



With Poland assuming the presidency of the Council of the European Union, we began implementing the new Trio programme, under which Poland had the privilege of cooperating with Denmark and Cyprus. Our planned efforts focused on promoting initiatives aimed at improving the health of European Union citizens and protecting European societies from shared risk factors. In addition, our plan emphasised actions aimed at ensuring an adequate quality of healthcare for the citizens of the Member States.

#### The three main themes of the Trio Programme in the field of health were:

- 1. Non-communicable diseases and healthy ageing;
- 2. Diseases without borders, including health security;
- 3. Innovation and good practices.

The above topics not only continued the work of previous presidencies but were also linked to the 2006 Council of the European Union's Conclusions on Common values and principles in European Union Health Systems. They were also significant for the EU health strategy at the time and for the Europe 2020 Strategy. From today's perspective, these priorities remain relevant.

We have been pursuing two main priorities of the Polish Presidency in the field of health:

- 1. Reducing disparities in the health of European societies;
- 2. Prevention of cerebral and neurodegenerative diseases, including Alzheimer's Disease.

As part of the first priority, we focused on reducing health disparities between European Union countries in the context of health determinants. Despite universal access to healthcare for all citizens of European countries, significant and well-documented health inequalities persist between Member States. Differences also exist within individual countries (between regions, districts, etc.). Currently, 86% of all deaths in the European Union are attributed to chronic non-communicable diseases. They also represent the most significant and continuously growing burden on healthcare budgets. Communicable diseases once accounted for nearly 90% of deaths but are now under control and cause less than 2% of premature deaths. The prevalence of chronic non-communicable diseases, such as cardiovascular and respiratory diseases, various cancers, and metabolic disorders, including diabetes, is closely linked to risk factors such as smoking, poor diet, insufficient physical activity, and excessive alcohol consumption. Addressing health disparities is a significant challenge. It is evident that the measures and actions taken will yield results only over the long term and across many years. Despite the widespread awareness of the harmful effects of smoking and physical inactivity, the associated unhealthy habits and lifestyles are difficult to overcome. Smoking is the leading preventable cause of premature mortality. During the first Polish Presidency, cigarette smoking was responsible for approximately 650,000 deaths annually in the European Union, including 25% of all premature deaths. Alcohol is another factor with a significant impact on the health of Europeans. More than 13% of premature deaths annually in the European Union are attributed to alcohol abuse. Excessive alcohol consumption has both health and social consequences, placing a burden on society as a whole and on individual families. We recognized the need to enhance cooperation between Member States in this area. Another public health issue, which was one of the key priorities of the Polish Presidency, was the rising prevalence of overweight and obesity among Europeans. This phenomenon has had and continues to have the characteristics of an epidemic, with its prevalence among children and adolescents being particularly concerning. The global percentage of obese individuals has doubled over the past 30 years. Overweight and obesity are the fifth leading cause of death, contributing to the rising incidence of cardiovascular and musculoskeletal diseases, certain cancers, and metabolic disorders, including diabetes. Recent data indicate that 17 million young Europeans are affected by overweight or obesity. Overweight and obesity are not only medical issues but also significant economic challenges, due to the rapidly escalating costs of patient care.

Health determinants driving health inequalities in the European Union pose a significant challenge to public health. That is why we selected this topic as one of our priorities during the Presidency.



We also aimed to highlight the prevention, diagnosis, and management of respiratory diseases in children. Chronic non-communicable respiratory diseases are the most prevalent non-communicable conditions in childhood, with an average prevalence ranging from 10% to over 30% in Europe. These diseases significantly impact quality of life by limiting physical fitness and concentration ability, negatively affecting children's development, and often leading to social exclusion. Impaired respiratory function in childhood also increases the risk of developing chronic lung disease and cardiovascular conditions. Unfortunately, these chronic diseases are often a precursor to disability and a cause of premature death. Early detection, prevention, and monitoring of non-communicable respiratory diseases, with a particular focus on children and adolescents, can help mitigate the negative social and economic impacts caused by this group of conditions. We believed that these actions would positively contribute to improving the quality of life for these patients. By addressing the topic of chronic non-communicable respiratory diseases, particularly allergies and asthma – the most common conditions of developmental age, which significantly impact health later in life – we aimed to present a new approach to this issue.

During the 2011 Polish Presidency, we focused on the early detection and treatment of communication disorders in children, including the use of e-health and innovative solutions. We know that the proper functioning of the organs of hearing, vision, and speech forms the foundation of social communication and the development of the modern information society. Disorders in the functioning of sensory organs in pre-school and school-aged children are among the main causes of developmental delays, difficulties in acquiring language skills, and challenges in effective communication with their surroundings. According to Polish data and pilot studies from other parts of Europe, one in five children experiences various types of hearing problems, one in three has vision problems, and one in four suffers from articulation disorders. We believed that efforts should be made to detect these dysfunctions early and to initiate early therapy and rehabilitation. In many Member States, initiatives have been implemented over the past several years to promote hearing, vision, and speech screening in children. Early detection of communication disorders and appropriate medical intervention, including the use of e-health and new technologies, can support proper development in children. This significantly impacts their quality of life and may, in the future, translate into improvements in their social, professional, and economic circumstances. We are convinced of the need to implement universal hearing, vision, and speech screening programmes for children, already at the pre-school age. We are also aware of the activities that have been undertaken in this area within the European Union, particularly in the field of e-health. Within the three thematic areas discussed, related to reducing health inequalities in European societies, we sought to emphasise the importance of developing screening programmes and establishing a network of institutions to monitor health trends. We aimed to emphasise the need to strengthen cooperation between Member States, particularly in the exchange of experiences and best practices. We believed that preventing childhood diseases would help create better conditions for young patients in later stages of life and, in turn, promote equal opportunities for them. It is important to remember that a healthy old age begins with a healthy childhood.

During the Informal Meeting of Ministers of Health held on 6 July 2011 in Sopot, we initiated a political dialogue with the ministers. Two days earlier, work in this area was also initiated by the Public Health Working Party, which presented the draft conclusions on preventing and treating communication disorders in children, along with the work programme of the Polish Presidency. The Polish Presidency also presented proposals for conclusions to the Council of the European Union concerning the elimination of health disparities in the European Union through actions addressing health determinants, and the conclusions on the prevention and management of non-communicable respiratory diseases in children.

As part of the substantive preparations at the Ministry of Health, the Team for the Polish Presidency in Health and four subcommittees were established. Minister of Health Ewa Kopacz appointed me as chair of this team. Professor Bolesław Samoliński was appointed head of the Ministry of Health subcommittee on health priorities. Professor Henryk Skarżyński, Professor Opala (former Minister of Health), and many other doctors actively contributed to the team. Through their exceptional



dedication and extensive subject-matter expertise, they developed high-quality content. Thanks to their efforts, documents were prepared that became the basis for the adoption of the Polish Presidency's conclusions at the Council of Europe meeting on 2 December 2011.

These conclusions served as the foundation for the development of health-promoting programmes by the European Commission, funded through European grants.

On 2 December 2011, EPSCO adopted three conclusions of the EU Council related to the priorities of the Polish Presidency in the field of public health:

- prevention, early diagnosis and treatment of chronic respiratory diseases in children (2011/C 361/05),
- early detection and treatment of communication disorders in children, including the use of e-Health tools and innovative solutions (2011/ C 361/04),
- conclusions on closing health gaps within the EU through concerted action to promote healthy lifestyle behaviours (2011/C 359/05).

The conclusions were well-founded, accepted by EU Health Ministers, and fact-based. However, much time has passed, and it must be acknowledged that little has improved.

Agnieszka Czupryniak, Chair of the Public Health Working Party during the Polish Presidency of the Council of the European Union, and the chair of the Subcommittee on Health Priorities at the Ministry of Health, Professor Bolesław Samoliński of the Medical University of Warsaw, made significant contributions to negotiating the conclusions during our Presidency. I want to emphasise that gaining the European Commission's support for our priorities was a challenging process.

A common theme of the conclusions was the emphasis on eliminating health disparities in European societies by promoting healthy lifestyles and addressing risk factors associated with diseases that impair quality of life, as well as individual, social, and intellectual development. Particular attention was given to childhood, focusing on disease prevention, early diagnosis, and appropriate treatment. The primary goal, therefore, was to create opportunities for better health in the coming decades for children at risk of these diseases or already affected by them, as well as to foster pro-health attitudes.

A key strength of the Polish Presidency and the conclusions adopted during its term is that their content extends beyond political declarations of intent in specific areas. It also lays the groundwork for providing expert and operational circles with the tools necessary to address these issues effectively. First and foremost, emphasis should be placed on strengthening the activities of institutional networks operating within the transnational and supranational EU framework. Their cooperation aims to build scientific foundations, develop health programmes, and facilitate their implementation across the EU. This adds a tangible and practical dimension to healthpromoting policies within the context of public health. Other aspects of broadly framed health issues, considering the division of competences and legislative proposals, were also discussed by members of the Council of the EU's working parties on foodstuffs and on pharmaceuticals and medical devices. During its Presidency, Poland initiated and participated in many meetings in the European Parliament. Notably, the Polish Presidency in Health began in Sopot on 6 July. This informal meeting of EU Health Ministers was an excellent opportunity to present our adopted priorities. It is worth emphasising that the Health Ministers received them very positively, giving us the green light for their implementation. Undoubtedly, such a strong start was made possible, among other factors, by an excellent lecture on communication disorders in children delivered by Professor Henryk Skarżyński, Director of the Institute of Physiology and Pathology of Hearing. The venue of the ministerial meeting at the historic Gdańsk Shipyard, the introductory remarks by Minister Ewa Kopacz, and the excellent atmosphere also contributed to the adoption of the conclusions and the highly praised Polish Presidency in Health.

I attribute the success of our Presidency to the excellent organisation of work within the Ministry of Health and the tremendous dedication of its staff. We began preparations 30 months prior to the start of the Presidency, which proved to be the right decision. The collaboration between



the staff of the Ministry of Health, the Chief Sanitary Inspectorate, the staff of the Permanent Representation to the European Commission, and highly skilled healthcare professionals resulted in the high quality of our work and the outcomes achieved. The combination of highly skilled and well-prepared staff from the Ministry of Health and the Chief Sanitary Inspectorate, together with the medical professionals from Polish universities and institutes, established a solid foundation for the Polish Presidency in 2011.

Our efforts notably centred on strengthening the activities of institutional networks operating within the transnational and supranational EU framework. Their cooperation aims to build scientific foundations, develop health programmes, and facilitate their implementation across the EU. This added a tangible and practical dimension to health-promoting policies within the context of international public health.

I wish Minister Izabela Leszczyna and the staff preparing the agenda for the upcoming Polish Presidency in 2025 much success, made possible through diligent, substantive, and well-organised work.

In preparing the above text, the author drew on materials from the Ministry of Health, the Chief Sanitary Inspectorate, the European Commission, and online information portals.

# Health Priorities of the Council of the European Union Presidencies, 2011–2025

## Jakub Gierczyński MD PhD<sup>5</sup>, Małgorzata Bogusz<sup>6</sup>

#### Introduction

The chapter presents a cross-cutting analysis of the health priorities of the Council of the European Union presidencies from 2011 to 2025, in the context of preparations for Poland's second Presidency, commencing in January 2025. It is based on official documents from each presidency, spanning Poland's first Presidency in July 2011 to its upcoming Presidency in January 2025. Additionally, the chapter outlines the key responsibilities of the Council of the European Union and examines the current priorities of the European Commission and the European Economic and Social Committee (EESC) in the area of health.

#### The Presidencies of the Council of the European Union, 2011–2026

The Council of the European Union is an important decision-making body of the European Union (EU). The Council of the European Union:

- 1. Negotiates and adopts European Union law,
- 2. Coordinates Member States' policies in the fields of economic and fiscal policy, education, culture, youth and sport, and employment;
- 3. Develops a common EU foreign and security policy, covering development and humanitarian aid, defence and trade, as well as the unity, consistency and effectiveness of the EU's external action;
- 4. Concludes international agreements, which may cover broad areas (such as trade, cooperation and development aid) or specific subjects (i.e. textiles, medicines, vaccines, human products, fisheries, customs, transport, research or technology);
- 5. Adopts the European Union budget.<sup>7</sup>

The Presidency of the Council of the European Union is not determined through elections. Since 2009, under the Treaty of Lisbon, Member States have each held the presidency of the Council of the European Union for six months in turn, working closely in groups of three countries.

<sup>5</sup> European Health Network.

<sup>6</sup> Institute for Social Policy Development, European Economic and Social Committee.

<sup>7</sup> https://www.consilium.europa.eu/pl/council-eu/.



The presidency of each country therefore falls every 14 years. Poland held its first presidency of the Council of the European Union from 1 July to 31 December 2011 and will hold the second presidency from 1 January to 30 June 2025.<sup>8</sup>

Date	Presidency of the Council of the European Union	
January 2025 – June 2026	Poland, Denmark, Cyprus	
July 2023 – December 2024	Spain, Belgium, Hungary	
January 2022 – June 2023	France, Czechia, Sweden	
July 2020 – December 2021	Germany, Portugal, Slovenia	
January 2019 – June 2020	Romania, Finland, Croatia	
July 2017 – December 2018	Estonia, Bulgaria, Austria	
January 2016 – June 2017	The Netherlands, Slovakia, Malta	
July 2014 – December 2015	Italy, Latvia, Luxembourg	
January 2013 – June 2014	Ireland, Lithuania, Greece	
July 2011 – December 2012	Poland, Denmark, Cyprus	

 Table.

 The Presidencies of the Council of the European Union 2011–2026:

 from the first to the second Polish Presidency.

Source: Own elaboration based on materials from the Council of the European Union

Each trio sets long-term goals and prepares a common agenda of topics and issues that the Council will address for the 18 months of the Presidency. Based on the common agenda, each of the three countries develops its own, more detailed programme for its six-month Presidency of the EU Council.<sup>9</sup>

For example, the current Trio – Spain, Belgium, and Hungary – pursues common goals aimed at enhancing the resilience and strategic autonomy of the European Union. These goals focus on enhancing the EU's global competitiveness by reinforcing its industrial base in line with the green and digital transitions and leveraging innovation; ensuring that these transitions are fair, equitable, and inclusive by bolstering Europe's social dimension, including addressing the demographic challenges facing the EU; strengthening international partnerships, multilateral cooperation, and security in all its dimensions; developing an ambitious and sustainable trade policy while defending the EU's interests more assertively and rooted in its core values; and enhancing the EU's capacity to act in the areas of security and defence.<sup>10</sup> On the other hand, the specific goals of the Hungarian Presidency include: a new European agreement on competitiveness; strengthening European defence policy; a coherent and merit-based EU enlargement policy; curbing illegal migration; shaping future cohesion policy; an agricultural policy centred on farmers; and addressing demographic challenges.<sup>11</sup>

#### The Health Priorities of the Council of the European Union Presidencies, 2011–2025

Health protection has long been identified by Europeans as a key challenge for the European Commission, the Council of the European Union, and national governments. The Covid-19 pandemic has elevated health to a strategic priority and has driven the necessary integration of Member States. In addition, the free movement of people, services, and goods is present in the healthcare system. The Treaty of Lisbon of 2009 defines the European Union's role in the health sector as one of shared competences between the European Union and Member States, primarily

 $<sup>8 \</sup>qquad \underline{https://www.consilium.europa.eu/pl/council-eu/presidency-council-eu/.}$ 

 $<sup>9 \\ \</sup>underline{https://www.consilium.europa.eu/pl/council-eu/presidency-council-eu/timeline-presidencies-of-the-council-of-the-eu/.}$ 

<sup>10</sup> https://belgian-presidency.consilium.europa.eu/en/programme/trio-programme/.

<sup>11</sup> https://hungarian-presidency.consilium.europa.eu/en/programme/priorities/.

covering epidemiological protection and the registration of medicines. The financing of medical services and the organisation of the entire healthcare system remain under the authority of national governments. This leads, among other things, to a threefold difference in healthcare funding per capita (in 2022, Poland spent EUR 1,200 per capita, while the EU average was approximately EUR 3,600 per capita).

Health priorities are an integral component of each Presidency of the Council of the European Union.

Outlined below are the health priorities of the Council of the European Union Presidencies from 2011 to 2025, listed in descending order from the most recent to the earliest Presidencies.

State	Period	Priorities in health
Poland	1 January – 30 June 2025	<ol> <li>Health security</li> <li>Digital transformation of healthcare</li> <li>Disease prevention and health education</li> <li>Mental health of children and adolescents</li> <li>Implementation of the European Health Data Space (EHDS) legislation</li> <li>Enhancing the cybersecurity of medical technologies</li> <li>Cooperation among EU Member States to develop cross-border e-health services.</li> <li>Regulation of pharmaceutical law in the context of ensuring the pharmaceutical security of the European Union.<sup>12</sup></li> </ol>
Hungary	1 July – 31 December 2024	<ol> <li>Regulation of pharmaceutical law</li> <li>Tackling cardiovascular disease</li> <li>Implementation of the Substances of Human Origin (SoHO) Regulation and the adoption of Conclusions by the European Council, including those of the Employment, Social Policy, Health, and Consumer Affairs Council (EPSCO)</li> <li>Rare diseases</li> <li>Improving access to and affordability of medicinal products</li> <li>Mental health<sup>13</sup></li> </ol>
Belgium	1 January – 30 June 2024	<ol> <li>Strengthening the prevention of health threats by enhancing societal resilience, including by reinforcing crisis management</li> <li>Supporting healthcare systems in addressing shortages</li> <li>Improving the security of medicine supply, ensuring continuous access, and addressing shortages</li> <li>Enhanced access to high-quality, safe, and affordable medicinal products</li> <li>Completion of the European Health Data Space (EHDS) and the remaining work on the Substances of Human Origin (SoHO) Regulation</li> <li>Enhancing innovation in healthcare</li> <li>Health promotion of and disease prevention</li> <li>Rare diseases<sup>14</sup></li> </ol>

Table.	
The Health Priorities of the Council of the European Union Presidencies, 2011–20	25

<sup>12</sup> The priorities published during the conference of the Ministry of Health on 17.12.2024, <u>https://www.gov.pl/web/zdrowie/</u> <u>bezpieczenstwo-europo-priorytety-polskiej-prezydencji-w-obszarze-zdrowia</u>.

<sup>13</sup> https://hungarian-presidency.consilium.europa.eu/en/programme/programme/.

<sup>14</sup> https://belgian-presidency.consilium.europa.eu/en/programme/the-belgian-presidency-programme/.



State	Period	Priorities in health
Spain	1 July – 31 December 2023	<ol> <li>Improving the protection of vulnerable patient groups</li> <li>Fostering preparedness and response initiatives for facing new health alerts</li> <li>Aligning the European health agenda with the 2030 Agenda for Sustainable Development (Agenda 2030) and the One Health approach</li> <li>Creation of a European Health Data Space (EHDS)</li> <li>A Regulation on standards of quality and safety for substances of human origin intended for human application (SoHO)</li> <li>Strengthening the European Medicines Agency (EMA)</li> <li>Disease prevention and health promotion culture in the European Union with respect to issues such as childhood obesity and lifelong vaccination</li> <li>Strengthening the capabilities of health systems in areas where the pandemic has exposed shortcomings, such as strategic autonomy in healthcare provision</li> <li>New actions on HIV and mental illness</li> <li>Rare diseases<sup>15</sup></li> </ol>
Sweden	1 January – 30 June 2023	<ol> <li>The regulation on the European Health Data Space</li> <li>A regulation on standards of quality and safety for substances of human origin intended for human application (SoHO)</li> <li>Implementing Europe's Beating Cancer Plan</li> <li>Renewal of the EU Global Health Strategy</li> <li>Priority for pharmaceutical products – updating pharmaceutical legislation and introducing new regulations on orphan medicinal products and paediatric medicines</li> <li>Implementation of the Medical Devices Regulation</li> <li>Effective treatment of bacterial infections and combating antibiotic resistance</li> <li>Rare diseases<sup>16</sup></li> </ol>
Czechia	1 July – 31 December 2022	<ol> <li>Addressing the COVID-19 pandemic and enhancing the EU's preparedness for future health crises</li> <li>The humanitarian crisis arising from the large influx of refugees to the EU due to the war in Ukraine</li> <li>Oncology screening</li> <li>European Health Data Space</li> <li>Pharmaceutical products</li> <li>Rare diseases</li> <li>Preventive vaccinations<sup>17</sup></li> </ol>

 $<sup>15 \</sup>quad \underline{https://spanish-presidency.consilium.europa.eu/media/e4ujaagg/the-spanish-presidency-programme.pdf.}$ 

 $<sup>16 \</sup>quad \underline{https://swedish-presidency.consilium.europa.eu/en/programme/programme-of-the-presidency/.}$ 

<sup>17 &</sup>lt;u>https://wayback.archive-it.org/12090/20230320173300/https://czech-presidency.consilium.europa.eu/media/ddjjq0zh/programme-cz-pres-english.pdf</u>.



State	Period	<b>Priorities in health</b>
France	1 January – 30 June 2021	<ol> <li>Completion of negotiations on the <i>Building a European Health</i> <i>Union</i> legislative package.</li> <li>Support for the establishment of a European Health Emergency Preparedness and Response Authority (HERA)</li> <li>Promoting an industrial strategy for health</li> <li>Innovation in healthcare</li> <li>Revision of the directives on the safety and quality of human blood and on the safety and quality of human tissues and cells for the purposes of scientific and technological developments</li> <li>Digital health</li> <li>European Health Data Space</li> <li>An international treaty to combat pandemics</li> <li>Prevention and fight against cancer</li> <li>Antimicrobial resistance</li> <li>Mental health of young people</li> <li>Pharmaceutical legislation</li> <li>Rare diseases<sup>18</sup></li> </ol>
Slovenia	1 July – 31 December 2020	<ol> <li>Strengthening the EU's response to health threats during potential and future pandemics</li> <li>Innovative solutions for healthcare systems</li> <li>Organisation, availability, quality, responsiveness and sustainable financing of healthcare systems</li> <li>Tackling cancer</li> <li>Strengthening the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) with respect to preparedness and emergency response mechanisms</li> <li>Initiation of the establishment of a European Health Emergency Preparedness and Response Authority (HERA)</li> <li>Improving the availability of medicines, including antimicrobials, generics, oncology drugs<sup>19</sup></li> </ol>

 $<sup>18 \</sup>quad \underline{https://www.consilium.europa.eu/media/56602/2022-jan-jun-fr-programme.pdf.}$ 

<sup>19</sup> https://www.consilium.europa.eu/media/56259/2021-jul-dec-sl-programme.pdf.



State	Period	<b>Priorities in health</b>
Portugal	1 January – 30 June 2020	<ol> <li>EU Health Programme (EU4Health)</li> <li>Digital transformation of the healthcare sector</li> <li>Telemedicine and telehealth</li> <li>Interoperability of electronic health records</li> <li>Availability of medicines and vaccines, medical equipment and devices</li> <li>Pharmaceutical Strategy for Europe</li> <li>Strengthening the role of European Agencies in coordinating with networks of National Agencies in Member States</li> <li>Strategic autonomy – management, production capacity, and supply within Europe</li> <li>Sustainable development – effective information, pricing policy and regional cooperation</li> <li>Accessibility – fair, cost-effective access to medical technologies</li> <li>Environmental health</li> <li>Tackling cancer</li> <li>Mental health<sup>20</sup></li> </ol>
Germany	1 July – 31 December 2020	<ol> <li>EU crisis management instruments</li> <li>Cross-system information exchange for pandemic prevention – creation of Member States' databases and early warning system</li> <li>Health Security Committee (HSC)</li> <li>Improving the supply of pharmaceuticals, medical products, and personal protective equipment</li> <li>Agreement on joint procurement in Europe</li> <li>Developing the EU ERAvsCorona Action Plan</li> <li>Artificial intelligence and quantum technologies</li> <li>Security of digital data</li> <li>Innovation in healthcare<sup>21</sup></li> </ol>
Croatia	1 January – 30 June 2020	<ol> <li>Cooperation among Member States in the field of organ donation and transplantation</li> <li>Healthcare in response to the challenges of ageing societies</li> <li>Health Technology Regulation<sup>22</sup></li> </ol>
Finland	1 July - 31 December 2019	<ol> <li>Digitisation and digitalisation of the health sector</li> <li>Artificial intelligence<sup>23</sup></li> </ol>
Romania	1 January – 30 June 2019	1. Digitisation and digitalisation of the health sector <sup>24</sup>
Austria	1 July - 31 December 2018	<ol> <li>Health Technology Assessment Regulation</li> <li>Strengthening cooperation to tackle disease</li> <li>Tobacco control<sup>25</sup></li> </ol>

 $<sup>20 \</sup>quad \underline{https://www.consilium.europa.eu/media/56256/2021-jan-jun-pt-programme.pdf.}$ 

 $<sup>21 \ \</sup>underline{https://www.consilium.europa.eu/media/56253/2020-jul-dec-de-programme.pdf}.$ 

<sup>22</sup> https://www.consilium.europa.eu/media/56250/2020-jan-jun-hr-programme.pdf.

 $<sup>\</sup>label{eq:linear} 23 \quad \underline{https://www.consilium.europa.eu/media/56247/2019-jul-dec-fi-programme.pdf.}$ 

<sup>24</sup> https://www.europarl.europa.eu/RegData/etudes/BRIE/2018/630313/EPRS\_BRI(2018)630313\_EN.pdf.

<sup>25</sup> https://www.consilium.europa.eu/media/56240/2018-jul-dec-at-programme.pdf.

State	Period	Priorities in health
Bulgaria	1 January – 30 June 2018	<ol> <li>Regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency</li> <li>Healthy diet for children</li> <li>Shortage of medicinal products for economic reasons and parallel exports<sup>26</sup></li> </ol>
Estonia	1 July - 31 December 2017	<ol> <li>Coordination in e-health</li> <li>Use of medical data</li> <li>Innovation in the health sector<sup>27</sup></li> </ol>
Malta	1 January – 30 June 2017	<ol> <li>Obesity in children</li> <li>Structured cooperation to enhance access to innovative medical technologies for rare diseases in the EU</li> <li>Challenges in human resources for the provision of highly specialized healthcare services</li> <li>Cross-border IT infrastructure</li> <li>Exchange of personal and health-related data between healthcare entities</li> <li>Tackling HIV/AIDS<sup>28</sup></li> </ol>
Slovakia	1 July – 31 December 2016	<ol> <li>regulatory framework for medical devices and on Community procedures for the authorisation of medicinal products</li> <li>Affordability and availability of innovative medicinal products</li> <li>Antimicrobial resistance</li> <li>Tuberculosis<sup>29</sup></li> </ol>
The Netherlands	1 January – 30 June 2016	<ol> <li>Access to medicinal products and medical devices</li> <li>Regulation on medical devices and in vitro diagnostic devices</li> <li>Antimicrobial resistance<sup>30</sup></li> </ol>
Luxembourg	1 July – 31 December 2015	<ol> <li>Regulatory framework for access to safe and high-quality medical devices</li> <li>Personalised medicine</li> <li>Tackling dementia</li> <li>Management of Ebola outbreaks</li> <li>Mental health of children<sup>31</sup></li> </ol>
Latvia	1 January – 30 June 2015	<ol> <li>Agreement with the European Parliament on medical devices and in vitro diagnostic devices</li> <li>Mental health of children</li> <li>Obesity in children</li> <li>Patient-centred care</li> <li>Cancer screening programmes in Europe</li> <li>E-health</li> <li>Use and safety of health data<sup>32</sup></li> </ol>

26 https://www.consilium.europa.eu/media/56264/2018-jan-jun-bg-programme.pdf.

- $28 \quad \underline{https://www.consilium.europa.eu/media/56234/2017-jan-jun-mt-programme.pdf.}$
- 29 https://www.consilium.europa.eu/media/56231/2016-jul-dec-sk-programme.pdf.
- $30 \ \underline{https://www.consilium.europa.eu/media/56229/2016-jan-jun-nl-programme.pdf.}$

32 <u>https://eu2015.lv/images/PRES\_prog\_2015\_EN-final.pdf</u>.

<sup>27</sup> https://www.consilium.europa.eu/media/56237/2017-jul-dec-ee-programme.pdf.

 $<sup>31 \</sup>quad \underline{https://www.consilium.europa.eu/media/56226/2015-jul-dec-lu-programme.pdf.}$ 



State	Period	Priorities in health
Italy	1 July – 31 December 2014	<ol> <li>Digitisation and digitalisation of healthcare</li> <li>Access to medical devices</li> <li>Rare diseases</li> <li>Dementia</li> <li>HIV/AIDS</li> <li>A European Health Technology Assessment Agency<sup>33</sup></li> </ol>
Greece	1 January – 30 June 2014	<ol> <li>Access to medical devices and in vitro diagnostic devices</li> <li>Health technologies</li> <li>Pharmacovigilance Fee Regulation</li> <li>Directive on prices and reimbursements, access to innovative medicinal products and generics, and defining the development of research in the EU pharmaceutical sector.</li> <li>E-health</li> <li>Mental health<sup>34</sup></li> </ol>
Lithuania	1 July – 31 December 2013	<ol> <li>Directive on ensuring competitiveness in clinical trials while safeguarding the safety and rights of clinical trial participants</li> <li>Tobacco Products Directive</li> <li>Access to new and innovative medical devices</li> <li>Directive on the regulation of prices of medicinal products</li> <li>Directive on cross-border threats to health<sup>35</sup></li> </ol>
Ireland	1 January – 30 June 2013	<ol> <li>Cross-border health threats, including communicable diseases, biological, chemical or environmental hazards</li> <li>Tobacco Products Directive</li> <li>Regulation concerning clinical trials on medicinal products</li> <li>Medical devices and in vitro diagnostic devices<sup>36</sup></li> </ol>
Cyprus	1 July – 31 December 2012	<ol> <li>Directive on cross-border threats to health</li> <li>Organ donation and transplantation</li> <li>Healthy ageing</li> <li>Pharmacovigilance</li> <li>Clinical trials</li> <li>Transparency of measures setting the prices of medicinal products</li> <li>Medical devices<sup>37</sup></li> </ol>
Denmark	1 January – 30 June 2012	<ol> <li>Innovation in the healthcare sector</li> <li>Medical devices</li> <li>Antimicrobial resistance</li> <li>Diabetes<sup>38</sup></li> </ol>

<sup>33 &</sup>lt;u>http://italia2014.eu/en/presidency-and-eu/programme-and-priorities/programme-of-the-italian-presidency-of-the-council-of-the-european-union/</u>.

<sup>34 &</sup>lt;u>https://issuu.com/gr2014eu/docs/programme\_en\_28012014</u>.

 $<sup>35 \ \</sup>underline{https://www.uems.eu/\_data/assets/pdf\_file/0013/1534/Programa\_EN\_Lithuanian\_Presidency.pdf.}$ 

 $<sup>36 \ \</sup>underline{https://emnbelgium.be/sites/default/files/attachments/eu-pres\_prog\_en\_a4.pdf.}$ 

 $<sup>\</sup>label{eq:http://www.cy2012.eu/index.php/en/file/MAZ6Cvaoj0L2nxXo9+AUZw==/.$ 

 $<sup>38 \ \</sup>underline{https://wbc-rti.info/object/document/7192/attach/1Europeatwork\_DanishPresidency\_2012.pdf.}$ 



State	Period	Priorities in health
Poland	1 July – 31 December 2011	<ol> <li>Prevention, early diagnosis and treatment of chronic respiratory diseases in children</li> <li>Early detection and treatment of communication disorders in children</li> <li>E-health and innovation in the health sector</li> <li>Promotion of healthy lifestyles</li> <li>Healthy ageing</li> <li>Tackling neurodegenerative diseases, including Alzheimer's disease</li> <li>Research into brain diseases</li> <li>Pharmacovigilance<sup>39</sup></li> </ol>

Source: own elaboration.

#### **Cross-sectional analysis**

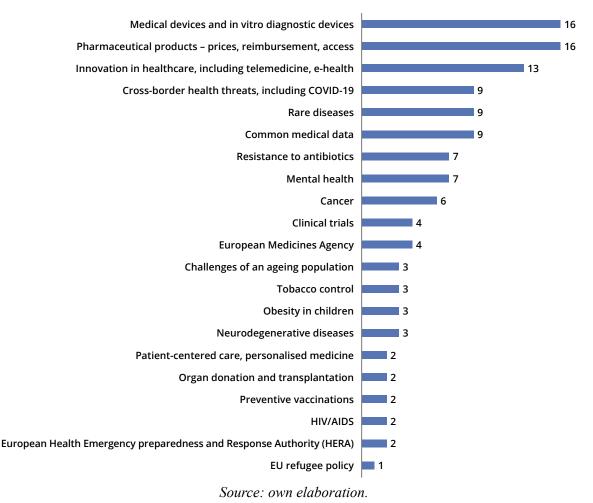
Among the areas identified in the programmes of the presidencies of the Council of the European Union developed by Member States from 2011 to January 2025, 16 countries highlighted activities related to the availability of pharmaceutical products, including those designed to address shortages, pricing, and reimbursement of medicinal products. An equal number of countries highlighted in their programmes a focus on medical devices and in vitro diagnostics – referring both to access to medical devices and the regulatory framework under the applicable Directives. Thirteen countries highlighted the need to enhance innovation in healthcare within the European Union, including the introduction of telemedicine and e-health solutions. Nine European countries highlighted actions addressing cross-border health threats, including those caused by Covid-19, as well as measures to counter epidemics and strengthen crisis management in Member States. A further nine presidencies highlighted the prioritisation of rare diseases and the focus on shared medical data, including the European Health Data Space (EHDS). Seven countries highlighted antibiotic resistance as a key focus in their programmes. Similarly, seven countries indicated the undertaking of actions related to mental health. Cancer was prioritised in six programmes. Four Member States highlighted activities in their presidency programmes related to clinical trials, regulations concerning the European Medicines Agency and its operations. Additionally, four countries pointed to activities supporting organ donation and transplantation, including efforts towards the introduction of the Substances of Human Origin (SoHO) Regulation. The programmes of three countries included activities addressing the challenges of an ageing population, tobacco control, childhood obesity, neurodegenerative diseases, and the promotion of preventive vaccinations. Only two countries highlighted in their presidency programmes the strengthening of patientcentred care and personalised medicine. Similarly, two countries highlighted actions related to HIV and AIDS policies. Regulatory activities of the European Health Emergency Preparedness and Response Authority (HERA) were included in the Presidency programmes of two countries. One country highlighted activities related to the prevention of cardiovascular diseases in its Presidency programme. Similarly, one country also undertook actions related to refugee policy under its Presidency.

<sup>39</sup> http://oide.sejm.gov.pl/oide/en/images/files/prezydencja/Raport\_koncowy.pdf.



#### Chart.

Member States' health priorities within the framework of the Presidency programmes of the Council of the European Union – a cross-cutting analysis for 2011–2025 (from the first to the second Polish Presidency)



#### **Summary**

As outlined above, the most frequent health priorities of the countries holding the Presidency of the Council of the European Union from 2011 to 2025 were issues related to pharmaceutical policy and medical devices. Pharmaceutical security gained additional importance during the COVID-19 pandemic and geopolitical disruptions. Another group of priorities concerns rare diseases, mental health, and cancer. The one-off emergence of cardiovascular diseases as a priority is surprising, despite the fact that these diseases are the leading cause of death (ahead of cancer) in the European Union. Poland plans to priorities mental health disorders in children and adolescents, drawing on extensive experience from several years of reforming the care model focused on community-based care. Preventive healthcare and the digitisation of the healthcare system are Polish priorities that remain consistently relevant across all countries of the European Union. Poland will continue efforts related to the implementation of legislation on the European Health Data Space and pharmaceutical law, including the pharmaceutical security of the European Union.

The most important health priorities outlined in the European Commission's EU4Health programme for 2021-2027, which aims to support strong, resilient, and accessible healthcare systems in Member States, should also be recalled here. The implementation of the programme is based on four objectives: improving and supporting health (including health promotion, disease prevention, and cooperation in health), protecting citizens against health threats and crises (including epidemiological, medicine and product safety), strengthening healthcare systems, and increasing



access to healthcare for citizens of the EU-27.<sup>40</sup> At the same time, it should be noted that the Council of the European Union urged the European Commission to keep health as a priority in its upcoming five-year term. In the approved conclusions, Member States acknowledge the progress made in improving health policy coordination at the EU level, emphasise the current challenges facing the EU healthcare system, and outline key areas of focus to strengthen the European Health Union.<sup>41</sup>

## A Challenge for Europe: Protecting Health in an Era of Global Dynamic Social Changes

### Andrzej Ryś MD PhD<sup>42</sup>, Karolina Wasielewska<sup>43</sup>

Poland assumes the new Presidency during a particularly significant period. Wiser from the experiences of the COVID-19 pandemic, the country must now confront further challenges: ageing populations, health-related disinformation, the mental health crisis among children and adolescents, and disruptions in the global supply chain, including medicines and raw materials for their production. In an interview with Karolina Wasielewska, **Andrzej Ryś**, Principal Scientific Adviser at the Directorate General for Health and Food Safety of the European Commission, discusses how to prepare for this challenge by thoughtfully leveraging the support and tools of the European Union.

**Karolina Wasielewska:** Focusing on health topics, how do the circumstances surrounding Poland's upcoming Presidency of the Council of the European Union compare to those of 2011? It seems that the pandemic has transformed every aspect of the healthcare landscape.

Andrzej Ryś: The pandemic has brought significant change, yet certain priorities from the past remain the same. It is worth revisiting EU documents from before Poland's first presidency, which outlined long-term goals in health and healthcare. In 2008, the EU's first health strategy, *Together for Health*, was published, highlighting both European and global trends that, as we now observe, remain unchanged: population ageing, health security, the rapid advancement of medical technologies, and patients' expectations for their public funding. Europe is indeed ageing, and this must be factored into the planning of healthcare system reforms and even national development strategies, as seniors are set to become the predominant demographic in society. Two pressing questions remain: how to address the challenges of longevity and, conversely, the issue of declining fertility.

Among the priorities of the current presidency is digitisation in health, a topic we also addressed in a document published 16 years ago. New technologies are transforming our lives and can drive both progress and challenges in healthcare – a reality that was evident even then and will likely always need to be considered in health regulations and policies.

And, of course, there is also the third trend we highlighted at the time – health security. In the *Together for Health* strategy, we discussed it in the context of Member State cooperation in addressing large-scale, pan-European and global health threats. As it turned out, we developed this strategy just before the first pandemic of the 21st century – the H1N1 virus pandemic, commonly known as "swine flu". At that time, we had the opportunity to witness the value of collective efforts for shared security. COVID demonstrated this even more profoundly, as it proved to be a health issue that extended far beyond the scope of medicine and healthcare systems – impacting countries at political, social, organisational, and economic levels. We were unprepared for the sudden

<sup>40</sup> EU4Health programme 2021-2027 – a vision for a healthier European Union, <u>https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union\_en</u>.

<sup>41</sup> European Health Union: Council calls on Commission to keep health as a priority, <u>https://www.consilium.europa.eu/en/</u> press/press-releases/2024/06/21/european-health-union-council-calls-on-commission-to-keep-health-as-a-priority/.

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transition to remote work, remote schooling, and administrative operations, as well as the abrupt restrictions on the flow of people and goods. We were all surprised by the extent to which this transition impacted the economy, scientific research, employment relations, the education system, and the healthcare system – as well as its long-term consequences. Although I have long engaged with many experts, both from the European Commission and global cooperation networks, they were unable to foresee such dramatic scenarios and their consequences.

**Karolina Wasielewska:** So you are saying that phenomena once described as future trends – such as the adoption of telemedicine – became part of our daily lives virtually overnight during the pandemic.

Andrzej Ryś: Yes. The pandemic accelerated the use of digital tools in healthcare systems and patient interactions, such as electronic prescriptions, and highlighted the importance of health data in clinical decision-making and crisis management within healthcare systems. We successfully developed digital tools that operate across the EU, such as electronic "COVID passports". The events of 2020 also provided a strong impetus for the development of a new regulation on the European Health Data Space.

The truth remains, however, that we still do not fully understand the effects of the COVID-19 pandemic. During my recent sabbatical leave in Oxford, I reviewed selected articles from among half a million publications on the subject. And I'm talking only about articles in peer-reviewed journals, but countless other publications by authors and institutions of varying credibility continue to circulate globally. The pandemic has already provided us with vast knowledge, spanning biological and medical sciences to sociology, economics, and geopolitics – and this body of knowledge will only continue to grow in the years to come.

Winston Churchill famously said, "Never let a good crisis go to waste".

Of course, there is a natural psychological need to distance ourselves from this ordeal. However, we must value the knowledge gained during the pandemic and, above all, learn from it. This knowledge is invaluable for analysing the current state of post-pandemic societies and could prove equally helpful when we face the next pandemic – something experts agree is inevitable.

**Karolina Wasielewska:** Has the experience of united efforts to counter the threat led the authorities of Member States to view the deepening of EU cooperation in health more favourably, not just in crisis situations but also in everyday matters? It seems that neither the pandemic nor Russia's aggression against Ukraine has significantly cooled the debate over where Brussels' competences end concerning the health of citizens in individual EU countries.

Andrzej Ryś: During the pandemic, the Commission and Member States collaborated very effectively. The discussion about community competences has always been, and will continue to be, let's say, intense and deeply principled. However, the EU's competences in public health have been clearly defined since the Maastricht Treaty. It's not as though we were operating under a different set of laws during the pandemic. All decisions – from border closures by individual countries to the common regulation introducing COVID passports – were grounded in existing European treaties. It is interesting that no other area sees such heated disputes over the limits of the European Union's authority as those that erupt around health. After all, the treaties clearly define such competences in other equally important matters affecting all Europeans, such as occupational safety and, indirectly, employee health. And in those areas, treaty provisions rarely provoke such controversy. Also, let's not forget that many initiatives are founded on cooperation between Member States and the European Commission. These include the joint establishment of 24 European Reference Networks (ERNs) for rare diseases and Europe's Beating Cancer Plan.

**Karolina Wasielewska:** And what are the latest advancements in healthcare that have been developed with the use of these existing instruments?

Andrzej Ryś: An interesting example is the history of the directive on cross-border services, which was designed to facilitate the functioning of the single market – including healthcare services.



Ultimately, healthcare services were excluded from the directive. In its subsequent rulings, the Court of Justice of the European Union, approached by patients, shaped the direction of the future directive on patients' rights in this area. This directive also includes provisions on areas of cooperation between Member States, enabling the creation of concepts such as the aforementioned European Reference Networks, as well as cooperation in the fields of digital health and health technology assessment (HTA). These activities were praised the most in a report analysing the 10 years of the directive's application.

Karolina Wasielewska: An important example is the article obliging Member States to share good practices in healthcare.

Andrzej Ryś: True! And this is nothing new – as far back as the Middle Ages, scholars travelled from one university to another, sharing knowledge about human health. Today's EU instruments include the possibility of supporting health reforms in a given country with the assistance of experts from another country where similar reforms have been successful. Of course, it is not always possible to transfer such solutions from one country to another without modifications, but the advice of a foreign expert can also assist in tailoring newly introduced laws to local realities. There are also many groups and expert forums, enabling Member States to share their experiences. We have also created a portal on European health policy that allows thousands of non-governmental organisations to collaborate and develop common positions across various areas of their activities. The fabric of European cooperation offers nearly limitless possibilities. Among other things, this is the purpose of the Presidency – to reflect on how we can further leverage it, including in Poland.

**Karolina Wasielewska:** Let's take a closer look at the first health priority of our Presidency. Child and adolescents psychiatry is a healthcare area that many Member States have neglected over the years, and the pandemic has heightened the need for urgent improvements in this field. As an example of good practice, Deputy Minister Wojciech Konieczny shared the concept of cooperation between the National Health Fund and the school healthcare system, allowing for the diagnosis of a student's mental health problems within schools – the environment where young people spend the most time – and ensuring that this diagnosis is also integrated into the general healthcare system. Thanks to this, we will avoid dual diagnosis, which can be a source of unnecessary stress for young people during the critical period of adolescence. However, for these solutions to be truly effective, the entire environment of such a young person – their carers, teachers, and peers – must be educated on the symptoms of mental disorders and trained to respond quickly when they appear. It seems that once again, we are discussing an idea that is self-evident. The only thing that is surprising is that it has not been implemented until now.

Andrzej Rys: This is an excellent idea, but concern for the well-being of young people – including those who do not require a diagnosis of mental disorders – should begin even earlier. I will illustrate this with the example of a Belgian school, as my children have attended schools in both Poland and Belgium, allowing me to compare these two systems. When my wife and I came to enroll our six-year-old in a Belgian elementary school, the teachers who would be leading the classes attended the meeting with the parents, and the headmistress was also present to explain how the school operates and its guiding principles. Although this particular school was run by a Catholic foundation, it welcomed children from Belgian families, as well as from other nationalities and various faiths. We were told by the headmistress that the school operates on Christian values, but understood in a more universal manner. She also spoke about the "triangle of responsibility and cooperation" between school, parents, and the child. A psychologist was also present. He spent considerable time with us, discussing the situations our children might encounter, the challenges they might face, and the roles each of us plays as participants in this process. He also emphasized that the school enforces a zero-tolerance policy for violence. Theoretically, this is true for every school, but having it explicitly stated gave children and parents greater confidence to address troubling incidents and student behavior. In my daughter's class, such a situation occurred involving one of her friends. This girl received a great deal of attention and was guided through a form of



psychological exercise aimed not at punishing her for an act of aggression, but at helping her understand why such behaviour was inappropriate. This was done discreetly and with full respect for the child's individuality – no one treated them like a criminal or pointed fingers. The moment of "reconciliation" between the children and the symbolic handshake were equally important. I really appreciated this approach, as such a method does not isolate the individual involved from the rest of the school community – which could otherwise lead to the perpetuation of aggressive behaviour.

Of course, this does not mean that everything works perfectly in every Belgian school. Western Europe faces the same challenges as Poland. Mental health reports prepared in collaboration with the OECD and WHO indicate that depression and suicidal thoughts among young people increased universally during the pandemic, and this effect has not yet been mitigated.

Karolina Wasielewska: When did this issue appear on the European Union's agenda?

Andrzej Ryś: It did, as early as 2009–2011, primarily in the context of public health, debates, and the mobilisation of Member States and other partners for joint actions in this area. In 2011, EU health ministers adopted the *Council conclusions on the European Pact for Mental Health and Well-being: Results and Future Action*.

I remember that we, as the European Commission, organised a conference to inaugurate a series of expert meetings in individual countries, which was opened with a speech by former Norwegian Prime Minister Kjell Magne Bondevik. He was one of the first public figures to openly discuss his depression. In 1997, while in office, he was diagnosed and published a statement about it in the press. He received many expressions of support from around the world. It was an act of courage on his part, as the stigmatisation of people with mental illnesses was a significant problem at the time. On the one hand, the pandemic exacerbated the severity of symptoms in many patients, but on the other hand, it significantly helped address the problem of stigmatisation. Today, young people, as well as their parents, speak more openly about mental health issues. They are seeking and expecting support.

**Karolina Wasielewska:** Perhaps it was because the situation became unbearable for them during the pandemic and a certain "critical mass" of what an adolescent can endure was exceeded.

Andrzej Ryś: Yes, this has been confirmed by research we conducted in collaboration with experts from the OECD and WHO. However, it is not just about isolation, distance learning, and the lack of contact with peers, although many teenagers reported these issues. The main issue lay elsewhere: it suddenly became evident that online relationships do not fulfill the same needs as face-to-face contact, even for this generation that lives simultaneously in both the real and digital worlds. The well-being of young people was also significantly influenced by their family situations. Parents were stressed and worried about job loss and not everyone managed to balance remote work with handling household responsibilities. In addition, there were situations where seniors in families succumbed to COVID, and their children and grandchildren were unable to see them in their final moments. These experiences have left us with a range of traumas that will continue to affect us for a long time.

Therefore, on 7 June 2023, the European Commission published a new EU strategy on mental health. The relevant EU programmes, including Horizon Europe and EU4Health, have allocated  $\notin$ 1.23 billion to support Member States in developing an approach that emphasises promoting mental health across all policy areas. The European Commission also supports mental health research and the exchange of information between scientists, clinicians addressing these issues, and other stakeholders, including employers.

These measures will support activities in particularly sensitive areas, such as the mental health of children and adolescents.

**Karolina Wasielewska:** What actions does the European Commission take when threats such as a pandemic emerge, and what does this look like from an insider's perspective?



Andrzej Ryś: Each such situation, on the one hand, requires following a well-established framework set out in EU laws, which have been refined following the experience of the last pandemic. On the other hand, every crisis teaches us something new. Compared to the H1N1 pandemic, COVID-19 has underscored even more clearly the importance of efficient communication in the context of an ever-changing timeframes. This was because certain instruments developed during the H1N1 pandemic were still at our disposal – for example, the Health Security Committee (HSC), which served as a forum for experts from the Member States to meet. Thanks to collective efforts, we secured the support of top-tier specialists, enabling smooth progress in work on the COVID certificate, coordinated by the eHealth Network in cooperation with the HSC.

COVID, as a new health challenge, also required coordinated communication at both the EU and global levels. The goal was not only to ensure that everyone worldwide received updates on new scientific findings, the spread of new virus variants, vaccines developed and approved for use, or travel regulations, but also to combat fake news. In this context, we greatly benefited from the expertise of specialists in this area at the Member State level and from two EU agencies: the EMA and the ECDC:

Developing mechanisms that enabled collective vaccine procurement and joint negotiations regarding these purchases was another challenge. This was another important lesson from the H1N1 pandemic. At that time, each country negotiated separate contracts, and priority was given to those who concluded their agreements earlier. However, many countries failed to secure such contracts and consequently didn't have access to vaccines. I was proud that this time it worked. However, there were, of course, voices from some media and critics in wealthier countries arguing that, since they had more money and were ready to spend it immediately, they should receive vaccines first. Ultimately, the decision was made to proceed with solidarity-based purchases, although even here there were challenges: too many vaccines were contracted, as some countries had assumed significantly higher vaccination rates. The virus's dynamics were also hard to predict – experts did not have a single scenario, and public expectations for equitable access to vaccines were high as well. Compounding the challenge, anti-vaccine movements found fertile ground in many countries.

**Karolina Wasielewska:** Does the Commission consider its actions at that time a success, despite these difficulties?

Andrzej Ryś: They can be considered a success, given that we did everything possible under the circumstances. The evaluation by the European Parliament's special committee on the Covid-19 pandemic was also generally positive. The problems we encountered at that time stemmed from geopolitics. In countries affected by poverty, conflicts, or where health systems are insufficiently developed, both managing the pandemic and ensuring vaccine access proved challenging. It is worth recalling that at the beginning of May 2020, the Commission organized a global meeting of leaders, at which it encouraged them to cooperate and raise funds to support access to vaccines and medicines in low-income countries. In turn, at the end of 2022, the European Commission adopted a new strategy on global health, and earlier, together with Member States, participated in negotiations on a Pandemic Treaty within the framework of the WHO.

I am all the more pleased with the results of these actions, and if I were to highlight specifics, I would call the COVID certificate a success – alongside vaccines. We made the certificate's technology available to many countries outside the EU, and ultimately donated it to the WHO free of charge, along with additional support for its further development and implementation as a certificate for various vaccines. In addition, we demonstrated that Europe is capable of taking decisive action and creating instruments to overcome the crisis – such as the Recovery Fund.

**Karolina Wasielewska:** Since we have already touched on the topic of disinformation, I must ask – how significant a factor will the hybrid warfare that Russia is waging, including against our country, be during the Polish Presidency of the Council of the European Union? After all, disinformation in healthcare and cyberattacks on hospitals are among the instruments of this



warfare.

Andrzej Ryś: We have been combating disinformation, including that related to vaccination, for years. Cybersecurity experts have already drawn our attention to troll farms employed solely to sow informational chaos, particularly, and unfortunately, among parents. The reluctance of many parents to vaccinate their children has led to the resurgence of measles, whooping cough, and even polio – something that would have been hard to imagine just a few years ago. We must address this challenge, and it is certainly not a task that can be accomplished within a six-month presidency – especially as Russia has been engaging in such activities for many years. Already back in the Soviet days, propaganda was intended to sow doubts in people about the value of science and progress in medicine, especially Western medicine.

**Karolina Wasielewska:** Are the ongoing war and the influx of migrants also issues that should be addressed as part of health priorities?

Andrzej Ryś: Yes, but we should draw on the experience of other European countries that have been dealing with migration for much longer. For Poland, this remains a relatively new phenomenon. And yet, Spain, France, Belgium, and Portugal have solutions that enable the integration of people from other cultural or religious backgrounds into the local healthcare system.

**Karolina Wasielewska:** Another priority is the digitisation of healthcare. Each country approached healthcare digitisation somewhat independently during the pandemic – e-prescriptions and e-referrals became widespread in Poland during that time – and now we have several well-functioning systems, which, however, are not interoperable. Is there a pan-European initiative to unify these systems or at least improve their interoperability?

Andrzej Ryś: In my opinion, this is the greatest challenge for the coming years, both for the entire Union and for each individual country. However, for actions towards interoperability or even a common system to be meaningful, the European Health Data Space (EHDS) must be established. We prepared a groundbreaking legislative framework on this matter, adopted by the European Parliament at the end of April. The Covid Passport is just a foretaste of the opportunities it offers us – and we know that this legislative framework is set to come into force at the start of the Polish Presidency.

Karolina Wasielewska: Collecting and processing health data across Europe is also a huge cybersecurity challenge.

Andrzej Ryś: This is just one of many challenges, as it also includes patient access to data, the quality and verifiability of this data, the possibility of using it in various contexts, and, of course, the human factor. Doctors and other healthcare providers, for example, need to learn how to consciously and securely acquire data and use it within a safe environment, yet some still depend on much simpler and older digital devices and tools that are already available. Some experienced doctors have no issue with calling a patient and speaking with them over the phone, yet the same conversation through a video messenger makes them uneasy. I accept this because everyone is entitled to their own habits, but in the long run, this will have to change if our goal is to enhance access to healthcare providers, foster better relationships with patients, and coordinate treatment more effectively.

**Karolina Wasielewska:** In Poland, many services are digitised at the patient level. However, when I spoke with Dr. Anna Gawrońska – an expert in streamlining operations in pharmaceutical warehouses and wholesalers – she told me that "paper still rules" there. Moreover, where digital solutions are in place, they are often outdated, semi-amateur, and developed on a shoestring budget, making discussions about their security or interoperability practically irrelevant.

Andrzej Ryś: There are more such gaps on the map of digitisation. It's encouraging that we are starting to identify them. New measures supporting the implementation of the EHDS, developed by the European Commission in collaboration with national experts, as well as the EU programmes E4Health and the Digital Europe Programme, will aid in addressing these gaps. The Polish



Presidency coincides with the period when we will collectively strive to put these initiatives into action. One of the first challenges of this term will be the discussion on how to implement this ambitious agenda.

Karolina Wasielewska: Also in the context of AI and healthcare?

Andrzej Ryś: That's right. This has already been successfully implemented in the administrative domain, reducing the burden on medical staff and improving data quality. Now, a critical issue is the quality and quantity of data that artificial intelligence algorithms must process. When AI supports doctors as a diagnostic tool, there is no room for errors or oversights. However, I believe that this is a matter of technological development, and the technology will continue to improve.

Acceptance of AI in medicine and healthcare is also not an issue among doctors or patients, as most of us have likely come to terms with the fact that it will eventually become the norm. The key question is where machine assistance should stop – at what point human and expert knowledge becomes indispensable, not only from doctors but also from nurses and physiotherapists. We are at the beginning of this journey, and I am aware that there is still much work ahead, but I remain optimistic.

**Karolina Wasielewska:** The third priority of our presidency is prevention, both "hard", such as vaccinations, and "soft", such as promoting a healthy lifestyle. We have already discussed the former extensively in the context of COVID, but what challenges can we expect regarding the latter? It seems to involve a set of "obvious" recommendations: engage in physical activity, get enough sleep, avoid processed foods and alcohol, and so on. However, that doesn't mean everyone adheres to these guidelines.

Andrzej Ryś: In this context, I really appreciate the joint initiative of the Ministry of Education and the Ministry of Health to introduce health education as a school subject in Poland starting next year. I had the opportunity to work on a new public health system in the early 1990s, and this idea was already being discussed. A lot of time has passed, and it likely won't be an easy task, as we are not accustomed to addressing these topics in school settings, nor do we have much experience in conveying this type of knowledge in educational environments. It's crucial that young people are actively engaged in these lessons – not merely passive recipients of the content – but motivated to implement it in their lives and understand its importance.

There's certainly much to improve in Poland in this area. We rank among the European leaders in a field we absolutely should not be proud of – smoking cigarettes. A growing challenge is also the prevalence of new tobacco and nicotine products, which are particularly popular among teenagers. There is an EU directive on this matter, but each country must develop its own, local solutions.

Regarding nutrition, obesity is the key issue, and the message is clear: we all need to learn how to manage our appetite. Neither the European Union nor any other institution can do this for us. Neither the European Union nor any other institution can do this for us. However, from the perspective of EU authorities, an often overlooked issue in the context of obesity is the relationship between consumers and the food production sector. Addressing this requires joint efforts by consumer organisations, the ministries of agriculture and health, as well as the Office of Consumer Protection and its counterparts across other EU countries.

Physical activity is equally important, but I would also emphasise the significance of simple hygiene practices. This topic is rarely discussed, yet the H1N1 and COVID-19 pandemics demonstrated that measures such as wearing masks in public transport and other shared spaces, along with handwashing, reduced the spread of these and other viruses.

Karolina Wasielewska: Thank you for speaking with me.



## New Mechanisms to Support the Health of European Union Citizens

## Agnieszka Gorgoń-Komor MD PhD

Senator of the Republic of Poland, Deputy Chair of the Health Committee of the Senate of the Republic of Poland

Since January 2025, Poland has held the Presidency of the Council of the European Union for the second time. This role provides an opportunity to set the direction of debates and shape the EU's work programme. It is also a chance to ensure that health-related issues receive the attention they deserve on the EU agenda.

Although health policy falls within national competence, the European Union also plays a significant role in its development. The EU's actions complement national policies, aiming to improve public health, combat epidemics, promote health education, and provide early warnings in the event of cross-border threats.

Under Poland's leadership, Europe should develop new mechanisms to safeguard the health of its citizens.

The Polish Presidency of the Council of the European Union coincides with the start of the new term of the European institutions. This presents a major opportunity for Poland to shape priorities and the political agenda, including health policy.

Over the past five years, Member States holding the Presidency of the Council of the European Union have highlighted numerous healthcare priorities. Most of them have focused on strengthening the Union's capacity to prepare for health crises and respond to emerging threats, advancing the digitisation of healthcare, and addressing key health challenges – including oncology, rare diseases, mental health, pharmaceutical sovereignty, prevention, and public health.

For its second Presidency of the Council, Poland has chosen the following priorities: prevention, digitisation, and the mental health of children and young people.

Throughout 2024, we prepared for the adoption of a Senate Resolution establishing 2025 as the Year of Health Education and Prevention. Numerous educational campaigns, conferences, and debates clearly highlighted the need to integrate preventive measures into practice. This was a fantastic experience for me, particularly the opportunity to engage with patient organisations and experts. In January 2024, as part of the Parliamentary Team for Research and Innovation in Healthcare, we addressed the issue of oncofertility in a debate titled Oncological Patients and Their Chances of Having Children in the Polish Reality. During this insightful discussion, we helped to demystify in vitro fertilisation (IVF) treatment for cancer patients, presenting a new perspective on the issue. During the April 2024 session of the Parliamentary Team for Cardiology, a concrete proposal was put forward to include cholesterol level measurement in health assessments for six-year-olds. Professor Małgorzata Myśliwiec had been advocating for this change for many years, and thanks to the Senate debate, we succeeded in convincing the Ministry of Health to implement this solution.

I believe that, through a series of meetings and debates, the Senate can develop recommendations and a Senate Declaration on Prevention and Public Health.

This declaration may form part of the contribution of the plenary session of the Conference of Parliamentary Committees for Union Affairs of Parliaments of the European Union (COSAC). The recommendations developed could also be included in the conclusions for the EU Council on prevention and public health.

This brought me to focus on patients living with obesity (ICD code E66). On May 22, 2024, the Senate hosted the European Day Against Obesity, and it was the patients themselves who changed my perspective on the 9 million untreated individuals affected by this disease. Addressing this



issue is a real challenge – one that should be a priority during the Polish Presidency. As a result of this collaboration, numerous meetings have taken place, leading to the establishment of the Team for Counteracting Obesity within the Public Health Council at the Ministry of Health. The Polish Society for Obesity Treatment and the FLO Foundation played a key role in driving further efforts to prevent and treat this condition.

## Health security as the cornerstone of a stable and resilient Poland and Europe.

### **Jacek Siewiera MD PhD**

Head of the National Security Bureau (2022–2025)

Based on previous declarations by representatives of the Polish Government and the President of the Republic of Poland – expressed, among others, during the Arraiolos Group summit in Kraków in October 2024 – seven strategic security areas can be outlined that will shape the priorities of the Polish Presidency of the Council of the European Union in the first half of 2026. Military security is highlighted, with particular emphasis on developing the armaments industry and financing defence projects, including the *East Shield* initiative; information security, focusing on combating disinformation; energy security, encompassing the protection of critical infrastructure, ensuring supply security, and advancing development of nuclear energy; economic security, centred on enhancing competitiveness and reforming EU funds; food security, shaping the future of European agriculture; health security, emphasising the EU's drug independence and addressing the mental health of children and adolescents; and civil security.

These areas were identified as a result of inter-ministerial consultations and close cooperation with Denmark and Cyprus, which, together with Poland, form the Presidency Trio. In accordance with established practice, the Trio countries develop a joint 18-month programme to ensure continuity and coherence in the activities of the EU Council, while allowing each country to emphasise its own priorities during its six-month presidency. For Poland, this task was significantly affected by the parliamentary election schedule and the transition of power to a new government during the planning of the Trio programme. An additional challenge is to jointly establish the direction of the Polish Presidency's actions in the context of cohabitation, which is relatively uncommon in our political system. What is crucial, however, is that security is largely a bipartisan area where dialogue can and should take place beyond political and social divisions.

It should also be emphasized that the above-mentioned security areas do not operate in isolation, nor do they exist in a vacuum. On the contrary, they form a tightly interconnected system in which each element influences the others, generating new opportunities as well as risks. This is perfectly exemplified by health security, to which I dedicate a significant portion of this analysis. Health security is inextricably connected to information security, as evidenced by efforts to combat the spread of fake news in the field of public health. It is also linked to economic security, for example, through the development of the European Health Data Space (EHDS) or a unified pharmaceutical industry serving EU needs, and to civil security through the necessity of maintaining the readiness of healthcare systems for crises. This multidimensional interdependence therefore calls for a comprehensive and coordinated approach during the Presidency of the Council of the European Union.

An analysis of recent years' experiences and the series of unprecedented crises impacting both Europe and the global sphere clearly demonstrate that health security has become a pivotal element of contemporary security architecture – not only at the national level but also within the broader framework of the international community. In this perspective, the European Union plays a crucial role as a one-of-a-kind alliance on a global scale. The COVID-19 pandemic and its associated crises, followed by Russia's aggression against Ukraine, have clearly highlighted the deficiencies in European health systems and underscored the strategic importance of securing sovereignty over access to critical resources – particularly those essential in wartime, such as blood and plasma,



as well as a wide array of medicines and medical devices. These events also emphasised the critical importance of maintaining continuity in the supply of medical products, particularly amid potential disruptions to global logistics chains, whose resilience may be repeatedly challenged by ongoing geopolitical pressures.

#### Pharmaceutical sovereignty as a foundation of the European Union's strategic autonomy

The experience of the COVID-19 pandemic, particularly the crisis in the availability of basic medicinal products, serves as a compelling testament to the weaknesses of existing pharmaceutical security mechanisms. In light of these experiences, from the perspective of the National Security Bureau, the systematic development of European and Polish strategic sovereignty in the pharmaceutical and medical sectors is of critical importance – both during peace and prosperity and in times of war or other crises.

The diagnosis of the current situation is clear – approximately 80% of active pharmaceutical ingredients (APIs) used in EU medicine production are sourced from third countries, primarily China and India. Such reliance on non-EU countries represents a serious risk to the health security of EU citizens. Additionally, rising geopolitical tensions and disruptions to global supply chains heighten the risk of shortages in essential medicinal products. It is particularly important to note that these two countries, on which the EU depends heavily in this critical area, along with the Russian Federation, are members of the BRICS alliance, which has gained prominence in recent years. The growing influence of this alliance, especially in its efforts to de-dollarise international trade and establish alternative supply chains, could significantly impact the security of pharmaceutical supplies to the European Union. This situation, examined within the broader context of current geopolitical tensions, necessitates immediate and strategic EU-level actions. A comprehensive programme to diversify supply chains is essential, alongside the long-term objective of achieving complete production autonomy within the EU for medicines, active substances (APIs), and medical devices. Addressing the identified challenges requires the implementation of a robust and comprehensive package of systemic solutions.

In parallel to the ongoing work on the new EU pharmaceutical strategy, the Polish Presidency should aim to accelerate progress on a regulation on supporting pharmaceutical production within the EU. This initiative would introduce mechanisms such as public-private partnerships, including collaboration frameworks with universities and research institutions, a system of tax incentives, simplified administrative procedures, and support mechanisms for fostering innovation in the pharmaceutical sector. Equally important for the coordination of joint efforts and the exchange of best practices is establishing a programme to enhance competences in pharmaceutical production. This programme should include support for training specialists in critical fields, technology transfer, and strengthening cooperation among a broad spectrum of stakeholders, including policymakers, the academic community, representatives of the third sector, experts from non-EU countries, and international organisations.

In addition, it is essential to implement an advanced system for monitoring and risk management in the areas of pharmaceutical security, pandemic threats, and healthcare disinformation. These systems should incorporate not only a central database on the availability of medicines and raw materials but also an early warning mechanism for potential shortages and protocols for coordinating actions during emergencies. In my view, strategic pharmaceutical reserves – managed on a rotational basis and comprising products critical to public health – should play a pivotal role in this framework. A further key aspect is combating disinformation, which grows more pervasive each day. Mechanisms for identifying misleading content must be thoughtfully developed and recognised as an EU priority, aimed at reducing the risk of empowering unlawful entities, often orchestrated by trolls from Russia and other sources, that seek to manipulate the European public. In the context of information security, developing robust mechanisms for verifying and countering disinformation in cyberspace is equally critical. An analysis of modern hybrid threats underscores the necessity of prioritising this issue at the EU level. Special attention must be given to countering organised disinformation campaigns conducted by external actors with the aim of destabilising the



European information sphere. Systematic research in this area highlights the growing activity of foreign influence centres, employing advanced techniques to manipulate narratives in social and traditional media, as well as orchestrating public demonstrations. It is, therefore, recommended to establish a comprehensive system for the early detection and neutralisation of such threats, while maintaining respect for core democratic values and freedom of expression. Failure to address these challenges risks a significant erosion of information security at both national and regional levels. Experience thus far indicates that the absence of effective counter-disinformation mechanisms has severe consequences for the stability of democratic systems, both in Poland and across the Euro-Atlantic region.

The long-term goal of the proposed actions should be to achieve the EU's relative pharmaceutical sovereignty by 2030. This will require the development of a detailed, well-considered, and, above all, realistic roadmap. Such a plan should encompass, among other elements, the expansion of production capacity for active substances, investments in research infrastructure, and support for innovative initiatives in the pharmaceutical sector.

A key component of the proposed solutions is pharmaceutical solidarity, encompassing a system of mutual assistance during crises, coordination of strategic procurement, and joint negotiations with suppliers across all 27 EU Member States – as exemplified by the joint purchasing of masks and other medical devices during the pandemic.

For the effective implementation of the above solutions, close cooperation is required between EU institutions, Member States, social organisations, and the private sector. The Polish Presidency, occurring during a period of significant geopolitical change and the start of the EU institutional cycle, represents a unique opportunity to drive comprehensive reforms in the area of health security, including pharmaceutical safety. With its substantial production capacity in the pharmaceutical sector and proven experience in countering hybrid threats, Poland is well-positioned to play a pivotal role in advancing the EU's strategic autonomy in this domain.

When discussing health security, it is essential to highlight that cybersecurity in the medical sector – and in other health-related areas, such as the use of social media, smart home technologies, and other innovations – is an absolute priority. The ongoing digitisation of healthcare and nearly all aspects of our lives is undoubtedly necessary and offers opportunities for unprecedented progress, but it also introduces new risks that must be addressed openly and decisively. In this context, educating vulnerable groups – both the elderly and young people – on the conscious and secure use of digital technologies in health is becoming increasingly important. It cannot be overlooked that the growing frequency of hacker attacks on medical infrastructure can paralyse healthcare systems, while the theft of sensitive medical data is increasingly used in hybrid operations, which have recently intensified to an unprecedented scale due to the actions of the Russian Federation, Belarus, and even the People's Republic of China. Given its extensive experience in countering hybrid threats along its eastern border, Poland should propose comprehensive solutions in this domain and position itself as a pioneer. Poland's responses to the actions of Russian and Belarusian operatives should be effectively adapted and implemented at the Community level.

In the context of modern hybrid threats, particular attention should also be given to cybersecurity in the pharmaceutical sector, as well as in the MedTech and E-Health sectors. Safeguarding data on strategic reserves, securing production management systems, and countering cyberattacks on pharmaceutical infrastructure must swiftly become integral components of the EU's pharmaceutical security strategy and, more broadly, its health security framework.

#### Health Threats in the Context of the Migration Crisis – A National Security Perspective

From the perspective of the National Security Bureau, the escalating migration crisis presents significant concerns and unprecedented risks to security, posing one of the most urgent challenges to the health security of the Republic of Poland, its neighbouring countries, and the entire European Union. Poland's experiences from 2021–2024, involving the instrumentalisation of migration pressure on its eastern (and other) borders, clearly demonstrate the interconnection between



border security and health security. An in-depth analysis of the situation on Poland's eastern border reveals several threats to the country's health security. Chief among these are efforts to destabilize the healthcare system by creating sudden, large-scale medical demands in border regions. These actions are part of the broader context of hybrid warfare, where migratory pressure is used as a tool to exert influence on EU Member States.

Additionally, epidemiological surveillance in the context of uncontrolled migration flows is of particular importance – not only those stemming from hybrid warfare but also the challenging-to-control influx of migrants from Ukraine and other former Soviet Union countries. Medical services have identified cases of infectious diseases that have been eradicated in Europe or occur only sporadically but remain prevalent among individuals arriving from the East. Addressing this situation necessitates maintaining a high state of readiness among sanitary and epidemiological services, as well as fostering close cooperation between border services and healthcare units.

When discussing the migration crisis, it is also essential to highlight that, from a national security perspective, maintaining the operational capacity of medical facilities in border regions – whether in Poland, Lithuania, Greece, or Romania – must be an absolute priority. Recent years have clearly demonstrated that the instrumental exploitation of migrants can overwhelm local healthcare systems while increasing the risk of spreading various infectious diseases, including those previously believed to be eradicated. This undoubtedly poses a direct threat to the health security of Polish citizens.

Another equally important aspect of health security in the context of the migration crisis is the protection of critical healthcare infrastructure. This encompasses both the physical security of facilities and the cybersecurity of IT systems used in healthcare. Cyberattacks on medical systems can and will result in the paralysis of health facilities and jeopardize patient safety – hence the urgent need to develop a comprehensive set of scenarios to address such crises at their inception.

A crucial aspect from the perspective of the National Security Bureau, as well as Community agencies and bodies, is maintaining the state's capacity to effectively respond to health threats under increased migratory pressure. This necessitates close coordination among uniformed, medical, and sanitary services, along with the maintenance of adequate strategic reserves of medical supplies. However, I would stress that EU-wide coordination may not always be the optimal solution – hence, it is worth exploring the establishment of rapid response mechanisms for a smaller group of EU countries confronting similar challenges.

Poland's experience in countering hybrid threats, including those involving migratory pressure, should serve as a significant contribution to discussions on the EU's health security. As a frontline state, Poland possesses unique expertise in crisis management under conditions where military, migratory, and health threats converge.

The National Security Bureau maintains that effective protection of the EU's borders is a prerequisite for safeguarding the health security of the Union citizens. Simultaneously, it emphasises that modern health security threats are transnational in nature and demand a coordinated response at the Community level.

The recently published report Safer Together by Finnish President Sauli Niinistö, prepared at the request of the European Commission, offers an incisive diagnosis of the challenges Europe faces in the area of health security. As the head of the National Security Bureau, I wish to highlight the report's insightful conclusions, express support for its recommendations, and underscore the need to expand upon them during the Polish Presidency of the Council of the European Union, as well as within the broader Trio with Denmark and Cyprus.

An analysis of the conclusions from the above-mentioned report enables the formulation of key recommendations for the Polish Presidency that address the challenges identified in the document. Establishing a European Rapid Medical Response Mechanism that integrates civilian and military resources is of paramount importance, aligning directly with the report's call to enhance the EU's crisis response capabilities. To address the identified threats to supply chain continuity, it



is essential to implement a comprehensive program for building strategic medical reserves at the EU level and to develop an early warning system for potential disruptions in the supply chains of medical products.

Additionally, the Niinistö report highlights the importance of enhancing research infrastructure, as reflected in the recommendation to establish European Reference Networks. Amid escalating cyber threats, detailed in the report, the implementation of uniform cybersecurity standards in the medical sector across the entire European Union is becoming increasingly critical.

To conclude, I would like to reiterate that health security, in the broadest sense, must be regarded as an integral component of the EU's wider security architecture, and thereby its stability and prosperity as a supranational organisation. The subject should be approached holistically, aligning with the EU's *One Health Approach*. The Polish Presidency thus represents a unique opportunity to bolster the resilience of the Union in addressing the contemporary threats discussed above. As a nation directly bordering a zone of intense armed conflict, where Russian missiles have fallen on our territory, Poland holds a particular legitimacy in raising the issue of health security in the context of hybrid threats.

I am fully convinced that implementing the above recommendations will significantly enhance the health security of the European Union and, in doing so, strengthen the safety of its citizens.

### European Charter of Patients' Rights – A Call to Action

## **Bartłomiej Chmielowiec**

**Commissioner for Patient's Rights** 

#### Patients' Rights - The Foundation of Healthcare in Europe

Patients' rights are a key pillar of modern healthcare systems in the European Union. While the scope and implementation of these rights vary significantly across Member States, certain fundamental principles remain universal, and ensuring their enforcement is a priority for all healthcare systems.

These fundamental rights encompass key aspects of healthcare services – from ensuring equal access to healthcare for all citizens of the European Union, to maintaining high standards of quality and safety in care, to protecting patient dignity and privacy.

A central element of these rights is the right to information and informed consent, which stem directly from the fundamental human right to personal autonomy – the right of individuals to make decisions about their own treatment and actively participate in the process. These rights, combined with the ability to file complaints and seek compensation for harm suffered, ensure both patient empowerment and accountability within the healthcare system.

The varying levels of implementation and interpretation of these rights across Member States highlight the need for a coordinated approach, while respecting national competences in the organisation and provision of healthcare services. This diversity presents both a challenge and an opportunity to exchange experiences and enhance healthcare systems across Europe.

#### A strategic objective

An objective of the Polish Presidency of the Council of the EU is to institutionalise the principles of patients' rights at the European level and integrate them into the acquis communautaire. This objective stems from the conviction that in today's globalised healthcare environment – particularly in the post-pandemic context and amid a dynamic digital transformation – patients require clear and enforceable rights that extend beyond national borders.

We strive to ensure genuine access to high-quality healthcare services across all Member States – facilitated through standardised protocols for effective communication and information exchange. In an era of increasingly complex healthcare, ensuring fundamental rights – such as patient dignity and privacy – takes on new significance. Furthermore, establishing a robust framework



for monitoring and evaluating the implementation of patients' rights will help reduce health inequalities – both between and within Member States.

#### Activities of civil and patient organisations

The European Charter of Patients' Rights<sup>44</sup>, developed in 2002 by civil society and patient organisations from several Member States as part of the Active Citizenship Network and presented in Brussels on 15 November 2002, is a key social document in the field of patients' rights. It has become a benchmark for EU citizens' rights in healthcare and a milestone for those advocating for public health. Although several principles outlined in the European Charter of Patients' Rights have been incorporated into national legislation in some Member States – and the Charter itself has gained the support of the European Parliament and has been widely discussed in EU fora<sup>45</sup> – it has never been officially adopted.

Patient advocacy organisations – especially those active at the local and national level – hold invaluable insights into patients' needs and rights, gained through years of direct involvement in healthcare systems across Europe. The aim of this initiative is to translate patients' rights from abstract principles into concrete, measurable improvements in the provision of healthcare across Europe.

The movement for a formal European Charter of Patients' Rights encompasses more than two decades of sustained efforts by patient organisations. During this time, various EU institutions<sup>46</sup> have recognised the importance of patients' rights, yet a comprehensive, legally binding framework has still not been established.

#### Benefits of a Common European Charter

Each national healthcare system in the EU operates under different realities regarding patients' rights. The formal adoption of the European Charter of Patients' Rights – appropriately adapted – would mark a significant step in EU health policy, reinforcing the protection of citizens' rights in health-related matters. Such an initiative would establish a standardised framework for the implementation of patients' rights, enabling systematic monitoring and comparison of patient conditions across different Member States. This comparative capability would be invaluable for evidence-based policymaking and the continuous improvement of healthcare systems. Moreover, harmonised patient rights standards would facilitate cross-border healthcare and amplify the voice of patients in shaping health policy at both the national and EU levels.

#### **Planned Next Steps**

During the Polish Presidency of the Council of the European Union, a number of strategic initiatives have been planned to advance this important undertaking. In March 2025, an international conference will be held in Katowice, bringing together patient organisations to develop proposals on the adoption and scope of patients' rights in response to contemporary challenges.

Then, in May 2025, a second international conference will be held in Gdańsk, providing institutions responsible for protecting patients' rights with an opportunity to exchange best practices.

We aim for these efforts to culminate in the inclusion of the proposal for the adoption of the European Charter of Patients' Rights in the conclusions of the Polish Presidency of the Council of the European Union in June 2025.

<sup>44 &</sup>lt;u>https://ec.europa.eu/health/ph\_overview/co\_operation/mobility/docs/health\_services\_co108\_en.pdf</u>.

<sup>45</sup> European Parliament, Resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI); Resolution of 19 May 2015 on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance (2014/2207(INI)); etc.

<sup>46</sup> Opinion of the European Economic and Social Committee on 'Patients' rights' (2008/C 10/18); European Parliament resolution of 15 March 2007 on Community action on the provision of cross-border healthcare; etc.



### Recommendations in the Area of Healthcare and Pharmaceutical Policy from the Perspective of the Group of Socialists and Democrats in the European Parliament

## Krzysztof Śmiszek PhD (Legal Sciences)

Chair of the Polish Delegation of the Group of Socialists and Democrats in the European Parliament

#### Public Health as a Fundamental Human Right and a Key Element of EU Policy

Public health should be regarded as an inalienable human right rather than merely a public good. Within the Group of Socialists and Democrats (S&D) in the European Parliament, we advocate for the Health First Act, which aims to strengthen health as a fundamental pillar of European Union policy. By guaranteeing every EU citizen the right to access healthcare, including high-quality medical services, the S&D Group seeks to enhance the perception of health as a value that must be prioritized in EU policy. As part of this initiative, we are proposing not only regulations but also appropriate financing for the healthcare sector, aiming to make it a priority area for investment in the years to come.

#### Strengthening Healthcare Systems in the EU with a Focus on Equal Access

One of the main health pillars of the S&D Group is ensuring equal access to healthcare for all EU citizens, regardless of their place of residence, socio-economic status, ethnicity, or gender identity. Strengthening health systems must involve efforts to ensure equality in access to medical services, particularly for ethnic minorities and LGBTQI+ communities. In this context, the Polish Presidency should take steps to introduce unified healthcare standards across all Member States, covering both infrastructure and medical personnel, and ensure that no social groups are discriminated against in accessing these services.

#### **Reproductive Rights as a Priority**

Reproductive rights must be made one of the central priorities of EU health policy. The S&D Group strongly advocates for guaranteeing universal access to modern contraception and the right to safe abortion up to the 12th week, in accordance with local law. The Polish Presidency should support the implementation of European pilot programmes in reproductive health, such as expanding pharmaceutical services in the areas of reproductive counselling and contraception. The purpose of these actions is to ensure that every woman in the EU has the full right to make decisions about her reproductive health and has access to the appropriate health services.

#### Mental Health of Children and Adolescents as a Pan-European Priority

Mental health of children and adolescents is one of the greatest health challenges in Europe, and the COVID-19 pandemic has further exacerbated the issue. The S&D Group urges swift action at the EU level to establish a comprehensive Europe-wide strategy for supporting the mental health of children and adolescents. This strategy should include mental health education – incorporating the family environment – and ensure greater access to specialist psychological care. The Polish Presidency should take an active role in supporting initiatives aimed at creating a cohesive support system for young Europeans, in collaboration with the education, social care, and healthcare sectors.

#### Mental Health of Adults and Work-Life Balance

Both mental health and work-life balance are essential components of EU health policy, necessitating robust support from European institutions. The S&D Group advocates for policies that prioritise ensuring adequate working conditions for EU citizens, safeguarding their mental health from adverse effects. The Polish Presidency should concentrate on enhancing regulations regarding working time flexibility, promoting mental health support programmes in the workplace, and addressing negative workplace phenomena such as mobbing, sexual harassment, and discrimination based on personal characteristics



#### Strengthening European Pharmaceutical Policy and the EU's Productive Independence

The COVID-19 pandemic has highlighted the importance of the EU achieving independence in the production of medicines and medical equipment. The S&D Group emphasises the need to increase investment in research and development, as well as supporting European pharmaceutical companies to reduce dependency on supplies from third countries. In particular, from Asian nations, which, during the COVID-19 pandemic, drastically reduced the supply of medicines and substances crucial for pharmaceutical production, thereby threatening the security of EU residents. The Polish Presidency should take the lead in creating a unified European strategy for medicine production, ensuring future independence and supply security, while also serving as a powerful driver for economic growth and innovation.

#### **Prevention and Promotion of Healthy Lifestyles**

Prevention is a key component of effective health policy. The S&D Group advocates for preventive measures, including campaigns promoting a healthy lifestyle, to be prioritised at the EU level. The Polish Presidency should support initiatives aimed at raising citizens' awareness of health issues, with particular focus on a healthy diet, improving working conditions, physical activity, and the elimination of addictions such as smoking and excessive alcohol consumption.

#### International Cooperation in the Field of Health and the Use of the Passerelle Clause

In light of pandemic threats, strengthening international cooperation is essential. The Polish Presidency should explore the potential use of the passerelle clause<sup>47</sup>, which would allow for the improvement of rapid response mechanisms in emergencies. Such cooperation at the European level should include joint procurement of medicines, better management of medical resources, and coordination of research and development activities.

#### The EU's Role in Global Health Policy and International Solidarity

The European Union must play the key role in global health policy by promoting international solidarity. The Polish Presidency should support initiatives that will enhance the EU's ability to act internationally in the field of health, both by assisting developing countries and strengthening global health systems. Priority should also be given to ensuring access to vaccines and medicines in impoverished nations, reinforcing the EU's position as a leader in promoting global health solidarity.

The Polish Presidency has an opportunity to play a pivotal role in achieving these objectives by collaborating with the S&D Group and EU institutions to build stronger, fairer healthcare systems across Europe.

## EU Competences in Health – the Post-Pandemic Evolution of the Approach to EU Healthcare

### Robert Hyżorek, Jan Karsznicki

#### Institute for Social Policy Development

The European Union has held its own competences in the field of health since the Maastricht Treaty: health policy can therefore be the subject of EU action and cannot merely be considered an annex to other areas. However, the competences granted to the Union in this domain remain very limited. In principle, the Union cannot pursue an autonomous health policy, as the Member States remain the primary actors in health policy. The Union's actions are primarily restricted to supporting, coordinating, and complementing measures. According to Article 6 of the Treaty on the Functioning of the European Union (TFEU), "protection and improvement of human health" is

<sup>47</sup> The EU Treaties also provide for passerelle clauses that apply to six specific policy areas. These passerelle clauses apply to the following areas: 1. Common foreign and security policy (Article 31(3) TEU); 2. Family law with cross-border implications (Article 81(3) TFEU); 3. Social policy (Article 153(2) TFEU); 4. Environmental policy (Article 192(2) TFEU); 5. Multiannual financial framework (Article 312(2) TFEU); and 6. Enhanced cooperation (Article 333 TFEU).



classified as a supporting competence. When the EU holds a supporting competence, it may assist, coordinate, or supplement Member States' actions, but it does not have the power to legislate. Nevertheless, the current Treaty already provides some scope for EU legislation on public health matters. Article 4(2)(k) TFEU grants the EU and the Member States a shared competence for "common safety concerns in public health matters, for the aspects defined in this Treaty". In areas of shared competence, both the EU and the Member States can legislate. However, when the EU enacts legislation on a specific issue, the legislative powers of the Member States are proportionately restricted, as EU law takes precedence over national law.

The EU's competences in the area of public health are further defined in Article 168 TFEU. Article 168(1) includes what is known as a horizontal clause, which obliges the Union to ensure a high level of health protection across all its policies and activities. The fact that this clause is not included under the general provisions, as is the case with other horizontal clauses such as Articles 9–11 TFEU, does not diminish its binding nature or its equal status with other horizontal objectives and provisions.

Article 168(4) outlines three public health areas in which EU legislation may be enacted, utilising the exception provided in Article 4(2)(k): safety standards for organs and substances of human origin, veterinary and phytosanitary measures aimed at protecting public health, and safety standards for medicinal products and medical devices.

Article 168(4)(a) TFEU provides for measures to ensure high standards of quality and safety for organs and substances of human origin, as well as for blood and its derivatives. This special mandate was introduced to ensure that organs and substances of human origin are not subject to the economic logic of the internal market. Measures adopted under Article 168(4)(a) do not preclude Member States from maintaining or introducing more stringent protective measures. Consequently, the EU may establish only minimum standards.

Article 168(4)(b) authorises measures in the veterinary and phytosanitary fields with the direct aim of protecting public health. This provision was introduced in response to the crisis caused by bovine spongiform encephalopathy (BSE), commonly known as "mad cow disease", which impacted Europe in the 1980s and 1990s. The article distinguishes veterinary and phytosanitary measures from agricultural measures. Legally, Article 168(4)(b) constitutes a specific provision relative to the agricultural policy provisions outlined in Article 43 TFEU. The distinction relies on the principle that Article 168(4)(b) can only serve as a basis for measures with a "direct objective" of protecting public health, even though this boundary may be challenging to define in specific cases. In general, a legislative act can be grounded in Article 168(4)(b) only if the measure it introduces is primarily aimed at pursuing a health protection objective.

Article 168(4)(c) enables the adoption of measures establishing high standards of quality and safety for medicinal products and medical devices. This competence, newly introduced by the Treaty of Lisbon, functions as a lex specialis in relation to Article 114 TFEU.

In addition, Article 168(5) specifies further areas where the EU may legislate: measures to promote the improvement of human health and combat "major cross-border health scourges", measures to monitor and address serious cross-border health threats, and public health measures targeting tobacco and alcohol abuse. Importantly, measures adopted under Article 168(5) must exclude any form of harmonisation of Member States' laws or regulations. This makes it clear that the treaty drafters sought to prevent any direct or normative interference in national health systems by EU legislators. While "measures" – such as regulations, directives, and decisions – may be adopted, harmonisation is explicitly excluded.

The list of issues on which the EU can legislate illustrates the Treaty's clear intent to define the scope of the EU's powers in the field of public health. Article 168(7) reiterates that Member States are responsible for managing their health systems and allocating resources to them, as well as for defining their health policies. This can be explained by the fact that health and social security systems are organised and financed very differently in the Member States: for example, some national systems are financed by taxes, while others are financed by contributions.



Apart from health-focused provisions, the Treaties did not provide the necessary powers for the EU to achieve one of the objectives set out in the Treaties: in that case, the Council would be able to adopt the necessary measures unanimously. During the COVID-19 crisis, Article 352 was used as a legal basis to permit the postponement of general meetings for certain types of companies (Council Regulation 2020/699). However, it has never served as a basis for health policy measures, and the exceptional nature of this provision means that the threshold for its application remains high.

Finally, it is important to distinguish between Articles 168 and 114 TFEU. While Article 114(1) is widely used to harmonise rules within the internal market when its conditions are met, Article 168 provides a much narrower scope for EU legislation. As noted earlier, Article 168(5) explicitly excludes harmonisation in significant areas of public health. It is, therefore, unsurprising that the choice of legal basis in cases involving both the internal market and the health sector is contentious and has resulted in numerous rulings by the Court of Justice of the European Union. In all instances, the legislator must carefully consider where the emphasis of the proposed legal act lies to determine the appropriate legal basis.

The COVID-19 crisis significantly accelerated European integration in public health, leading to the emergence of a new crisis management framework during the pandemic. Although the EU's initial crisis response was perceived as delayed, it gradually gained momentum, with EU coordination becoming a key asset in managing the crisis. Notably, the European Centre for Disease Prevention and Control (ECDC) facilitated the exchange of information on the spread of the pandemic, while the joint procurement procedure under Article 5 of Decision 1082/2013 was utilised for the collective procurement of COVID countermeasures.

The EU Health Security Committee (HSC) played a pivotal role during the COVID crisis by directly linking the health ministries of the Member States. Originally established in 2001 at the request of national health ministers as an informal advisory group on health security at the European level, the committee operates under the auspices of the European Commission's DG SANTE. Its members primarily consist of officials from the health ministries of the Member States. In 2013, Decision 1082/2013 reinforced the HSC's role in coordinating and facilitating the exchange of best practices and information on national preparedness and response measures.

The increasing prominence of public health crisis management has led to new initiatives, such as the European Commission's proposal to expand the mandate of the ECDC (COM(2020)726) and the establishment of the Health Emergency Preparedness and Response Authority (HERA). HERA facilitates joint investments in health preparedness through a dedicated budget. The subsequent paragraphs elaborate on the roles of the ECDC, HSC, and HERA in managing health crises.

## Health Priorities of the Polish Presidency of the Council of the European Union in 2025

## Karolina Wasielewska

**Institute for Social Policy Development** 

Mental health of children and adolescents, broadly defined public health, digitisation of healthcare, and pharmaceutical security – these health priorities align with the overarching theme of security that guides the Polish Presidency.

On 17 December 2024, Minister of Health Izabela Leszczyna and Deputy Minister Katarzyna Kacperczyk announced the health priorities of the Polish Presidency of the Council of the European Union.

As the Minister of Health emphasised, the key theme of the presidency is security – and the four priorities she presented at that time are also maintained in this spirit. These include mental health of children and adolescents, broadly defined public health, digitisation of healthcare, and pharmaceutical security.



Izabela Leszczyna explained the selection of these priorities by referring to the goals set by her ministry: strengthening cooperation and ensuring health security across Europe.

"As a rule, the Union does not interfere in the health systems of Member States, but the experience of the pandemic and the consequences of the war beyond the Union's borders have made health one of the most important areas of cooperation between Member States", the minister explained.

Katarzyna Kacperczyk, on the other hand, emphasised that these priorities are also aimed at "placing the safety and well-being of the patient at the centre of all activities". Therefore, the first topic discussed at the conference was the mental health of children and adolescents, particularly in the context of the development of digital technologies and social media. "*We can boast of our first success – this topic will remain a priority in the European Union for four years – it will not disappear after the conclusion of our presidency*", said Deputy Minister Kacperczyk. At the end of the Polish Presidency of the Council of the EU, the Ministry of Health, in cooperation with the WHO, wants to prepare a report on the impact of technology on the health of children.

Another priority is the digital transformation of healthcare, which involves building a regulatory and institutional framework and establishing standards and rules for e-health in the European Union. Poland will also focus on the cybersecurity of medical devices that collect user data. It is also known that legislation on the establishment of the European Health Data Space (EHDS) is to be implemented during the presidency.

Our presidency will also be marked by health promotion and disease prevention. The main initiatives that the Ministry of Health plans in these areas include evaluating the effectiveness of actions in combating major health threats, developing a catalogue of good practices and proposed measures, and adopting an integrated approach to prevention and education, including the promotion of interdisciplinary health education. Poland is already implementing the latter at home – from September 2025, health education will be introduced as a subject in schools.

Pharmaceutical security is the last of the four priorities. According to officials from the Ministry of Health, this involves the revision of pharmaceutical legislation and the presentation of the framework for the Critical Medicines Act, which will serve as an implementing measure for the List of Critical Medicines that has already been introduced. These are medicines that are essential for public health, whose access is particularly secure and which are to be manufactured in the European Union, including Poland.

#### **Three Priorities, Many Viewpoints**

#### Karolina Wasielewska, Alicja Chybicka, Anna Gembicka, Wojciech Konieczny

# Karolina Wasielewska (Institute for Social Policy Development) in conversation with Alicja Chybicka (Civic Coalition), Anna Gembicka (Law and Justice), and Wojciech Konieczny (The Left).

The health priorities of the Polish Presidency of the Council of the European Union have been developed by the Ministry of Health. Each of the key political forces in the Polish Parliament highlights different aspects that should be given particular emphasis within these broadly defined priorities. This creates a space for discussion, the conclusions of which may be instructive for all EU Member States.

When formulating its priorities, the Ministry of Health focused on issues affecting both Poland and other European Union countries. Deputy Minister Wojciech Konieczny (the Left) hopes for a dynamic exchange of best practices: *"We aimed to maximise the benefits of this transnational discussion. Many of the challenges Poland faces are already being tackled in other EU countries – not always successfully, but certain solutions have been implemented, and we can now observe their effectiveness. This is evident, for instance, in child and adolescent psychiatry. Of course, this* 



## exchange works both ways: in areas such as healthcare digitisation, Poland itself can serve as a model for other nations."

According to the Supreme Audit Office (NIK) report from September 2024<sup>48</sup>, Poland still has significant ground to cover in providing psychiatric care for children and adolescents, although some progress has been made. At the *Road to the Presidency* conference<sup>49</sup>, organised by the Institute for Social Policy Development and the Medical Centre of the Medical University of Warsaw, many experts and community leaders highlighted that the care system, structured around three levels of reference, has already helped "de-medicalise" certain aspects. These problems stem not so much from mental illness in young people, but rather from loneliness and a lack of adequate support from parents and other adults in their environment. "However, the problem is the delayed response time. We do not want a child or teenager to receive specialist care only after a suicide attempt. That is why we must also invest in educational efforts, ensuring that caregivers, teachers, and peers are attuned to warning signs. They should be the first to talk to the student and reassure them that they are not alone and that help is available. This support, in turn, should be accessible within schools", says Wojciech Konieczny.

This means that the healthcare system for young people would need to be modified so that a diagnosis made by a school doctor is visible in the IT system and recognised by psychologists or psychiatrists working within the National Health Fund (NFZ). Currently, the school and general healthcare systems do not communicate with each other, which creates significant difficulties for young patients: a student receives a diagnosis from a school doctor but must undergo a second diagnosis within an NFZ facility to access psychiatric care provided by the Fund. "Let's not forget: we are talking about people who, firstly, are struggling with mental health issues, and secondly – most often teenagers who are already at a challenging stage of life. For someone in that situation, having to go through the entire diagnostic process again can be unbearable, especially given the persistent stigma surrounding mental illness in Poland. That is why this procedure should be simplified as much as possible, incorporating schools into the process", emphasizes Mr Konieczny.

As for the priority of digitising healthcare, Poland has indeed made achievements that are highly valued in Europe: our Online Patient Account (IKP), which enables the use of e-prescriptions and e-referrals, played a crucial role in easing the burden on the healthcare system during the pandemic. This experience convinced many Polish citizens to embrace the system. Within five years of its launch, the IKP has continued to expand its user base, reaching 18 million users as of April 2024.<sup>50</sup> However, further improvements are needed in the digitisation of access to services beyond vaccinations, which can already be scheduled via the IKP. In August 2024, a pilot programme for e-registration was launched, allowing entities contracted with the National Health Fund to offer appointments for cardiology services, as well as for basic preventive screenings within the cervical cancer programme (cytology) and the breast cancer prevention programme (mammography). Plans are in place to expand the pilot to cover additional medical services. However, this is only the first step in a broader strategy aimed at improving access to healthcare services, including at the cross-border level. "The goal is for a patient who crosses the Polish border with a given medical condition and wishes to continue treatment in another European Union country to be able to schedule an appointment anywhere using the same digital tools. They would also not need to carry their entire medical documentation with them, as all relevant health information would be stored online in a format recognised by foreign healthcare systems", says Wojciech Konieczny.

Prof. Alicja Chybicka, a paediatric hemato-oncologist and chair of the Parliamentary Team for Rare Diseases, also considers these changes important and necessary. However, she believes there is too little discussion about how the advancements in e-health transformation will benefit those who most frequently require medical assistance and yet remain the most digitally excluded group – seniors. *"I have not heard of any educational initiatives specifically targeted at older adults.*"

 $<sup>48 \</sup>quad https://www.nik.gov.pl/najnowsze-informacje-o-wynikach-kontroli/psychiatria-dziecieca.html.$ 

<sup>49</sup> https://politykazdrowotna.com/artykul/zdrowie-psychiczne-dzieci-n1369207.

<sup>50</sup> https://pacjent.gov.pl/aktualnosc/48-proc-polakow-uzywa-ikp.



I agree that healthcare must keep pace with the times and adopt new technologies where they can genuinely benefit patients and are feasible for the state. After all, this is a global trend – it will inevitably happen, and there is no turning back. However, we should ensure that society as a whole is prepared for this transition."

According to Prof. Chybicka, merely enabling unrestricted access to medical care across the European Union is insufficient – or at the very least, it is a goal that has been too broadly formulated. As a member of the Civic Coalition, she argues that even if EU countries establish interoperable IT systems and shared patient databases, treatment will only be truly effective if it follows the same standards everywhere. This, however, is no longer a question of digitisation but rather a matter of transnational agreements among specialists and the adoption of a unified strategy for managing specific patient groups. "It works well in my field, paediatric oncohaematology. In Poland, we follow the same treatment standards as in Europe and globally. We have common protocols, and children are treated uniformly across many specialised centres. What are the practical implications? When I started working 50 years ago, the survival rate for leukaemia patients was 15 percent - now, it is 85 percent." That is why Alicja Chybicka regrets that rare diseases were not included among the health priorities of our Presidency. According to her, individuals affected by these conditions should also be able to rely on a pan-European system of care – where, at the slightest suspicion of a rare disease, they could seek full diagnosis and treatment in another EU country with expertise in managing that specific condition. Deputy Minister of Health Wojciech Konieczny points out that such an approach is already in place through the European Reference Network. This initiative connects healthcare providers across EU countries, enabling them to collaborate in diagnosing and treating rare disease patients through the exchange of knowledge, resources, and expertise. In Poland, more than 20 such centres are already part of the network. "However, the truth is that Poland is somewhat behind many EU countries in the area of rare diseases. Our predecessors were supposed to address this issue, but they left it to us. Fortunately, Minister Urszula Demkow has developed the National Plan for Rare Diseases, which was drafted in consultation with relevant stakeholders", says Wojciech Konieczny. Alicja Chybicka has repeatedly stressed in interviews that while she supports the National Plan for Rare Diseases, its impact hinges on swift legislative action. Without formal adoption into law, she warns, the plan risks becoming nothing more than a well-intentioned blueprint left on paper.

According to information from government sources, the Polish Presidency will prioritize strengthening the EU's pharmaceutical security, with a particular focus on diversifying drug supply chains and boosting production within the bloc. Dr. Adam Jarubas, an MEP from the Polish People's Party (Polskie Stronnictwo Ludowe, PSL) and chair of the European Parliament's Subcommittee on Public Health (SANT), highlights a major challenge: persistent medicine shortages across the EU and the unequal access to essential treatments. "Medicines that are readily available in some EU countries may take two years or more to reach others. According to European Commission estimates, patients in Western and larger Member States have access to nearly 90% of newly approved medicines, whereas in smaller and Eastern European countries, this figure drops to just 10%." Adam Jarubas highlights that while a list of critical medicines was established in December 2023, an official Critical Medicines Act is still missing. In practice, this means that although the medicines requiring special protection have been identified, there is no binding regulation mandating their safeguarding or outlining concrete measures to achieve this. Brussels aims to assess supply chain vulnerabilities and promote investment incentives and public procurement strategies to enhance the production of these essential medicines within EU countries. Jarubas sees this approach as a positive step, also from Poland's perspective: "This could serve as an economic stimulus for countries like Poland, which has a dynamic pharmaceutical sector, a highly skilled workforce, and strong competitiveness within the EU."

According to Mr Jarubas, as part of implementing the prevention priority, Poland should also encourage the EU to develop comprehensive plans to tackle various health threats – following the model of the 2021 *Europe's Beating Cancer Plan*. He argues that similar strategies should be created for cardiovascular, diabetic, and neurodegenerative diseases, particularly since many



measures designed to combat one group of diseases could also prove effective for others. "However, beyond treatment itself, attention must also be given to the social and economic aspects of care, including long-term care and professional participation", Adam Jarubas notes.

In this context, as all my interlocutors agree, Poland should use its presidency to advance initiatives for healthy aging and prevention – understood not only as vaccination and screening but also as the promotion of a healthy lifestyle. A less obvious yet equally important aspect of the prevention priority is ensuring equitable access to healthcare services. Adam Jarubas emphasises that this applies not only to bridging gaps between countries but also to addressing disparities within individual Members States: *"It will also be crucial to design the Cohesion Funds in a way that facilitates the elimination of disparities in access to health services, both between and within EU Member States. As I often say, health depends on your DNA, but it should not be determined by your postcode."* To make this possible, it is necessary to focus, among other things, on e-health and telemedicine solutions, which will allow everyone to obtain an initial diagnosis and register for a medical appointment without leaving home.

Anna Gembicka, a Law and Justice parliamentarian serving on the Health Committee, believes that implementing such solutions is one of the few tangible actions Poland can realistically achieve during its Presidency. "Six months is a short time, so I understand that some issues will be highlighted rather than fully resolved. However, given the level of development of digital health services in Poland – especially those introduced during the Law and Justice Government, such as the Online Patient Account and e-prescriptions – we could take steps toward implementing cross-border healthcare", emphasises Ms Gembicka. One initiative that could help facilitate this is the European Health Data Space (EHDS), which allows each Member State to operate under internally developed regulations while enabling doctors across the EU to access standardized patient health data. However, Anna Gembicka stresses that this must be implemented with strong privacy and data security standards to ensure that patients retain full control over their personal health information.

At the same time, she proposes that Poland, as a leader in e-health solutions, should use its Presidency to promote the adoption of artificial intelligence in medicine and healthcare: "Discussions in the EU about AI mainly focus on the limitations and restrictions that should be placed on it, rather than on how we can use it effectively. Meanwhile, we should first and foremost consider how to harness its potential. The number of AI-powered applications that support treatment and even save lives is growing rapidly." Another tangible outcome of Poland's Presidency, according to Gembicka, could be the development of a European standard for child and adolescent psychiatric care. She points out that this is a pressing issue across all Member States, yet the exchange of best practices has been insufficient: "A good starting point for this discussion could be Poland's threetier mental healthcare system, which was at the pilot stage under our government and, according to many industry experts, has proven effective. We should also consider conducting a comprehensive assessment of the situation across different countries. Experts must determine how to measure the effectiveness of mental healthcare systems, as the number of diagnoses or suicide attempts alone does not provide a complete picture of young people's mental well-being. If we could identify the countries that excel in this area, we could analyse their strategies and apply those insights to improve mental healthcare across the EU."

Anna Gembicka also argues that the health priorities should be defined with greater specificity. "Prevention" is always a popular slogan and a relevant objective, but I feel that we need a more concrete approach to oncology patients. How can we speed up cancer diagnosis? How can we ensure that every patient diagnosed with cancer knows exactly where to turn and what kind of assistance they can access? There are no universally established international standards in this area, and while Europe's Beating Cancer Plan outlines goals, it lacks specific methodologies for achieving them. Meanwhile, it is clear that patient awareness – especially regarding these practical aspects – significantly improves their chances in the fight against cancer", emphasises Ms Gembicka, who is herself an oncology patient and has closely analysed the experiences of



cancer patients within Poland's healthcare system during her own treatment. She believes that beyond promoting a healthy lifestyle, practical knowledge on how to navigate the healthcare system should be a fundamental part of all government-led public awareness campaigns. It should also be a core element of the curriculum for the newly introduced *Health Education* subject in schools. According to Anna Gembicka, this initiative has the potential to deliver positive outcomes, but she stresses that it should steer clear of "ideological matters" that might provoke opposition from some parents.



# **Part III.** Expert Debates on the Health Priorities of Poland's EU Presidency

The expert debates, a key element in the preparations for Poland's Presidency of the Council of the European Union in 2025, took place between 2023 and 2024. Organised by the Institute for Social Policy Development, they brought together a wide range of experts from various fields of medicine, public health, technology, as well as representatives of non-governmental organizations, public institutions and the private sector. The aim of these meetings was to develop recommendations in key health areas that Poland could advocate for during its presidency.

Each of the debates was devoted to one of the health priorities of the Polish Presidency. The main topics included mental health of children and adolescents, digital transformation of healthcare, promotion of prevention, and pharmaceutical security. Discussions covered both the analysis of challenges and the identification of opportunities, as well as the development of concrete actions that could be implemented at the EU level. Experts emphasised the importance of international cooperation, exchange of best practices, and the need to adapt health policies to the changing social and technological realities.

During the debates, special attention was paid to mental health problems of children and adolescents, which have been intensified by the COVID-19 pandemic. Among other things, the impact of new technologies and social media on the mental well-being of young people, the need to strengthen the psychiatric care system, and the development of prevention programmes were discussed. Another important topic was the digitisation of healthcare, including the implementation of the European Health Data Space (EHDS), ensuring the interoperability of systems, and combating digital exclusion, particularly among older people.

The debates also addressed the issue of preventive healthcare, highlighting the importance of preventive measures as the most effective and cost-efficient way to improve public health. Experts emphasised the need to develop a catalogue of best practices in prevention and to integrate educational and healthcare initiatives. In the area of pharmaceutical security, discussions focused on the necessity of strengthening European pharmaceutical production, developing a list of critical medicines, and ensuring the stability of supply chains in times of crisis.

As a result of these debates, detailed analyses and recommendations were formulated and incorporated into the White Paper. These meetings not only facilitated the exchange of knowledge and experience but also provided a platform for dialogue between various stakeholders, contributing to the development of comprehensive and practical solutions in the field of healthcare.

#### Health Priorities for the Polish Presidency from the Perspective of Selected Fields of Medicine, as Presented by Experts During Three Conferences of the Institute for Social Development's *Road to the Presidency* Series (2023–2024)

## Edited by Jakub Gierczyński MD PhD

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#### Introduction

The health priority proposals for the Polish Presidency presented in this chapter are based on expert positions put forward during three conferences of the Institute for Social Policy Development (IRSS) as part of the Road to the Presidency series in 2023–2024:

- On 6 September 2023, the first conference entitled *Health Priorities of the Polish Presidency of the Council of the European Union* took place as part of the 32nd Karpacz Economic Forum.
- On 4 October 2023, the second conference entitled *Healthcare Policy Summit: Health Priorities* of the Polish Presidency of the Council of the European Union 2025 took place.
- On 30 January 2024, the third conference entitled *Road to the Presidency: Discussion on the Health Priorities of the Polish Presidency of the Council of the EU* was held.

The chapter contains proposals for 166 health priorities for the Polish Presidency put forward by 39 experts from 13 fields of medicine (cardiology, oncology, rare diseases, infectious diseases, paediatrics, rheumatology, neurology, psychiatry, diabetology, public health, women's health, policy on ageing, and scientific research). This highlights the scope of successes, challenges, and issues within the Polish healthcare system in the context of health challenges in the European Union, as well as the complexity of healthcare systems.

## Cardiology

#### **Prof. Robert Gil MD PhD**

President of the Polish Cardiac Society, Head of the Invasive Cardiology Department at the National Medical Institute of the Ministry of the Interior and Administration

In the field of cardiology, the key priorities for the Polish Presidency are:

- **1. Comprehensive Cardiac Care, Coordinated Post-Infarction Care Programme** This programme is crucial for improving the prognosis of patients after a heart attack, combining cardiac rehabilitation with appropriate consultation and treatment. It aims to ensure continuity of care and treatment after discharge from the hospital, which is necessary to ensure effective recovery.
- **2. National Cardiovascular Programme** The programme covers a wide spectrum of activities in the field of cardiology, including prevention, epidemiology and new diagnostic technologies. It is an important element in the development of holistic cardiac care.
- **3. Implementation of New Diagnostic Technologies and Genetic Diagnostics.** Modern diagnostic methods, such as MRI and CT, allow for more accurate and non-invasive diagnosis of cardiovascular diseases. Their development and implementation are essential for more effective treatment. Introducing genetic diagnostics into cardiology practice is crucial for understanding and treating heart diseases, including rare conditions. The Polish Cardiac Society is actively working on setting new directions in this field.



**4. Expansion and Improvement of Cardiac Prevention.** Prevention is the most cost-effective form of treatment for cardiovascular diseases, which are the leading cause of death. Expanding preventive and educational programmes is essential to reducing the prevalence of these diseases. The necessity of shifting health policy from curative to preventive medicine addresses the rising costs of treatment and the growing incidence of chronic conditions. Prioritising prevention will enable more efficient use of healthcare resources and improved health outcomes at the population level.

#### Prof. Przemysław Mitkowski MD PhD

Past President of the Polish Cardiac Society, Head of the Laboratory of Cardiac Electrotherapy at the Lord's Transfiguration Clinical Hospital in Poznań

In the field of cardiology, the key priorities for the Polish Presidency are:

- **1. Implementation of cardiovascular care and prevention programmes** These programmes are essential for enhancing the care provided to patients with cardiovascular diseases. In Poland, there are already programmes such as the treatment of acute coronary syndromes, but their further development and the implementation of new strategies are needed, especially in the context of prevention.
- **2. Increasing the effectiveness of post-infarction care.** Improving post-myocardial infarction care is essential for ensuring the long-term recovery of patients. This involves rehabilitation, appropriate treatment, and regular consultations, providing patients with a better quality of life after a heart attack.
- **3. Expansion of cardiac diagnostics and therapies.** The development of modern diagnostic methods, such as MRI and CT, and the implementation of innovative therapies, is crucial for accurate diagnosis and more effective treatment of heart disease.
- **4. Implementation of cardiovascular care programmes.** These programmes are being implemented in the current presidency trio of Spain, Belgium, Hungary, which is why they should also be implemented during the presidencies of Poland, Cyprus, and Denmark.
- 5. Digitisation and innovation in cardiology creating a platform for digital data exchange, and the purchase of medical technologies at the EU level. Cardiology produces the most digital data in relation to imaging examinations. It is necessary to build a data exchange platform, as most of this data is stored locally and is not accessible from any system. We have many new medical devices and medications, but access to them is delayed in Poland and other EU countries. Given the cost of these technologies, it would be worth considering joint purchases at the EU level.

#### Prof. Piotr Jankowski MD PhD

Deputy Director for Healthcare Services and Head of the Department of Internal Medicine and Cardiology at the Professor Orłowski Clinical Hospital in Warsaw, Chair of the Health Promotion Committee of the Polish Cardiac Society

In the field of cardiology, the key priorities for the Polish Presidency are:

- **1. Preventing cardiovascular diseases through lifestyle changes** Effective public health policies can significantly reduce the risk of cardiovascular disease by promoting a healthy lifestyle. The example of Finland in the 1970s and 1980s shows how lifestyle modification at the societal level can lead to long-term health benefits.
- **2. Effective detection and treatment of underlying cardiovascular risk factors** Early detection and effective treatment of risk factors such as hypertension, high cholesterol, obesity, and diabetes are key to preventing cardiovascular disease.
- **3.** Development and implementation of modern technologies in the diagnosis and treatment of cardiovascular diseases The introduction of new technologies, such as computed tomography



or magnetic resonance imaging, in diagnostics and modern treatments, can significantly improve the care of patients with heart disease.

**4. Improving post-myocardial infarction care is essential for ensuring the long-term recovery of patients** The development and implementation of coordinated post-heart attack care programmes, including cardiac rehabilitation and appropriate consultations, is essential to ensure a better quality of life for patients.

## Oncology

#### Prof. Tadeusz Pieńkowski MD PhD

President of the Polish Society for Breast Cancer Research, Head of the Department of Oncology and Breast Diseases, Centre of Postgraduate Medical Education

In the field of oncology, the key priorities for the Polish Presidency are:

- **1. Creation of a European database to assess the results of cancer treatment** It is necessary to use e-health and artificial intelligence in monitoring patients after treatment and conducting preventive examinations. Creating an algorithm for assessing an individual's risk of cancer will strengthen prevention and effectiveness of treatment.
- **2.** Promotion of healthy lifestyles and limiting the availability of stimulants It is important to promote a healthy lifestyle and fight overweight, alcohol abuse and smoking. Such measures can significantly reduce the risk of cancer.
- **3. Equal access to preventive examinations and vaccinations** Ensuring equal access to preventive examinations and vaccinations is essential for the prevention and early detection of cancer. Education and the promotion of public health awareness play a crucial role in cancer prevention. Effective educational initiatives and the encouragement of healthy lifestyles can help reduce exposure to cancer risk factors, such as obesity, alcohol misuse, and smoking.
- **4.** Accreditation and certification of oncology centres All oncology centres, regardless of their size, should provide equal quality of activities and be accredited by independent bodies.
- **5. Improving access to screenings and vaccinations** Availability for screening and vaccination, e.g. against HPV and hepatitis, is crucial in the early detection and prevention of cancer. Despite the existence of programmes, their use is at a low level, which requires further promotional and educational activities.

#### **Janusz Meder MD PhD**

President of the Executive Board of the Polish Oncology Union, Head of the Conservative Department of the Lymphatic System Cancer Clinic at the Maria Skłodowska-Curie National Institute of Oncology – National Research Institute

In the field of oncology, the key priorities for the Polish Presidency are:

- 1. Utilisation of existing health infrastructure in Poland as a model for the European Union. Poland boasts a well-developed health infrastructure, including national programmes addressing lifestyle diseases, which can serve as a model for European cooperation. Particular emphasis is placed on leveraging advancements in oncology, cardiology, and other medical fields.
- **2. Positioning Poland as a leader in health within the EU.** Poland has the opportunity to become a leader in health within the European Union, thanks to its advanced medical infrastructure and expertise in implementing health programmes.
- **3.** Coordination, cooperation and interdisciplinarity in healthcare. A key element of effective healthcare is cooperation between different medical specialties and institutions. Interdisciplinarity and a comprehensive approach to healthcare are essential for the effective treatment of chronic and malignant diseases.



- **4.** Use of the National Cancer Registry. Poland has one of the most advanced cancer registries in the world. Leveraging data from this registry, combined with modern information technologies and e-health, could significantly contribute to enhancing the diagnosis and treatment of cancer.
- **5. Application of Europe's Beating Cancer Plan.** The Polish National Oncology Strategy is consistent with Europe's Beating Cancer Plan.

## Rheumatology

## Prof. Brygida Kwiatkowska MD PhD

National Consultant in Rheumatology, Head of the Early Arthritis Clinic, Deputy Clinical Affairs Director of the National Institute of Geriatrics, Rheumatology and Rehabilitation in Warsaw

In the field of rheumatology, the key priorities for the Polish Presidency are:

- 1. Comprehensive care for patients with rheumatic diseases. Rheumatic diseases are extremely common, and their effects impact both younger and older patients. A comprehensive approach to the diagnosis and treatment of these conditions is essential to minimise their impact on patients' quality of life and to prevent premature deaths due to complications.
- **2. Prevention and treatment of autoimmune diseases.** Autoimmune diseases significantly affect patients' ability to work and maintain independence. Effective prevention and early initiation of treatment can help keep patients in good health, which is important both for them and for the healthcare system.
- **3.** Psychological support for patients with chronic diseases. Chronic diseases often lead to mental health issues, such as depression, which can exacerbate patients' overall health. Providing psychological support and integrating psychiatric care with somatic treatment is crucial for enhancing both the quality of life and the effectiveness of treatment.
- **4. Integration of care for patients with multiple morbidity.** The co-occurrence of multiple diseases in a single patient is becoming increasingly common, especially among the elderly. This requires a holistic approach to treatment that takes into account all aspects of the patient's health and ensures coordination between various medical specialists.

## Neurology

## Prof. Konrad Rejdak MD PhD

Past-President of the Polish Neurological Society, Head of the Department of Neurology at the Medical University of Lublin

In the field of neurology, the key priorities for the Polish Presidency are:

- **1. Introducing innovations in neurology.** In neurology, innovation in the treatment and diagnosis of diseases is crucial. Due to the broad spectrum of neurological diseases, ranging from pain to inflammatory and neurodegenerative conditions, progress in this field is of fundamental importance. Collaboration with other fields of medicine and the utilisation of the latest technologies, such as artificial intelligence.
- **2. Integrating diseases of the nervous system into overall health priorities.** Diseases of the nervous system should be an integral part of overall health priorities, considering that 40% of rare diseases affect the nervous system. This requires an interdisciplinary approach that integrates neurology with cardiology, psychiatry, and other medical disciplines.
- **3. Promoting neurology across Europe.** The active promotion of neurology at the European level, including through the framework of the Belgian Presidency and in cooperation with the European Academy of Neurology, is essential for increasing awareness of neurology. Work on international projects such as the Human Brain Project.



- **4. Preventing diseases of the nervous system through the promotion of brain health.** Diseases of the nervous system are often characterised by irreversible consequences. Prevention, through education on healthy lifestyles and early diagnosis, is essential in reducing the incidence of these diseases. Preventive efforts aimed at the prevention and early detection of conditions such as stroke can substantially enhance patients' quality of life.
- **5.** Early diagnosis and treatment of inflammatory diseases of the nervous system. Diseases such as multiple sclerosis, although not directly linked to lifestyle, require prompt diagnosis and treatment. Early intervention can modify the course of the disease and prevent its progression to advanced stages, thereby improving patients' quality of life.

#### Prof. Anna Kostera-Pruszczyk MD PhD

Chair of the Council for Rare Diseases at the Ministry of Health, Head of the Department of Neurology at the Medical University of Warsaw

In the field of neurology, the key priorities for the Polish Presidency are:

- **1. Support for patients with disabilities** A major challenge for patients under the care of neurologists is disability, which is often motor-related or multifaceted. Ensuring adequate access to therapy and support, such as personal assistants, is crucial. Such assistance helps patients better integrate into society, enhancing their quality of life and fostering independence.
- **2. Raising public awareness of neurological diseases.** Neurological diseases pose a greater burden than oncology and cardiology combined, yet public awareness of these conditions remains insufficient. Raising awareness is crucial to ensuring that both the public and policymakers understand the needs and challenges associated with neurological care.
- **3. Integration of neurology with medical and demographic initiatives.** Neurology should be an integral part of health priorities, particularly in the context of medical and demographic challenges. Raising awareness and providing adequate support for neurology will enable us to better address the growing needs of patients, especially in an ageing society.

#### Psychiatry

#### Prof. Małgorzata Janas-Kozik MD PhD

Head of the Department of Psychiatry and Psychotherapy at the Medical University of Silesia in Katowice, Head of the Clinical Department of Psychiatry and Psychotherapy for Developmental Age at the Medical University of Silesia

In the field of psychiatry, the key priorities for the Polish Presidency are:

- 1. Promotion of the systemic reform of child and adolescent psychiatry in Poland as a model for the EU. Poland's reform of child and adolescent psychiatry could serve as a model for other EU countries, given the growing demand for access to child and adolescent psychiatrists and other mental health professionals.
- **2. Development of child and adolescent psychiatry specialists.** The reform involves training specialists, not only doctors but also community therapists, clinical psychologists, and psychotherapists, which is crucial for ensuring effective care.
- **3.** Collaboration with the education sector in providing support for children with ASD. Children with Autism Spectrum Disorder (ASD), particularly those who are high-functioning, require an individualised educational approach and specialised support programmes.
- **4. Improvement of the availability and quality of psychotherapeutic services.** In addition to pharmacological treatment, ensuring access to high-quality psychotherapeutic services is essential for effective psychiatric care.
- **5. Strengthening of cross-sectoral cooperation.** An important element in improving the care of children and adolescents with mental disorders is increasing cooperation between different



sectors, especially between healthcare, education, and the Ministry of Family, Labour, and Social Policy. Such cooperation will enable a comprehensive approach to the issue, addressing not only treatment but also the support of the child's family and school environment.

- **6. Development and implementation of universal prevention programmes.** Universal prevention programmes, aimed at all children and adolescents, should include education on life hygiene, sleep, diet, and other aspects that affect mental health. Implementing such programmes at the preschool and school stages can significantly reduce the risk of developing mental disorders and improve the overall quality of life for young people.
- 7. Improvement of the accessibility and effectiveness of screening. Early diagnosis of disorders, such as autism spectrum disorders, is crucial for effective treatment and support of the child. It is therefore essential to ensure that screening is accessible to all children and conducted in a timely manner. The knowledge and skills of healthcare professionals in early diagnosis of disorders must be strengthened.
- **8.** Facilitation of the from paediatric to adult care. The transition of adolescents from child and adolescent psychiatric care to adult care presents a systemic challenge. This process should be facilitated through better coordination among specialists and the creation of dedicated programs to support young people during this transitional period. Such actions will help avoid treatment interruptions and ensure continuity of care.

#### Aleksandra Lewandowska MD PhD

national Consultant in Child and Adolescents Psychiatry, Head of the Psychiatric Department at Babiński Hospital in Łódź

In the field of psychiatry, the key priorities for the Polish Presidency are:

- **1. Addressing mental health issues in a global context.** Highlighting the fact that the mental health of children and adolescents is not limited to Poland alone, but represents a global challenge, with an emphasis on the need for international cooperation and the exchange of best practices.
- **2. Development and strengthening of the prevention and treatment system.** The need to continue and support a care model that includes both prevention and treatment of mental disorders, taking into account the specific needs of children and adolescents
- **3.** Strengthening interdepartmental cooperation in the prevention of mental disorders. Cooperation between the Ministry of Health and the Ministry of Education is crucial for the primary prevention of mental disorders among children and adolescents. Integrated actions aim to facilitate early detection and interventions, which can significantly help reduce the growing number of young patients requiring specialist psychiatric care. During its Presidency of the EU, Poland should promote an interdisciplinary and interdepartmental model as the standard for mental health prevention.
- **4. Development and implementation of screening research programmes.** Neurodevelopmental screening plays a crucial role in enabling early diagnosis and intervention, reducing the risk of comorbidity with other mental disorders in the future. The promotion and implementation of these programmes at both national and European levels should be supported, as this will help reduce hospitalisations and improve patients' quality of life.
- **5. Restriction of access to potentially hazardous substances.** Effective methods of suicide prevention include limiting access to substances that can be used in suicide attempts, such as NSAIDs. Poland should initiate regulations to restrict access to these substances, especially for young people, which could significantly reduce the number of suicide attempts
- **6. Promotion of educational programmes concerning healthy lifestyles.** Educational programmes focusing on healthy lifestyles and mental hygiene are essential in the prevention of mental disorders. It is advisable to increase the availability and promotion of such programmes, particularly in schools, to build health awareness from an early age. Poland, leveraging the EU Presidency platform, should encourage the creation and support of such initiatives at the European level.



#### **Prof. Marcin Wojnar MD PhD**

Head of the Department and Psychiatric Clinic, the Medical University of Warsaw

In the field of psychiatry, the key priorities for the Polish Presidency are:

- Strengthening of preventive actions against addiction. The growing issues related to the use of psychoactive substances, including nicotine and alcohol, pose a significant threat to the mental health of society. It is essential to implement more effective prevention methods, including education and limiting access to these substances, particularly among young people. As part of its Presidency of the Council of the European Union, Poland should promote and support European initiatives focused on combating addiction.
- **2. Introduction of regulations limiting the availability of e-cigarettes.** The increasing use of disposable e-cigarettes by adolescents and even children requires an immediate response. Regulations on the sale of e-cigarettes, particularly disposable ones, should be tightened, and the addition of flavours that attract younger consumers should be banned. Poland should also initiate discussions at the EU level aimed at harmonising regulations on the sale of tobacco and nicotine products.
- **3. Imposition of restrictions on the sale of nicotine products in the vicinity of schools.** Establishing tobacco and nicotine-free zones around schools can significantly reduce the availability of these products to children and adolescents. Implementing such a ban within a radius of 100–200 metres from educational institutions will protect young people from easy access to addictive substances, which is crucial for addiction prevention.
- **4. Raising the minimum age for purchasing nicotine products.** Raising the minimum age for purchasing nicotine-containing products to 21 is a step that can effectively reduce the initiation of smoking among young people. This action, supported by Poland at the EU level, will contribute to reducing the number of new addiction cases and improve the overall health situation of society.

## Women's health

#### Katarzyna Kotula

Minister for Equality

In the field of women's health, the key priorities for the Polish Presidency are:

- **1. Strengthening of women's reproductive rights.** Poland should use its presidency to promote comprehensive access to healthcare services related to reproductive rights, emphasising the importance of women's autonomy in making decisions about their health and bodies.
- **2. Education on reproductive health.** The need for education as a key element in preventive healthcare and the promotion of reproductive rights. The Presidency should promote the introduction of educational programmes at all levels of education to enhance awareness of reproductive health and sexual rights.
- **3.** Increasing of access to healthcare services for women. Access to modern therapies, such as in vitro fertilization and the removal of barriers to emergency contraception, are examples of actions that should be promoted at the European level. The Polish Presidency offers an opportunity to share experiences and promote best practices in ensuring comprehensive healthcare for women.
- **4. International support for women's rights.** The Polish Presidency can serve as a platform to intensify efforts for gender equality and strengthen the protection of women's reproductive rights at the international level, fostering dialogue and cooperation among Member States.



## Prof. Violetta Skrzypulec-Plinta MD PhD

head of the Department of Women's Health and the Department of Reproductive Health and Sexology at the Medical University of Silesia in Katowice

In the field of women's health, the key priorities for the Polish Presidency are:

- **1. Introduction of comprehensive sexual and reproductive health education in schools.** Comprehensive sexual and health education plays a crucial role in preventing sexually transmitted diseases and unintended pregnancies. The statement highlights the importance of introducing this education at every stage of a child's development, starting from an early age. Integrated educational programmes should cover topics such as puberty, contraceptive methods, body awareness, and respect for diversity.
- **2. Development of prevention programmes and screening initiatives focused on women's health.** Introducing and promoting prevention programmes and screenings for breast and cervical cancer can significantly contribute to earlier detection and more effective treatment of these diseases. It is particularly important for information campaigns to also highlight lesser-known risks, such as HPV and its link to cervical cancer, while promoting vaccination as a highly effective preventive measure. These initiatives should target both women and men to foster greater awareness and shared responsibility for sexual and reproductive health at the societal level.
- **3. Support for women during menopause and postmenopause.** Menopause is a significant stage in every woman's life, often accompanied by various health and emotional challenges. This priority underscores the importance of developing comprehensive support programmes for women during menopause, encompassing access to hormone therapy, education on sexual and mental health, and the promotion of physical activity and healthy lifestyles.
- 4. Promotion of sexual and reproductive health within the framework of comprehensive healthcare. Sexual and reproductive health should form an integral part of the healthcare system at every stage of a woman's life. This priority calls for the implementation of coordinated measures to ensure women's access to comprehensive care, including sexual education, contraception, screening, and hormone therapy. Additionally, efforts must focus on improving the availability and quality of medical services for women affected by conditions such as endometriosis and polycystic ovary syndrome, thereby enhancing their quality of life.

#### Wanda Nowicka

Vice-Chair of the New Left, Member of the Sejm of the Republic of Poland, Chair of the Parliamentary Group on Women's Rights

In the field of women's health, the key priorities for the Polish Presidency are:

- **1. Integration and stabilisation of the women's reproductive health system.** The current legal and political situation in Poland creates significant confusion regarding access to reproductive health services. Polish women face instability and uncertainty about their rights and the availability of services. Strong political action is needed to ensure the stability and predictability of the health system, including access to contraception, in vitro treatments, and abortion services.
- **2. Sex education and preventive healthcare.** Insufficient sex education and the absence of comprehensive social campaigns result in a lack of awareness and the perpetuation of stereotypes regarding sexuality and reproductive health. Greater investment in educational and preventive programmes is necessary to empower women to make informed decisions about their health and sexual well-being.
- **3. Improvement of the accessibility and quality of healthcare services for women.** The Polish healthcare system requires reforms to ensure improved access to high-quality medical services for women. This includes prevention, diagnosis, and treatment of conditions specific to women, such as endometriosis, cancer, or complications related to pregnancy and menopause.



**4. Increase in the role and accountability of politicians in shaping health policy.** Politicians must assume greater responsibility for shaping health policies that prioritise women's rights and needs. Efforts should focus on removing ideological and political barriers that restrict access to comprehensive reproductive and sexual healthcare.

#### Prof. Bolesław Samoliński MD PhD

Chair of the Subcommittee on Health Priorities during the Polish Presidency of the Council of the European Union 2011, Head of the Department of Environmental Hazard Prevention, Allergology, and Immunology at the Medical University of Warsaw, Chair of the Council of the Discipline of Health Sciences, Medical University of Warsaw

In the field of women's health, the key priorities for the Polish Presidency are:

- **1. Promotion of work-life balance.** Faced with the challenges of an aging population and inequalities in the labour market, particularly those affecting women, Poland should focus on creating conditions that make it easier for women to return to work after maternity. Ensuring access to childcare facilities and reducing working hours to allow for child care will benefit all parties: employees, employees, and their families. Such measures not only support the professional development of women but also contribute to greater demographic and economic stability in the country.
- **2. Support for women in returning to the labour market.** Creating conditions for women to continue their professional careers while fulfilling parental responsibilities is crucial for ensuring gender equality in the labour market. Such actions should include not only facilitating access to childcare but also training and skills development programmes that will help women update their qualifications and re-enter the workforce more effectively. The implementation of this priority will contribute to reducing the gender pay gap and increasing the participation of women in the labour market.
- **3. Improving of access to childcare services.** Ensuring that childcare is accessible, available, and affordable for working parents is essential for achieving gender equality and enabling women to actively participate in the workforce. The Polish Presidency should promote initiatives aimed at increasing the number of places in nurseries and kindergartens, as well as supporting parents in harmoniously balancing work and family life. This, in turn, will contribute to higher female employment rates and economic growth.
- **4. Raising of awareness about gender equality.** Education and social campaigns play a key role in raising awareness of gender equality and dismantling stereotypes. By fostering understanding and respect for equality and supporting initiatives aimed at transforming social attitudes, Poland can help build a more inclusive society where women and men enjoy equal opportunities for professional and personal development.

#### **Policy on ageing**

#### Marlena Kondrat PhD (Social Sciences)

member of the Management Board of the Polish Institute of Silver Economy

In the field of policy on ageing, the key priorities for the Polish Presidency are:

1. Education and support of digital competences among seniors Poland is among the countries with the lowest levels of digital literacy, particularly in the 45+ age group. Fewer than 10% of seniors possess basic or advanced digital skills, and only 6% are able to operate a computer. Therefore, it is essential to implement dedicated educational programmes and tools to help seniors acquire digital skills, enabling them to effectively access and use digital health services.



- **2.** Access to devices and the Internet for seniors. Almost half of seniors in Poland still use feature phones, which limits their ability to access digital health services. It is essential to provide seniors with access to modern devices and high-speed internet so they can fully benefit from eHealth services, such as online patient accounts or the ability to fill prescriptions online.
- **3. Protection against online disinformation.** Older people often uncritically trust information found on the Internet, which can lead to dangerous situations, especially in the context of health. Trusted sources of medical information should be created and promoted, along with educational campaigns to help recognise fake new.
- **4. Human-centred approach to digitisation.** An important aspect is also embracing a humancentred approach to digitisation, ensuring that seniors have the opportunity to connect with medical staff through digital communication channels. This is not just about consultations with doctors, but also support from nurses or paramedics, which can serve as the first step towards ensuring comprehensive healthcare.
- **5.** Support for organisations advocating for seniors. The government should actively support foundations and organisations dedicated to enhancing the digital skills of older adults. Initiatives such as the Digital Seniors Coalition and similar programmes play a vital role in educating and assisting seniors in adapting to the digital world, which is crucial for their active participation in the digital health ecosystem.

## Prof. Bolesław Samoliński MD PhD

Chair of the Subcommittee on Health Priorities during the Polish Presidency of the Council of the European Union 2011, Head of the Department of Environmental Hazard Prevention, Allergology, and Immunology at the Medical University of Warsaw, Chair of the Council of the Discipline of Health Sciences, Medical University of Warsaw

In the field of policy on ageing, the key priorities for the Polish Presidency are:

- **1. Introduction and promotion of health-oriented policies targeting older adults.** Due to the ageing population and increasing demographic challenges, it is essential to create comprehensive preventive and educational programmes aimed at seniors. These programmes should focus on promoting a healthy lifestyle, including physical activity, healthy nutrition, and the management of chronic diseases. The implementation of a health-promoting policy for seniors can improve their quality of life and help reduce the burden on healthcare systems.
- **2. Reduction of inequalities in access to healthcare for the elderly.** Inequalities in access to healthcare and geriatric services are a significant issue that impacts the quality of life for older individuals. The Polish Presidency should focus on ensuring equal access to high-quality healthcare for all seniors, regardless of their place of residence or financial situation.
- **3. Promotion of active ageing.** Active ageing is a crucial component in ensuring the well-being of seniors and maintaining their independence. The Polish Presidency should promote initiatives that encourage participation in social, cultural, and educational activities, contributing to the improvement of both the mental and physical health of older adults. Implementing programs that motivate physical and social engagement, such as workshops, courses, or exercise classes, can significantly enhance the quality of life.
- **4. Support for research and innovation in the fields of geriatrics and gerontology.** Investment in research and development of technologies supporting ageing is essential to understanding the needs and challenges posed by an ageing population. The Polish Presidency should encourage research into new methods of diagnosis, treatment, and care for seniors, which will facilitate the implementation of innovative solutions that improve their quality of life.
- **5.** Strengthening of the role of non-governmental organisations in shaping a policy on ageing and adopting an integrated, intergenerational approach to the policy development. Non-governmental organisations, due to their close connection with seniors and understanding of their needs, should play a key role in shaping a policy on ageing. Actively involving seniors and organisations representing their interests in the decision-making process will enable the



development of more appropriate and effective strategies. A policy approach that recognises the continuity and interdependence of generations should be adopted. Policies should promote healthy ageing from early childhood and encompass a broad range of educational, health, and social initiatives for all age groups.

#### Marzena Rudnicka

Founder and President of the Management Board of the Polish Institute of Silver Economy

In the field of policy on ageing, the key priorities for the Polish Presidency are:

- 1. Development of interdisciplinary support programmes for older adults A policy on ageing should extend beyond healthcare to encompass a broad spectrum of initiatives supporting active and healthy ageing. Educational, cultural, and social projects that enhance the engagement of older people in community life should be actively promoted. An interdisciplinary approach will contribute to creating an inclusive society for all generations, with particular attention to the needs and potential of seniors.
- **2.** Support for long-term planning of senior life from an early age. Demographic changes require long-term planning and the preparation of society for ageing. Education about healthy living, financial management, and building social relationships should start in childhood. Promoting awareness of the ageing process and preparing for it at different stages of life will enhance the quality of life for seniors and reduce the burden on health and social care systems.
- **3. Integration of older adults into the labour market.** Professional activation of older adults is crucial for maintaining their financial independence and sense of self-worth. Mechanisms should be established to enable a longer presence of older adults in the labour market, including flexible forms of employment and retraining programmes. Supporting entrepreneurship among older adults and adapting the working environment to their needs could contribute to increasing their professional activity.
- **4. Development of day care homes to support seniors and their families.** Day care homes offer essential support for seniors, particularly those losing their independence, and ease the burden of 24-hour care on families. Building and expanding such facilities near workplaces and in smaller towns will improve access to care and help seniors maintain social engagement. Investing in such facilities will help improve the quality of life for older adults and their families.

#### Krystyna Lewkowicz

President of the Polish Alliance of Universities of the Third Age

In the field of policy on ageing, the key priorities for the Polish Presidency are:

- 1. Undertaking a comprehensive amendment to the Act on Older Adults. The current Act on Older Adults, hastily adopted, primarily centres on monitoring the situation of seniors, which, in practice, amounts to collecting statistical data without making a tangible difference in their quality of life. A revision of this law is essential to establish effective mechanisms that support and enhance the living conditions of older adults. The amendment should prioritise targeted actions and programmes aimed at fostering senior activity and aligning the provisions with the present needs of the senior community.
- **2.** Strengthening the role of Universities of the Third Age. Universities of the Third Age have played a pivotal role in the education and activation of older adults. However, they require additional support and greater promotion of their activities. Expanding infrastructure and educational programmes tailored to seniors can significantly enhance their participation in social and cultural life, which is crucial for improving their overall well-being. The Polish Presidency should champion initiatives that strengthen these institutions as vital support hubs for the senior population.



- **3. Promoting healthy lifestyles among older adults.** A healthy lifestyle is fundamental for maintaining good physical and mental health in later life. The introduction of educational programmes focused on healthy eating, physical activity, and chronic disease management can significantly improve the quality of life for older adults. This priority entails developing and supporting initiatives that promote healthy habits among seniors.
- **4.** Developing a policy on ageing based on intergenerational solidarity. Intergenerational solidarity plays a key role in fostering a harmonious society and providing support for older adults. The Polish Presidency should launch projects and programmes that promote the exchange of experiences and knowledge between generations, which can greatly contribute to a better understanding of the needs of seniors. Such actions may include joint educational initiatives, volunteering programs, and social projects that engage different age groups, creating opportunities for collaboration and mutual support.

#### Małgorzata Bogusz

President of the Board of the Institute for Social Policy Development, member of the European Economic and Social Committee, member of the Council of Non-Governmental Organisations for the Polish Presidency of the Council of the European Union

In the field of policy on ageing, the key priorities for the Polish Presidency are:

- **1. Permanence and continuity of the policy on ageing.** Maintaining the Permanent Committee on Policy on Ageing in the Sejm of the Republic of Poland as a key achievement in ensuring the continuity of the policy discourse. It is essential to ensure the continuity and permanence of actions for older adults in order to build upon the foundation of work and achievements from previous years.
- **2. Integration of the areas of health policy and the policy on ageing into the EU strategy.** The importance of close cooperation with European Union institutions in shaping health policy, particularly in the context of ageing populations and women's health. The Polish Presidency should align with European health priorities, such as the fight against cancer, the promotion of healthy ageing, and addressing demographic challenges.
- **3.** The importance of education and prevention in health management. Shifting the balance of spending from a dominant focus on the treatment of diseases to an equivalent emphasis on prevention and health education. This approach can significantly reduce future burdens on the healthcare system and improve the quality of life for the population.
- **4. The development and integration of policies aimed at supporting healthy and active ageing.** Emphasising the importance of long-term planning and implementation of strategies to support healthy and active ageing during the Polish Presidency. Particular attention should be given to the necessity of integrating actions at both national and EU levels to effectively address the challenges posed by demographic changes and the needs of senior citizens.

#### **Rare diseases**

#### Prof. Mieczysław Walczak MD PhD

National Consultant in Paediatric Endocrinology and Diabetology, Head of the Department of Paediatrics, Endocrinology, Diabetology, Metabolic Diseases and Developmental Age Cardiology at the Pomeranian Medical University in Szczecin

In the field of rare diseases, the key priorities for the Polish Presidency are:

1. Plan for Rare Diseases, including genetic research and the introduction of novel orphan drugs. This is one of the model plans that will be widely discussed in European fora. Year by year, we are introducing more and more compounds in Poland, and if this trend continues, within the next few years, we will move from being at the back of Europe, as was the case not long ago, to being at the forefront.



- **2. Assessment of treatment effectiveness in rare diseases.** Perhaps it would be worth discussing within the EU how effective treatments for conditions such as Hunter or Pompe disease are in Poland compared to Germany or other EU countries. Assessing their effectiveness is particularly crucial given the high cost of these medications. It would also be beneficial to determine which additional factors should be considered in individual therapeutic programmes to maximise the effectiveness of these expensive treatments.
- **3.** Access to treatment and digitisation in diabetes glycaemic monitoring systems, telemedicine. Thanks to our efforts, the latest insulins are now reimbursed for children with type 1 diabetes, and there is universal access to the most advanced glycaemic monitoring systems including for pregnant women with type 2 diabetes on intensive insulin therapy. Polish children are the best-managed diabetes patients in Europe, or even globally. We have much to be proud of, and I believe this aspect should also be highlighted at the EU level. Thanks to digitalisation and telemedicine, glycaemic monitoring systems for children are exceptionally effective.

#### Prof. Anna Kostera-Pruszczyk MD PhD

Chair of the Council for Rare Diseases at the Ministry of Health, Head of the Department of Neurology at the Medical University of Warsaw

In the field of rare diseases, the key priorities for the Polish Presidency are:

- 1. Improving access to modern diagnostic techniques and strengthening centres of expertise for rare diseases. Access to advanced diagnostic techniques is crucial for optimising the treatment of rare diseases. Strengthening existing centres and integrating new Polish centres into the European network of reference centres will contribute to improved diagnosis and treatment of these diseases. Thanks to advances in medicine, patients with rare diseases now have access to new diagnostic and therapeutic options that were previously unavailable. Providing psychological support and integrating psychiatric care with somatic treatment is essential for enhancing both the quality of life and treatment effectiveness for these patients.
- **2. Integrated actions at the population health level.** Actions at the population health level are essential to meet the needs of patients with rare diseases. Effective solutions in this area require international cooperation and knowledge exchange to ensure patients have access to the best possible care.
- **3. Enhancing care for adults with rare diseases.** Given that approximately half of rare disease patients are adults, there is an urgent need to develop solutions that ensure these patients have access to specialised care, diagnostics, and therapies.
- **4. Integration of patients with rare diseases into society.** Patients with rare diseases, particularly those who reach adulthood, can make a substantial contribution to society. It is essential to create conditions that enable their full participation in social and professional life.

#### Prof. Anna Latos-Bieleńska MD PhD

National Consultant in Clinical Genetics and Head of the Department of Medical Genetics at the Medical University of Poznań

In the field of rare diseases, the key priorities for the Polish Presidency are:

- 1. Development of gene medicine within the framework of legislation governing genetic testing for medical purposes. The Nobel Prize in Medicine for genetics highlights the significance of genetic research in medicine. The regulation of this research is essential for the continued advancement of gene medicine, ensuring appropriate standards and safeguarding patients' rights.
- **2. The creation of a shared genome database.** A shared genome database will facilitate more effective use of genetic information in research and treatment, contributing to a deeper understanding and improved management of genetic diseases.



- **3. Medical and postgraduate education in gene medicine.** The education of physicians and other healthcare professionals in the field of genetics is essential to ensure the effective application of advancements in this field to clinical practice.
- **4.** Educating the public about the possibilities and limitations of gene medicine. Public awareness of gene medicine is crucial for shaping rational attitudes towards genetics. Education will help reduce both fetishism and unfounded fear of genetics.
- **5.** Preparing the healthcare system and society for the era of genomic medicine. Genomic medicine is developing rapidly, and approximately 40–50 percent of people will develop a disease associated with congenital or somatic genetic changes. Genome sequencing is also developing. However, legislation is lagging behind the progress of genetics, as is the ability of doctors to utilise genetic advancements, and, above all, society is not keeping pace.

## Prof. Jolanta Sykut-Cegielska MD PhD

National Consultant in Metabolic Paediatrics, President of the Polish Society of Inborn Errors of Metabolism and Head of the Department of Inborn Errors of Metabolism and Paediatrics at the Institute of Mother and Child in Warsaw.

In the field of rare diseases, the key priorities for the Polish Presidency are:

- **1. Neonatal screening as a preventive action.** Neonatal screening is a key component of secondary prevention. They play an important role in detecting rare diseases, including inborn errors of metabolism, which aligns with the priorities of the current Presidency.
- **2. Harmonisation of screening programmes at the European level.** A higher number of detected diseases does not necessarily indicate more effective screening. Harmonisation of screening programmes at European level can improve diagnostics by considering the specific circumstances of each Member State and the prevalence of certain diseases.
- **3. Patient care and tertiary prevention.** Appropriate care and treatment are crucial upon disease detection. Hence, the need for well-equipped reference centres with qualified staff and experience in managing patients with rare diseases.
- **4. Access to new, innovative drug technologies and medical devices.** Better access to new pharmaceutical and other medical devices is crucial for the effective treatment of patients with rare diseases. The development and integration of such technologies at the European level could be a key priority of the Presidency.

## Prof. Piotr Podolec MD PhD

Head of the Clinic of Heart and Vascular Diseases and Plenipotentiary of the Director for Rare Diseases at the John Paul II Specialist Hospital in Kraków

In the field of rare diseases, the key priorities for the Polish Presidency are:

- **1. Centralisation of diagnostic services for rare diseases.** The diagnostic process should be expedited and centralised in well-equipped centres, allowing for faster and more accurate diagnosis of rare diseases.
- **2. Establishment of a network of. European centres based on leaders in the field** International cooperation and knowledge exchange are essential to identify and treat a wide range of rare diseases, and Poland should work towards establishing such a network.
- **3. Outpatient treatment of rare diseases at the place of residence.** The introduction of outpatient treatment will help alleviate the burden on patients and their families, especially in cases requiring frequent visits and therapies.
- **4. Monitoring of telemedicine and simplification of reporting procedures.** The development of telemedicine monitoring and the simplification of reporting are crucial for the effective oversight and treatment of patients in home care settings.



**5.** Supporting research and development in the field of rare diseases. Intensifying research on rare diseases, including supporting innovation in treatment and diagnosis, is crucial for enhancing the effectiveness of therapies and improving the quality of life for patients.

#### Prof. Beata Wilk MD PhD

Head of the Laboratory of Rare Metabolic Diseases at the Clinical Department of the Department of Metabolic Diseases at Kraków University Hospital

In the field of rare diseases, the key priorities for the Polish Presidency are:

- **1. The key role of reference centres.** Reference centres play a fundamental role in ensuring highquality care for rare disease patients. They are essential for the effective diagnosis, treatment, and monitoring of their condition.
- **2. Organisation of healthcare for adult patients.** There is a significant issue related to the organisation of healthcare for adult patients with rare diseases, particularly those transitioning from paediatric care. It is essential to develop effective strategies to ensure continuity of care for this patient group.
- **3.** The evaluation of reference centres. Reference centres should be regularly assessed for the effectiveness and quality of the services they provide. This evaluation should consider the centre's capacity to manage a broad spectrum of rare diseases, rather than focusing on a single condition.
- **4. Development of metabolic specialisation for adults.** There is a need to establish a metabolic specialisation for adults in order to provide a trained cadre of specialists capable of delivering an appropriate level of care for adult patients with rare diseases. Such a specialisation would contribute to improving the quality of medical care.

#### Stanisław Maćkowiak

President of the Federation of Polish Patients and President of ORPHAN, the National Forum for Rare Disease Therapies

In the field of rare diseases, the key priorities for the Polish Presidency are:

- **1. Implementation of the rare disease plan.** The rare disease plan documents outline the main actions to be implemented. It is crucial to focus on these guidelines in order to improve care for rare disease patients.
- **2. Development of diagnostics, including genetic testing.** There is a need for the development of diagnostics, particularly genetic diagnostics, supported by appropriate legislation. This will enable better detection and faster identification of rare diseases.
- **3. Strengthening expert centres.** Efforts should be made to strengthen expert centres at both the national and European levels. These centres are essential for the effective care and treatment of rare disease patients.
- **4. Development of home-based and outpatient treatment pathways.** Treatment pathways should be developed, with a focus on home-based and outpatient care, to improve patients' quality of life and reduce the burden on the healthcare system.
- **5. Leveling the playing field for rare disease patients.** The rare disease plan should include solutions aimed at levelling the playing field for patients with rare diseases. It is important that these patients have the same opportunities as other citizens in terms of access to healthcare and support.



#### Diabetology

## Prof. Małgorzata Myśliwiec MD PhD

Provincial Consultant in Paediatric Endocrinology and Diabetology, Head of the Department and Clinic of Paediatrics, Diabetology and Endocrinology of the Medical University of Gdańsk, Plenipotentiary of the Board of the Polish Diabetes Association for Cooperation with the Ministry of Health and the Parliament

In the field of diabetology, the key priorities for the Polish Presidency are:

- **1. Access to modern technologies for the treatment of diabetes.** Patients with type 1 diabetes should have equal access to the latest technologies, such as insulin pumps and integrated glucose monitoring systems. This is essential for improving their quality of life. The use of modern glucose monitoring systems and insulin pumps enables precise regulation of blood sugar levels, which is key to preventing the long-term complications of diabetes. Ensuring access to these methods for all patients, along with a modest increase in coverage, could position Poland as a global leader in diabetes treatment and significantly enhance the quality of life for patients.
- **2.** Combating obesity in children and adolescents. Obesity programming begins at an early age. The focus should be on interdisciplinary, non-pharmacological treatment to effectively prevent obesity in children and adolescents. Obesity in children and adolescents is increasing at an alarming rate, leading to many serious health issues in adulthood. Efforts should begin with education and changes in the availability of food products, eliminating the most harmful ones, such as highly processed foods rich in fructose. Interdisciplinary collaboration (nutritionists, psychologists, paediatricians) and comprehensive care for overweight and obese children can help reverse this worrying trend.
- **3.** Screening for type 1 diabetes. Early diagnosis of type 1 diabetes allows for delaying its onset and the introduction of effective treatment, including biological therapies.
- **4. Improving access to modern treatments for children with type 2 diabetes.** The early introduction of modern therapies in the treatment of type 2 diabetes in children, rather than waiting for the failure of standard methods, can significantly delay or even prevent the development of complications. Such an approach requires a shift in treatment strategies and greater availability of modern medications and healthcare services.

## **Paediatrics**

#### Prof. Teresa Jackowska MD PhD

President of the Polish Paediatric Society, Head of the Paediatrics Clinic at the Centre of Postgraduate Medical Education, Head of the Clinical Department of Paediatrics at the Bielany Hospital

In the field of paediatrics, the key priorities for the Polish Presidency are:

- **1. A preventive programme focused on adolescents.** There is no comprehensive prevention programme for children and adolescents in Poland. Developing such a programme would improve the detection and prevention of health issues among young people, including suicidal ideation, eating disorders, and risky behaviours such as alcohol and drug use.
- **2. Integration of vaccination programmes in preventive healthcare.** Vaccinations are a vital element of preventive healthcare, especially in preventing diseases like cervical cancer (HPV) and respiratory illnesses. Optimising and better organising vaccination programmes will enhance their effectiveness and contribute to improved public health outcomes.



- **3. Development of educational programmes focused on prevention.** Teaching children healthy habits from an early age is crucial. Education plays a significant role in preventing diseases such as diabetes and hypercholesterolemia, which can be effectively mitigated through early intervention and educational activities.
- **4. Improving the accessibility and implementation of preventive vaccinations.** Despite free access to vaccinations, their uptake in Poland remains suboptimal. This underscores the need for better public education on the importance of vaccinations and improvements in the vaccination delivery system.

#### Marek Migdał MD PhD

**Director of the Children's Memorial Health Institute** 

In the field of paediatrics, the key priorities for the Polish Presidency are:

- **1. Revision of pharmaceutical legislation.** There is a need for a thorough analysis of the current pharmaceutical legislation, in particular in the context of orphan drugs and rare diseases. Incorporating the perspectives and expertise of the paediatric community and rare disease specialists into the decision-making process is essential.
- **2. Medical devices.** Existing legislation on medical devices may result in discrimination against children, particularly newborns, due to certification gaps. Emphasis should be placed on revising and adapting regulations to ensure equitable access to cutting-edge medical devices across all age groups.
- **3.** Support for the mental health of children and adolescents. Mental health is a critical area that demands focused attention and support. Crafting and implementing strategies to promote mental well-being, particularly during challenging events like military conflicts or pandemics, is vital to ensure comprehensive care and assistance for individuals experiencing mental health challenges.
- **4. Education and Community Campaigns for Mental Health.** Increasing awareness about mental health is essential and can be achieved through education and community-driven campaigns. Leveraging media platforms to promote mental health, share information about available resources, and highlight support methods can play a crucial role in reducing stigma and enhancing access to healthcare.

## **Communicable diseases**

## Prof. Robert Flisiak MD PhD

Head of the Clinic of Infectious Diseases and Hepatology at the Medical University of Bialystok, president of the Polish Association of Epidemiologists and Infectiologists

In the field of infectious diseases, the key priorities for the Polish Presidency are:

- **1. A Holistic Approach to Prevention and Health Promotion.** Preventive efforts too often prioritise education alone, neglecting equally critical elements such as access to modern vaccines and their timely updates. While health education is indispensable, its effectiveness depends on the availability of practical tools and resources. Prevention should be viewed as a cohesive system that integrates education with access to cutting-edge medical interventions.
- **2. Increasing Funding for Prevention and Health Promotion.** Poland lags behind the European Union average in terms of the percentage of GDP allocated to preventive healthcare. Boosting financial support for prevention is essential to effectively implement comprehensive preventive programmes. Strengthening funding in this area will yield long-term benefits by alleviating the strain on the healthcare system through a reduction in disease incidence and severity.
- **3. Advancing and Implementing Modern Vaccination Programmes.** Access to cuttingedge vaccines is essential for the prevention of numerous diseases. Poland must prioritise the development and deployment of more sophisticated vaccination programmes capable



of providing robust protection against a broad range of conditions. Allocating resources to vaccination is a forward-looking investment in public health.

**4. Enhancing Access to Screening and Diagnostics.** Effective prevention involves more than education and vaccination – it requires broad access to screening that enables early disease detection. In Poland, decisive measures are necessary to increase the availability of such services, which could substantially improve the early diagnosis and treatment of conditions like HCV. This, in turn, would help reduce the incidence of severe and costly cases, easing the burden on the healthcare system.

## **Public Health**

## Prof. Andrzej Fal MD PhD

President of the Polish Society of Public Health, Head of the Clinic of Allergology, Lung Diseases and Internal Diseases at the National Medical Institute of the Ministry of the Interior and Administration in Warsaw

In the field of public health, the key priorities for the Polish Presidency are:

- 1. Addressing the primary risk factors of non-communicable diseases through comprehensive preventive measures. Addressing the five primary risk factors for non-communicable diseases (NCDs) tobacco use, excessive alcohol consumption, unhealthy diet, physical inactivity, and excessive stress is essential. Effectively mitigating these factors can significantly reduce the incidence of chronic diseases and enhance overall public health. Preventive measures should be implemented concurrently, encompassing public education on associated risks and diseases, ensuring access to improved vaccines, and facilitating interventions to modify unhealthy behaviours.
- **2.** Advancing health policies and enhancing healthcare coordination. Implementing fiscal policies that encourage healthier choices, such as reduced taxes on less harmful products, and emphasising health education from the earliest stages of schooling can significantly lower the prevalence of lifestyle-related diseases. Improving coordination and collaboration across various healthcare sectors can greatly enhance the efficiency and impact of preventive and therapeutic efforts.
- **3. Emphasising health education as primary prevention and advancing health education.** Health education from an early age is vital for preventing numerous chronic diseases. A comprehensive approach that integrates schools and other educational institutions can serve as a powerful means of addressing health issues arising from lifestyle choices.
- **4.** Promoting the preventive management of non-communicable diseases, especially in the context of population ageing. Prevention plays a key role in curbing the development of lifestyle diseases. It not only significantly reduces the prevalence of such diseases but also contributes to lowering future healthcare costs. By fostering a healthy lifestyle, we pave the way for a healthier ageing population in the years to come.

## Prof. Jarosław Pinkas MD PhD

National Consultant in Public Health (2018–2024), Secretary of State at the Ministry of Health (2015–2017), Specialist in General Surgery, Family Medicine and Public Health

In the field of public health, the key priorities for the Polish Presidency are:

**1. Enhancing health literacy across Europe.** Informed health choices are fundamental to public health and represent a key paradigm. During our Presidency, we should strive to positively influence the health literacy of Europeans – it is our civic duty to empower individuals to make sound decisions about their health.



- **2. Combating health misinformation and disinformation.** The internet is rife with "medfakes" that disrupt rational decision-making regarding health. Addressing disinformation in healthcare is, in essence, a cornerstone of prevention.
- **3. Tackling addictions.** Europe must take proactive steps to avoid replicating the U.S. experience with addiction crises. This includes addressing dependencies on painkillers, particularly opioids and fentanyl, which are exacerbated by their widespread availability.

#### **Piotr Winciunas**

Chief Medical Officer of the Social Insurance Institution (ZUS); Centre of Postgraduate Medical Education in Warsaw – School of Public Health – Department of Medical Law and Medical Certification

In the field of public health, the key priorities for the Polish Presidency are:

- 1. A comprehensive overview of public and private payers' expenditures on healthcare and social benefits due to incapacity to work as a result of specific disease groups. In the European Union, it is crucial to maintain the productivity of the ageing population. This can be achieved through adequate financing of prevention, diagnosis, treatment, and rehabilitation in both preventive and restorative medicine in order to reduce the costs of disability pensions and sickness absence within social benefits.
- **2. Promoting medical rehabilitation as an annuity prevention.** The Social Insurance Institution runs a comprehensive rehabilitation programme for individuals who fall ill during their professional activity, as part of pension prevention, with the aim of keeping them in the workforce or restoring their ability to work.

#### Stanisław Maćkowiak

President of the Federation of Polish Patients and President of ORPHAN, the National Forum for Rare Disease Therapies

In the field of public health, the key priorities for the Polish Presidency are:

- **1. Introducing health classes at every level of education.** The importance of health education from an early age is immeasurable in preventing numerous diseases and promoting healthy lifestyles. Implementing a dedicated health class at every educational level would enhance health awareness from early childhood, playing a pivotal role in the long-term improvement of public health.
- **2. Expanding and effectively utilising screening.** Early diagnosis of rare diseases and other conditions can markedly improve treatment outcomes and prognosis. Broadening the scope of screening programmes and optimising the use of existing infrastructure and healthcare personnel to facilitate additional screenings would significantly advance public health outcomes.
- **3.** Banning the sales of cigarettes and alcohol and restricting the availability of such products. The harmful effects of tobacco smoking and alcohol abuse are well-documented. Implementing bans and restrictions on the sale of these products could significantly reduce the incidence of cancer and other diseases associated with these factors.
- **4. Strengthening information campaigns on vaccination and improving communication in the field.** The low response to vaccination programmes underscores the need to enhance communication and implement effective information campaigns. Increasing awareness of the importance and accessibility of vaccines is essential for improving public health.



#### Prof. Marcin Czech, MD PhD

President of the Polish Society of Pharmacoeconomics, Head of the Department of Pharmacoeconomics at the Institute of Mother and Child, and Undersecretary of State at the Ministry of Health (2017–2019)

In the field of public health, the key priorities for the Polish Presidency are:

- **1. Strengthening the role of prevention and health education.** Prevention and health education are fundamental to averting diseases and promoting healthy lifestyles. Well-designed educational programmes that engage people at every stage of life can significantly lower the prevalence of many diseases, including chronic conditions, which place a heavy burden on healthcare systems. Enhancing preventive initiatives is essential for improving public health.
- **2. International cooperation in the field of prevention.** International cooperation in the field of prevention can facilitate the exchange of experiences, best practices, and innovative solutions that can be effectively implemented across different countries. By sharing its own expertise in prevention, Poland can also benefit from global knowledge, enhancing the effectiveness of its national preventive initiatives.
- **3. Increasing investment in primary and secondary prevention.** Investing in primary and secondary prevention represents an investment in the future of the healthcare system. Such measures enable earlier detection of diseases and help prevent their progression, which, in the long term, results in cost savings for the healthcare system by reducing the need for hospitalisation and complex treatments.
- **4. Development of innovative tools to support prevention.** Modern technologies and innovations, such as digital tools and artificial intelligence, have the potential to significantly enhance preventive efforts. The development and deployment of innovative tools for health monitoring, health education, and early disease detection could revolutionise preventive healthcare and improve its effectiveness.

#### **Scientific Research in Medicine**

## Prof. Marcin Moniuszko MD PhD

Rector of the Medical University of Bialystok, Head of the Allergology and Internal Disease Clinic and the Department of Regenerative Medicine and Immunoregulation of the Medical University of Bialystok

In the field of scientific research in medicine, the key priorities for the Polish Presidency are:

- **1. The importance of good epidemiological research for tackling lifestyle diseases.** High-quality epidemiological research is essential for understanding and addressing civilisation diseases. Ensuring robust and reliable data will enable more effective planning and implementation of health strategies at both the national and European levels.
- **2. Use of existing data sets in healthcare.** Poland holds extensive health data sets that remain underutilised. The integration and effective use of these data could significantly enhance the quality of healthcare and the efficiency of the healthcare system.
- **3. Discussion on access to archival data.** There is a need to address the issue of access to archival data in healthcare, particularly concerning patient rights and privacy. Striking a balance between safeguarding privacy and leveraging data to enhance healthcare is vital for the advancement of health systems.
- **4. Emphasising the importance of quality in epidemiological research.** The quality of data and research is essential for developing effective healthcare solutions, including the application of artificial intelligence algorithms. High-quality research facilitates a deeper understanding of health trends and the efficient formulation of health policies.



#### **Wojciech Nowak**

Biotechnology expert, Chair of the Healthcare Biotechnology Council of EuropaBio association

In the field of scientific research in medicine, the key priorities for the Polish Presidency are:

- 1. Increasing investment in R&D and biotechnology. Europe is facing a significant innovation challenge, particularly when compared to the United States and China. Allocating resources to research and development (R&D) in the biotechnology sector is essential for securing Europe's position as a global leader in innovation. These investments must originate from both public and private sources to fully maximise the potential for innovation and ensure a high return on investment. Strengthening Europe's biotechnology sector through increased funding will enable the development of new technologies and medicines, significantly contributing to improvements in public health.
- **2.** Streamlining the registration process for medicinal products. The current process for registering new medicinal products in the European Union is slower than in the United States, delaying patients' access to the latest therapies. Accelerating and improving registration processes through the harmonisation of procedures and enhanced collaboration between Member States and the European Medicines Agency can significantly reduce waiting times for new medicines and therapies, thereby improving the availability of innovative solutions for patients across Europe.
- **3.** Strengthening the uptake of innovation in healthcare systems. The challenge for the European Union lies not only in the creation of innovations but also in their adoption within healthcare systems. Patients in Europe gain access to new therapies significantly later than their counterparts in the United States, presenting a major public health challenge. Priority should be given to developing mechanisms and policies that support the faster integration of innovative medical solutions into clinical practice, thereby enhancing their availability and impact on improving patients' health.
- **4. Promoting European self-sufficiency in biotechnology production.** In the geopolitical context, where Europe is positioned between eastern and western powers, it is vital to define the continent's strategic role within the global innovation ecosystem. Strengthening the European biotechnology sector by fostering self-sufficiency in the production of active ingredients and medicines is essential to safeguarding the EU's health and economic security. Achieving this will require the creation of favourable conditions for manufacturers, including policies that support local production, research, and development, enabling Europe to sustain and enhance innovation within its own territory.

#### Rafał Staszewski MD PhD

Deputy President for Research Funding at the Medical Research Agency (2023–2024)

In the field of scientific research in medicine, the key priorities for the Polish Presidency are:

- **1. Supporting Innovation in Medicine, Including Telemedicine and Artificial Intelligence.** The role of the Medical Research Agency is crucial for the promotion of large- and small-scale innovation in medicine, aligned with European objectives. Supporting the development of telemedicine and artificial intelligence is fundamental to the future of healthcare.
- **2. Developing medical workforce.** Qualified medical personnel are a critical element in any healthcare system, and their development is essential not only in Poland but also across all countries of the European Union.
- **3. Promoting prevention as an element of cross-sectoral healthcare.** Prevention should be regarded as a broad issue that extends beyond the traditional remit of the Ministry of Health. Focusing on prevention is vital to fostering a healthy society.



**4. Developing and co-financing joint European medical research.** Joint European studies, particularly those conducted under uniform protocols, are essential for advancing medical science. The ability to co-finance research through various European research agencies enhances their efficiency and overall impact.

# Mental Health of Children and Adolescents as a Priority of the Polish Presidency of the Council of the European Union in 2025

## Edited by Jakub Gierczyński MD PhD

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#### Introduction

A conference entitled *Road to the Presidency: Child and Adolescent Psychiatry* was held at the Medical University of Warsaw on 30 October 2024. It was devoted to one of the health priorities of the Polish Presidency of the Council of the European Union, starting on 1 January 2025. According to the Ministry of Health in the field of mental health of children and adolescents, the Polish Presidency plans the following scope of activities:

- 1. Promotion of mental health of children and adolescents in the era of the development of digital technologies, new media in the context of opportunities and threats,
- 2. Prevention of mental disorders and diseases of children and adolescents,
- 3. Prevention of addictions (including behavioural addictions),
- 4. Adoption of Council conclusions.<sup>51</sup>

The event, organised by the Institute for Social Policy Development, gathered numerous experts specialising in child and adolescent mental health, as well as professionals from related fields such as paediatrics, pharmacology, psychotherapy, and activists. The debate focused on a collaborative analysis of the challenges associated with the mental health of young individuals. Its outcome aims to develop recommendations addressing the key topics of the Polish Presidency of the Council of the European Union in the domain of mental health.

#### Małgorzata Bogusz

President of the Board of the Institute for Social Policy Development, member of the European Economic and Social Committee, member of the Council of Non-Governmental Organisations for the Polish Presidency of the Council of the European Union

I welcome you all and thank you on behalf of the Institute for Social Policy Development<sup>52</sup> for the opportunity to meet within the esteemed walls of the Medical University of Warsaw. Our discussion today is devoted to the scope of health priorities under the Polish Presidency of the Council of the European Union, commencing on 1 January 2025. As we know, the Polish Ministry of Health has defined four key priorities for Poland's Presidency in the field of health: the digital transformation of healthcare, mental health for children and adolescents, the promotion of preventive measures, and pharmaceutical security.<sup>53</sup>

The topic of mental health among children and adolescents is of paramount importance, addressing an issue that gained significant visibility within the European Union, especially in Brussels, early in 2023. Through various legislative initiatives, the EU has sought to enhance the mental health

<sup>51</sup> Polish Ministry of Health, Bezpieczeństwo, Europo! Priorytety polskiej prezydencji w obszarze zdrowia [Security, Europe! Health Priorities of the Polish Presidency], <u>https://www.gov.pl/web/zdrowie/bezpieczenstwo-europo-priorytety-polskiej-prezydencji-w-obszarze-zdrowia</u>.

<sup>52</sup> Institute for Social Policy Development Foundation, <u>https://irss.org.pl/kontakt/</u>.

<sup>53</sup> Polish Ministry of Health, Bezpieczeństwo, Europo! Priorytety polskiej prezydencji w obszarze zdrowia [Security, Europe! Health Priorities of the Polish Presidency], <u>https://www.gov.pl/web/zdrowie/bezpieczenstwo-europo-priorytety-polskiej-prezydencji-w-obszarze-zdrowia</u>.



and well-being of both adults and children. I must highlight that the dialogue on prioritising mental health for children and adolescents builds on discussions initiated by the preceding trio of Member States holding the Presidency – Spain and Belgium – who underscored this as a critical issue. Child and adolescent psychiatry was a primary focus of the Spanish Presidency at the beginning of 2023, while Belgium carried forward the theme by concentrating on mental health in the workplace. In the post-pandemic era, it has become particularly crucial to consider how we can better support the youngest members of society. Policies must be implemented with a long-term vision to ensure that the society of the European Union remains healthy and fosters mental well-being. As a member of the European Economic and Social Committee (EESC) – an advisory body of the EU comprising 329 members<sup>54</sup> I witness firsthand how each document prepared by the European Commission is reviewed and debated within our three constituent groups: employers, trade unions, and the non-governmental sector, the latter of which I am honoured to represent. These deliberations are vigorous, and while some may find it surprising that such intense debates occur in Brussels, they are reflective of our collective responsibility. Throughout this term, a central focus has been advocating for the swift implementation of EU mental health policies across Member States.

The establishment of a robust legal framework to improve mental health across Europe is already underway, and Poland has a unique opportunity to contribute. We have legal acts that support the policy of caring for mental well-being. The Regulation on the European Pillar of Social Rights emphasises the right to health, including mental health, and access to affordable and high-quality health services. The EU Directive on work-life balance for parents and carers aims to reduce stress and burnout by facilitating the reconciliation of work and family responsibilities. Resolutions of the European Parliament on mental health in the labour market are aimed at preventing mental health problems in the workplace and supporting people affected by such problems. The latest conclusions of the Council of the European Union on an economy conducive to mental health encourage investment in promoting mental health in workplaces, schools, and the broader social environment.

#### Justyna Mieszalska

#### President of the Medical Centre of the Medical University of Warsaw

The conference titled *Road to the Presidency: Child and Adolescents Psychiatry* is the first of three conferences addressing the challenges and priorities in healthcare during Poland's Presidency of the Council of the European Union. We are organising this series in collaboration with the Institute for Social Policy Development. For many years, I headed the Department of Public Health, which included the psychiatry of children and adolescents within its remit. I believe that today's discussion topic resonates with us all, not only on a professional level but also on a deeply personal one, as mental health crises among children and adolescents are affecting an increasing number of people every year. According to the Ombudsman for Children's Rights, only six out of ten children describe their lives as joyful, with this proportion worsening as they age. When asked how often they feel satisfied with their lives, many children and adolescents struggle to respond positively, with some admitting they never or rarely experience such satisfaction. This distressing trend, though global, sees our country unfortunately ranking near the bottom. Such a perspective is deeply concerning – not only for practitioners but also for anyone who interacts with children, whether professionally or personally. Reflecting on this issue, I realise I don't even know the names of the children living in my building. I never see them. It's not because I work late or leave early, but because children no longer engage in communal play, like gathering outdoors to play or drawing with chalk on the sidewalk. Instead, they spend their time indoors with phones, smartphones, and computers. However, recognising this behaviour does not absolve us of the responsibility to foster connection and build community. Asking, "How are you?" - a question that once might have been asked out of politeness with little interest in the response - should

<sup>54</sup> European Economic and Social Committee (EESC), https://european-union.europa.eu/institutions-law-budget/institutionsand-bodies/search-all-eu-institutions-and-bodies/european-economic-and-social-committee-eesc\_pl.



now hold deeper significance. In today's era of mental health crises and strained relationships, it's essential that we genuinely care about the answer. Our social interactions must evolve to prioritise meaningful connection. Showing interest in someone should not be perceived as meddling but as a demonstration of responsibility and care. As adults, we are the architects of ecosystems at home, in schools, in workplaces, and in public spaces.

#### **Prof. Marcin Sobczak MD PhD**

Vice-Rector for Science and Technology Transfer, Medical University of Warsaw

The topic of children and adolescents' mental health is highly relevant, and the scale of the problem continues to grow. We have an increasing number of young patients with mental disorders in need of professional care, but the number of specialists has not kept pace. On the one hand, there is an immense need to care for these young patients, yet on the other, the number of available specialists remains insufficient. I am very pleased that the conference at the Medical University of Warsaw has brought together diverse stakeholders – clinicians, as well as representatives of various key institutions that support the healthcare system – in addressing the challenges facing Polish psychiatry. Such a distinguished gathering is a strong assurance that this discussion will lead to new ideas, which will, at least in part, help address the issues plaguing the still underperforming care system. The needs are, indeed, pressing.

#### Prof. Bolesław Samoliński MD PhD

Chair of the Subcommittee on Health Priorities during the Polish Presidency of the Council of the European Union 2011, Head of the Department of Environmental Hazard Prevention, Allergology, and Immunology at the Medical University of Warsaw, Chair of the Council of the Discipline of Health Sciences, Medical University of Warsaw

Great respect is due to the Institute for Social Policy Development, as the Polish Presidency of the Council of the European Union has not yet begun, yet we are already discussing the priorities it will address. Typically, we engage in debates on issues related to health policy and health promotion, but stepping into the EU Council Presidency elevates these discussions to a unique and exceptional level. The six months from 1 January to 30 June 2025 will bear the hallmark of a pan-European debate. When Poland held its first presidency in 2011, we defined five priorities and achieved three Council of the European Union conclusions - documents which mandated the European Commission and Member States to implement policies agreed during the Presidency. This was a significant success for Poland, recognised as delivering the best presidency since the Treaty of Lisbon. We are now aiming to follow a similar path. During the 2011 Presidency, the Medical University of Warsaw led two of the five health-related priorities, hosting two conferences, one of which directly supported a Council of the EU conclusion. We partnered with the European Commission and Member State ministers, contributing to the finalisation of key policy documents and participating actively in the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO). This included the informal ministerial meeting that concluded the presidency in December 2011. This time, Poland holds the presidency in the first half of the year, offering a distinct advantage over the second half. The July-December presidency is constrained by the EU holiday month of August and the shortened work schedule in December. Between January and June, we have the opportunity for more comprehensive and focused debates.

Health is an inescapable priority, and public health, prevention, and promotion remain critical challenges for all EU Member States. While we are familiar with the risk factors of lifestyle diseases, we continue to face dramatic failures in addressing them. Alcoholism, overweight, obesity, smoking, and environmental pollution are all rising, falling squarely within the remit of public health. In mental health, issues affecting children, adolescents, and adults are growing at an alarming rate. These trends underline a crisis in communication and mental well-being, creating deeply troubling scenarios. Rather than redefining well-known risk factors, we should



focus on identifying effective practices from other countries that have successfully mitigated these issues. This Presidency's mission is to translate those best practices into actionable strategies that change the epidemiological landscape of lifestyle diseases and reduce risk factors. Lastly, I want to highlight a critical upcoming initiative: from 1 September 2025, health education will become part of the Polish school curriculum. This pivotal step should be a key point of discussion during Poland's Presidency.

#### Aleksandra Lewandowska MD PhD

national Consultant in Child and Adolescents Psychiatry, Head of the Psychiatric Department at Babiński Hospital in Łódź

Serious threats to the mental health of young people have increased in recent years. These include the COVID-19 pandemic, the war in Ukraine, the breakdown of relationships within families, society, and peer groups, the rise in tendencies toward addiction, inappropriate coping mechanisms for mental tension such as the use of alcohol and other substances, and the negative impact of digital technologies and social media.

In Poland, recent years have seen the implementation of a new model of psychiatric care for children and adolescents. This is a three-tier model based on Level One, Two, and Three reference levels. On 19 June 2019, the Regulation of the Minister of Health on guaranteed services in the field of psychiatric care and addiction treatment was published, introducing significant changes to psychiatric services for children and adolescents.<sup>55</sup> The foundation of this new model is the three levels of reference, designed to create a network of outpatient clinics, day wards, and 24-hour hospital wards. These levels aim to address the range of problems and difficulties faced by families with children requiring psychiatric support. These levels aim to address the range of problems and difficulties faced by families with children requiring psychiatric support. The system is structured as follows: Level One: Centres/Teams for Community-based Psychological and Psychotherapeutic Care for Children and Adolescents; Level Two: Centres for Mental Health for Children and Adolescents (comprising clinics and day wards, or operating separately); Level Three: Centres for Highly Specialised 24-hour Psychiatric Care (hospital wards). The new model was developed under challenging circumstances, coinciding with the COVID-19 pandemic. However, its concurrent implementation during the pandemic proved essential, as without it, the mental health crisis would have been far worse. Data from the National Health Fund and various reports clearly show that the number of children and adolescents requiring specialist mental healthcare has more than doubled in recent years, alongside a corresponding increase in access to specialist services.

Over the last few years, the reform of child and adolescent psychiatry in Poland has led to significant improvements. Accessibility to services has increased, as has the number of specialists and interest in working in this field. I do not know comprehensive statistics on specialists in clinical psychology or child and adolescent psychotherapy, but as far as child and adolescent psychiatry is concerned, the number of doctors is growing every year. In 2023, there were 63 more trainees in child and adolescent psychiatry compared to 2022, with 25 additional specialists. The staffing levels in this field continue to grow annually. However, while the number of child and adolescent psychiatrists is rising, real change requires collaboration across sectors. The increased number of child and adolescent psychiatrists itself will not change much if we do not work together in other areas. Prevention, a critical component of the system, remains underdeveloped and must be strengthened to provide a robust foundation for the three reference levels. Inter-ministerial cooperation,

particularly with the Ministry of Education, is vital in achieving this. The introduction of health education in schools is a positive step, but it is insufficient on its own. There is an urgent need for legal frameworks to support the development of a clear care pathway for children and adolescents. The system currently suffers from a lack of clarity, with parents and guardians often unsure where

<sup>55</sup> Regulation of the Minister of Health of 19 June 2019 on guaranteed services in the field of psychiatric care and addiction treatment. Journal of Laws 2019, item 1285, <u>https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20190001285</u>.



to seek help for specific problems. The situation remains chaotic and difficult, also for parents and guardians who do not know where, with which problem, to whom and to which centre we should turn. Collaboration between the education system, social welfare system, and the Ministry of Justice must be improved. For example, since the enactment of the 2022 Act on Supporting the Rehabilitation of Minors, the Regulation of the Minister of Health established the Committee on Medicinal Measures for Minors. However, the Act has faced criticism for its limited alignment with the principles of supporting minors. In each of my reports I point out that this is an appeal and that I and the environment are in favour of changing this law, because I say this with full responsibility: this law has little and little to do with supporting minors. To the contrary, I have the feeling that the rights of a child and a teenager are being violated. Many children are transferred from one facility to another, with hospital wards often becoming the final destination. This contradicts the reform's focus on community-based care, which relies on cooperation with the child's natural environment. Geographic constraints frequently hinder this approach, with children being sent to hospitals over 100 kilometres away, making collaboration with caregivers nearly impossible. Children and adolescents adapt to hospital conditions, are discharged, return to their communities and again the medical board must comply with a court order extending the child's or teenager's placement in a medical institution because they are unable to function in their natural environment. So interdepartmental cooperation is crucial. We have not yet had the opportunity to present our recommendations to the team set up under the Mental Health Council at the Ministry of Health. One of the main recommendations of the team is the creation of an inter-ministerial team to ensure cohesive inter-ministerial collaboration and provide clear directions for care.

I would like to express my gratitude to everyone involved, all the specialists, the entire community, and our patients. I often emphasise that patients themselves motivate us to seek solutions and to refine what has been introduced – though, in some respects, it is still not working entirely as intended. It should also be acknowledged that we, as specialists, have had to learn this model ourselves, as community psychiatry for underage patients did not previously exist in our country.

The reform of child and adolescent psychiatry did not include a pilot phase, so we had to work collectively across Poland. The results of these efforts are now evident, as any gaps in coverage have virtually disappeared over the past few years. Most districts and provinces now have an increasing number of Level One community care centres. According to the National Health Fund, nearly 500 such centres now operate across the country. Additionally, as of 7 October 2024, there were nearly 90 Level Two centres offering outpatient services and nearly 90 centres with both outpatient and day ward facilities. Unfortunately, a significant disparity remains in the funding between the first and second reference levels, which needs to be addressed. Beyond increased funding, horizontal coordination among the three reference levels must also be improved. I am pleased to note that every province now has at least one Level Three facility, including a stationary ward with an emergency room. In response to the reform's demands, a new amendment to the Regulation of the Minister of Health on guaranteed services will soon be published. This amendment introduces numerous new services, focusing on the need for group interventions and offering greater flexibility in tailoring services to patients' needs. Key changes include updates to the day ward formula, such as diagnostic and therapeutic stays. Additionally, inter-level support will be strengthened by introducing supervision of the diagnostic process, with Level Two reference facilities providing oversight to Level One centres. Furthermore, new technologies, such as transcranial stimulation, will be introduced as a reimbursed service under the National Health Fund.

As far as suicidal behaviours among children and adolescents are concerned, it is clear that experiencing peer violence, or violence in general, increases the risk of such behaviours several times over. Child and adolescents psychiatry operates within the dynamics of the school year, and during this time both inpatient wards and outpatient care are heavily burdened. This highlights the challenges of the system in which these children are functioning. As healthcare professionals supporting children and adolescents who require special care and are diagnosed with various mental disorders, we frequently issue recommendations to schools. However, there is a significant lack of cooperation with educational institutions, Which greatly exacerbates the risk of re-hospitalisation



or a deterioration in mental health. We observe a crisis in relationships within the immediate environments of our patients. Children who often have no one to turn to feel profoundly isolated, frequently retreating into the virtual world. Another alarming factor is the impact of digital technologies. While there is nothing inherently wrong with digital technology – it is a tool that can be used in a useful way – adults have failed to teach children and young people how to use these tools responsibly and safely. To address this, we need actions grounded in mental health promotion, prevention, and specialist care. However, legislative regulation is equally essential. Education alone will not make significant changes if children and adolescents continue to have unrestricted access to harmful content, such as pornography, on the Internet. Recent statistics reveal that 20% of surveyed adolescents reported accessing pornography before the age of 10. Additionally, 20% admitted to viewing pornography several times a day, while another 20% watched it at least once a week.

Another challenge is the accessibility of psychoactive substances to children and adolescents. Recent research clearly indicates that alcohol is the most commonly used substance among teenagers, and their patterns of consumption have evolved. Similar to adults, young people observe how we fail to manage our emotions constructively, often using alcohol as a coping mechanism, and they emulate this behaviour by turning to strong alcoholic beverages. Nearly two-thirds of respondents admitted to such behaviour. What is particularly concerning is that an increasing number of young people are binge drinking, with the risk of suicidal behaviours associated with alcohol intoxication rising by 94 percent. Regarding e-cigarettes, while 95% of surveyed teenagers are aware of the risks associated with their use, an alarming 80% still smoke them. Two-thirds of adolescents reported turning to these products or other psychoactive substances because they struggle to cope with challenges. They often lack the tools and skills to manage stress effectively, to better understand themselves, and to communicate their needs to adults in a meaningful way.

#### Prof. Małgorzata Janas-Kozik MD PhD

Plenipotentiary of the Minister of Health for the Reform of Child and Adolescent Psychiatry, Head of the Department of Psychiatry and Psychotherapy at the Medical University of Silesia in Katowice, Head of the Clinical Department of Psychiatry and Psychotherapy for Developmental Age at the Medical University of Silesia

The unique nature of mental disorders in children and adolescents, alongside the role of the so-called "third party" in treatment (parents/legal guardians and the educational obligation), plays a pivotal role in the therapy of minors. These factors should inform planned changes in the mental health protection system for children and adolescents, guiding its transformation. Most mental health disorders in children and adolescents can – and should – be treated within a community-based system, as close as possible to the home and environment of the minor patient. Strategic documents from the World Health Organisation, UNICEF, the European Union (EU), and the Republic of Poland highlight the importance of increasing service availability close to the family and child, ensuring inter-sectoral coordination, and shifting financial resources from hospital to outpatient and community care. For child psychiatry, the implementation of such recommendations is particularly crucial, as many mental health issues in minors stem from unresolved crises or difficulties that do not necessitate pharmacological or psychiatric treatment but rather the support of psychologists and psychotherapists specialising in child and adolescent care.

The reform of child and adolescent psychiatry began in 2019, though initial meetings of experts to establish its principles took place as early as 2017. At that time, the psychiatric care system for children and adolescents faced a significant crisis, with inefficiencies severely limiting access to care. The system was simply inefficient. In doing so, we have tried to solve the problem of making care more accessible within the available budget. Addressing the question of how to improve access given existing resources was critical. A key conclusion reached by experts was that psychiatric consultations were not essential at the first reference level. Consequently, the reform introduced a network of Level One psychological and psychotherapeutic clinics, tasked



with providing immediate support during mental health crises, assisting families, and identifying cases requiring psychiatric intervention. The objectives of the reform were aligned with principles of deinstitutionalisation, the introduction of structured patient pathways within the mental health system, and the optimisation of medical staff use in public services. These goals also aimed to facilitate rapid interventions by non-psychiatric specialists, such as psychologists, psychotherapists, and community therapists for children and adolescents. Another priority was increasing the availability of outpatient and community services at the district level by contracting psychological and psychotherapeutic clinics located close to municipalities. Strengthening community-based services required mandating collaboration with family and school environments outside medical institutions. Ultimately, the reform aims to establish a comprehensive national system to support minors experiencing mental health issues, reduce disparities between regions in Poland, and ensure the dynamic development of medical staff equipped to implement the new system.<sup>56</sup>

In 2020, there were 138 Level One facilities in operation, while nearly 500 (489) are operational today. Although not located in every district, the network of facilities evenly covers the entire country. Level One facilities are funded through a mix of lump-sum payments and a fee-for-service model, ensuring financial stability. According to data from the National Health Fund (NFZ), these facilities currently serve approximately 300,000 children and adolescents with mental health disorders. This represents a significant achievement of the reform, as it has also led to a decrease in the hospitalization rate among this group. However, Level Three reference wards still face a heavy workload. This is, in part, a byproduct of the proper functioning of Level One facilities, which identify and refer patients needing psychiatric consultation to higher levels. Meanwhile, Level Two facilities constitute a bottleneck in the psychiatric care system for children. Since 2021, these facilities have been allowed to operate in two variants: as mental health outpatient clinics only or as clinics with day wards. The former dominate, with approximately 90 such facilities currently operational, meaning that day wards are far fewer. In the coming years, new legal regulations will mandate providers operating day wards for children and adolescents to establish on-site schools, a move that will also receive financial incentives. Managing Level Two centres poses many financial and organisational challenges for providers, and a model of optimal cooperation between Levels One and Two has yet to be achieved universally. In my view, the most effective centres are those encompassing all three levels of reference. There is a clear need to increase the number of day wards significantly, as opposed to increasing the number of 24-hour inpatient wards, which should remain a last resort. Level Two should also be financed under the same model as Level One facilities.

The reform of child and adolescent psychiatry has led to systemic changes that are still evolving and being continuously evaluated. We already understand what has worked well and what needs improvement. From the outset, we were aware of the workforce shortages in child and adolescent psychiatry. According to WHO recommendations, there should be one specialist per 12,000 children and adolescents in the population. Hence, the reform followed a dual approach: improving access to care while simultaneously strengthening the workforce. The number of child and adolescent psychiatrists is steadily increasing, though gaps cannot be filled overnight. Young doctors are now trained under the new model, with mandatory training at Level One and Two facilities. Additionally, a new profession, community therapist for children and adolescents, has been introduced, along with a new specialisation in child and adolescent psychotherapy. There are currently 358 child and adolescent psychotherapists in the system.

As a paediatrician by training, I fully support making health check-ups mandatory. In the past, wellchild clinics conducted early screenings for children with mental and behavioural disorders through dispensary groups. This served as a preliminary filter, and I believe it is worth revisiting this practice and teaching future paediatricians how to conduct proper health checks. Many disorders can be

<sup>56</sup> Reports on the activities of the Plenipotentiary of the Minister of Health for the Reform in Child and Adolescent Psychiatryfor the years 2019–2023. Author of the report: Prof. Małgorzata Janas-Kozik MD PhD. Editorial Team: Prof. Agnieszka Słopień MD PhD, Prof. Anita Bryńska MD PhD, Aleksandra Lewandowska MD PhD, Tomasz Rowiński PhD, 2024.



detected at this stage. Schools also play a pivotal role at the ground level, identifying behavioural and mental disorders and implementing universal prevention. Today, we can take pride in the ground-level psychological and psychotherapeutic outpatient clinics, which serve as the Primary Care units of child and adolescent psychiatry. There are concerns about the overmedicalisation of the child and adolescent environment and suggestions that child and adolescent psychiatrists are unnecessary. I think we should raise awareness of the primary care level, perhaps by launching a better campaign on this issue. Many parents remain unaware of the nearly 500 level-one centres available nationwide. We should reserve child and adolescent psychiatrists for cases that require pharmacological intervention while increasing the training of community therapists, clinical psychologists, and psychotherapy specialists for children and adolescents. We should do our best to succeed there as these professionals are the first line of non-stigmatising support for families and children. Again, the task of a child and adolescent psychiatrist is to treat children who already need medication.

The successful implementation of the reform depends on addressing the growing demand for psychological and psychiatric support among young people. Improved access to psychological, psychotherapeutic, and psychiatric care is essential. Regarding direct coercion, I believe its use should adhere strictly to the statutory guidelines. There is a legally established, well-known protocol for documenting the use of direct coercion. While its application must be monitored to ensure proper use in psychiatric facilities, it remains a necessary measure in certain situations to safeguard young patients. However, direct coercion should always be a last resort.

Public funding for child and adolescent psychiatry has nearly quadrupled in recent years. It is vital to maintain this level of support while addressing areas needing improvement, such as financing Level Two facilities or mandating schools at treatment sites. Cooperation between Level One centres and schools and other educational institutions must also be enhanced. Additionally, the process of reporting data to the National Health Fund requires significant improvement to ensure efficiency and transparency.

### Dominik Kuc

#### Member of the Board of the GrowSPACE Foundation

As the GrowSPACE Foundation, we monitor the mental health of children and adolescents while also examining the broader care system. In 2024, the GrowSPACE Foundation published a report revealing an increase in suicide attempts among children and adolescents in Poland in 2023. According to police reports, 2,139 individuals under the age of 18 attempted suicide in 2023, compared to 2,031 in 2022. This represents a 150 percent increase compared to 2020. The number of suicide attempts by children and adolescents in 2023 that resulted in death was 146 cases (compared to 150 in 2022). Data from eight Polish provinces (województwa) indicate a rise in suicide attempts among those under 18. The highest number of attempts was recorded in the Pomorskie province, with 406 cases, followed by the Śląskie and Łódzkie provinces, with 295 and 219 attempts, respectively. According to the GrowSPACE Foundation, these figures highlight the significant work still needed in addressing the mental health needs of children and adolescents. The average waiting time for a consultation with a psychiatrist or child psychiatrist under the National Health Fund was 238 days. Improving access to care, particularly at the "ground level", is essential. This means not only increasing hospital and ward capacity but also enhancing outpatient services, psychological and community-based support, prevention efforts, and psychoeducation.<sup>57</sup>

In the context of discussions about the priorities of the Polish Presidency in the field of psychiatry, I would like to present the system from the perspective of young people who rely on this support. An increasing number of young people are seeking help, and more of them are experiencing mental health challenges following the Covid-19 pandemic. While the pandemic and remote learning

<sup>57</sup> Fundacja GrowSPACE alarmuje, że dramatycznie rośnie liczba prób samobójczych wśród najmłodszych. Najnowsze dane [GrowSPACE Foundation warns: number of suicide attempts among the youngest has grown dramatically]. 2024, <u>https://glos.pl/fundacja-growspace-alarmuje-ze-dramatycznie-rosnie-liczba-prob-samobojczych-wsrod-najmlodszych-najnowszedane</u>.



were not the sole causes of these issues, they acted as a catalyst, accelerating certain trends and highlighting key priorities for the younger generation in both the healthcare and education systems. The healthcare and education systems must collaborate to address these challenges. Another pressing issue is the accessibility of mental health services for young people. Furthermore, we must tackle the social stigma still surrounding child psychiatry, which affects young patients. Addressing persistent stereotypes, especially at the grassroots level, is equally crucial.

The first challenge relates to the coordination of activities between the healthcare and education systems. Among young people, we observe, quite naturally, a significant need for psychoeducation and learning at the most basic level. Before discussing individual reference levels of care, let us focus on the "ground level", which encompasses psychoeducation, early detection, and collaboration with schools. Strengthening care at the ground level will reduce the number of crises escalating to higher levels of care. Another critical aspect of the "ground level" is the patient pathway, which addresses not only access to care but also the specialists to whom young people are referred. A recurring scenario involves young people visiting multiple paediatricians or cardiologists, only to discover that the root cause of their issues lies elsewhere and requires not only psychiatric but also psychological intervention. At this stage, access to psychologists remains a challenge. The integration of healthcare and education systems also plays a vital role in ensuring that patients can continue their schooling uninterrupted. These are young people who, upon returning from day or inpatient wards, face the pressure of catching up on tests and pop guizzes. The education system must not add undue pressure on individuals already grappling with mental health challenges. To reduce the frequency of mental health crises, we need to address root causes, prevent peer violence, and counteract domestic violence. Schools remain one of the few institutions to initiate measures like domestic violence prevention protocols. School psychologists, while not providing therapy, play a crucial role in identifying and monitoring mental health issues within the school community. This is the first issue. The other aspect – and an essential component of the "ground level" – is the concept of psychological first aid, which educators can help deliver. In this context, we must also address the socio-economic disparities affecting access to care. For many families, the cost of private mental health treatment is prohibitive, creating an insurmountable barrier. Thus, when we speak of accessibility, we must include the equalisation of economic and social opportunities across regions. Moreover, the involvement of local communities can significantly enhance availability. Awareness among those surrounding young people – teachers, psychologists, and parents – is equally critical. A recent initiative by the Office of the Ombudsman for Children's Rights aims to improve access to psychological support for individuals under 18 without requiring parental consent. Often, young people were discouraged from seeking help due to parental resistance. The proposed changes, spearheaded by Minister Monika Horna-Cieślak, are an opportunity to improve access to psychological support, including by removing these barriers. We know that due to the social dimension of stereotyping and stigma, parental approval is unfortunately sometimes simply decisive. If it cannot be obtained, there's no meaningful support to speak of.

Stigma and stereotypes continue to be significant obstacles in how mental health is perceived in schools and among young people. For instance, a young person visiting a school psychologist may face ridicule or gossip, with their story potentially shared on social media. This form of secondary stigma also affects individuals who have undergone psychiatric treatment in hospitals. Such stigma discourages many young people from seeking help from psychologists or psychiatrists, pushing them to seek solutions online instead. This stigma also extends to individuals openly discussing their anxiety or depression, leading to misunderstandings within their community. Unfortunately, in closed environments like schools, these attitudes persist and create substantial barriers to support. Addressing this issue requires targeted interventions within peer groups. Even something as simple as handing out the helpline number 116 111 can make a profound difference in someone's life.

From 1 September 2024, health education will be introduced in schools, offering a valuable opportunity for universal prevention. This initiative must focus on fostering not only knowledge but also skills and attitudes to empower young people. Health education should go beyond theoretical knowledge of mental health issues to build practical skills in psychological first aid



and peer group interactions. Obviously, no one will give a pop quiz on depression symptoms in morning class. Health education should not only focus on the mere knowledge of specific mental health issues, but on building skills and attitudes, in the context of psychological first aid and working with a peer group. Let us not forget that an authority figure to whom a young person turns is often a peer. And this is what is actually happening. Young people often turn first to their peers for support with mental health issues, with teachers, school psychologists, and even parents being sought out much later. This dynamic underscores the importance of involving peer groups in mental health initiatives.

### Daria Biechowska PhD (Humanities)

Vice-chair of the Scientific Section of Suicidology of the Polish Psychiatric Association

Data on suicides should always be contextualised within the relevant population. Suicide rates in Poland have been declining since 2009, nearing the European average. The rate has dropped from 14 individuals per 100,000 population to 12 per 100,000, a significant decrease. I highlight this not to downplay the problem of suicides but to emphasise that raw data, particularly those presented by the Police Headquarters, should not be taken at face value as they do not represent official suicide statistics. It is important to remember that these figures reflect police investigations into suspected suicides and do not capture the full scale of suicide attempts. According to the World Health Organisation, for every suicide among minors, there may be up to 200 suicide attempts.

The issue of suicide is highly complex and multifaceted. Despite extensive research over many years, it remains an area requiring further exploration. However, I would like to highlight some positive aspects of suicide prevention efforts. It may not be widely known, but since 2021, Poland has had a National Strategy for the Prevention of Suicidal Behaviour.58 This strategy is implemented as part of the National Health Programme for 2021–2025. Within the third operational goal, which focuses on promoting mental health, there is a comprehensive catalogue of 10 tasks dedicated to preventing suicide and suicidal behaviours. Of these tasks, two are particularly relevant to children and adolescents. The first involves the development and implementation of prevention programmes aimed at reducing suicidal behaviours. Four such programmes have been created, two of which target children and adolescents. The first is a universal prevention programme, S.O.S, which is designed for school-aged children and adolescents and implemented within schools. The second is a preventive programme currently under development, aimed at children and adolescents discharged from psychiatric hospitals – a particularly vulnerable group at risk of repeat suicide attempts. Another area of focus is the creation of standards of practice for those who work with children and young people on a daily basis. These standards, developed for teachers, are intended to guide them in identifying and supporting students in need. I encourage readers to visit the website https://zapobiegajmysamobojstwom.pl/ for further information.

### Prof. Tomasz Wolańczyk MD PhD

Head of the Clinic of Psychiatry of Developmental Age at the Medical University of Warsaw and the Clinical Department of Psychiatry of Developmental Age at the Clinical Centre of the Medical University of Warsaw

A key aspect of our discussion is the need to distinguish between individuals in a mental health crisis or those with a psychiatric diagnosis and the general well-being of the population. Linking the state of child and adolescent psychiatry to the fact that 60% of adolescents in Poland report dissatisfaction with life is a misrepresentation. The psychiatric care system is not responsible for the overall satisfaction of the population. The responsibility for the population's satisfaction lies with families, teachers, employers, and indirectly, politicians. Therefore, I stress that the aim of the psychiatric treatment system is not to influence the general population's well-being. Mental health crises affect approximately 16% of children and adolescents in Poland.

58 National Strategy for the Prevention of Suicidal Behaviour, <u>https://zapobiegajmysamobojstwom.pl/o-projekcie/</u>.

Another pressing issue is the rise in suicide attempts, which has been observed across all EU countries. This increase has been similar across the EU–27, despite the diversity in care systems. For example, the psychiatric care system in Germany and Belgium primarily relies on social assistance, while in France, it is based on private healthcare. What we see is that diverse care systems have all experienced similar increases in suicide attempts in response to the Covid-19 pandemic. This demonstrates that there is no ideal solution as no national system is immune to a stressor as profound as the pandemic.

In Poland, we have a ratio of one child and adolescent psychiatrist per 12,000 children and adolescents, which meets the standards set by the World Health Organisation. While this figure aligns with international benchmarks, it does not alleviate the issue of long waiting lists and high demand for services. The reform of the psychiatric care system for children and adolescents aimed to "de-psychiatrise" care. However, a critical consequence of conflating dissatisfaction with life or self-harm with a diagnosis of depression is the over-reliance on psychiatric interventions. Currently, parents often turn to psychiatrists as their first point of contact for help. In the absence of sufficient child and adolescent psychiatrists, adult psychiatrists have filled the gap. Unfortunately, this has led to cases where, for instance, a seven-year-old's mental disorder was diagnosed online by an adult psychiatry resident with just six months of experience. The same resident then initiated treatment, within the private system, of course. By "over-psychiatrising" the care system, we deprive children and adolescents of holistic support. When a teenage patient sees a psychiatrist, they often receive an ICD-10 diagnosis from the F category, are prescribed medication, and are not provided with community or family support. This approach labels the individual as a patient without addressing crucial underlying factors such as school environment, or peer interactions. Consequently, these children are funnelled into treatment paradigms focused on drug-resistant depression or poorly tailored medication regimens. Premature "psychiatrisation" of life challenges in children and adolescents can paradoxically hinder access to comprehensive support. Patients treated by adult psychiatrists in the private sector rarely return to first-level reference centres, where they could access psychological and psychotherapeutic support. They miss out on family therapy, community interventions, and even consultations with school psychologists.

### Prof. Teresa Jackowska MD PhD

President of the Polish Paediatric Society, Head of the Paediatrics Clinic at the Centre of Postgraduate Medical Education, Head of the Clinical Department of Paediatrics at the Bielany Hospital

As part of the reform of child and adolescent psychiatry in Poland, I participated as a national consultant in paediatrics in preparing comprehensive actions in this area. In this context, I have observed that "we want to treat tooth decay by pulling teeth, whereas caries should be addressed through prevention". Unfortunately, prevention remains absent in many areas of medicine in Poland.

I am not sure if you are aware, but the Polish healthcare system allows for the possibility that a child may receive no healthcare oversight at all. There is no obligation for health check-ups, and it is only a matter of time before the requirement for preventive vaccinations may also be questioned. We systemically care for children's health until the age of seven, after which health checks are performed sporadically as part of the so-called health assessments. Regarding these assessments and their role in preventing and diagnosing mental health disorders in children and adolescents, I will omit the checks conducted during the first two years of life, as psychiatric issues are generally not observed at this stage. Cases of autism, developmental delays, or speech disorders may occur and should be referred to a child psychiatrist. However, when children begin school, i.e., at 6–7 years old, the next health check does not take place until they are 9–10 years old (in Year 3 or 4). Subsequent assessments occur at the end of primary school (around 13–14 years old) and in the second or third year of secondary school.



In 2024, Pediatric Review published an article entitled Analysis of Hospitalisations of Children Due to Suicide Attempts in 2017–2023 in One Paediatric Ward.<sup>59</sup> The study analysed hospitalisations at the Clinical Paediatric Department of the Bielany Hospital in Warsaw following suicide attempts from January 2017 to March 2023 (6 years and 3 months). It compared cases before and after the SARS-CoV-2 state of pandemic was declared. Medical records of patients hospitalised for poisoning between January 2017 and March 2023 (ICD-10 T36-T50 codes) were retrospectively examined. Of the 211 hospitalisations reviewed, 78 were ultimately analysed after excluding accidental poisonings and substance use for non-suicidal purposes. Group 1 (n=39) included patients hospitalised before 11 March 2020 (3 years 3 months), i.e., pre-pandemic. Group 2 (n=39) included patients hospitalised between 11 March 2020 and March 2023 (3 years). Female patients dominated in both groups (87.2%) in Group 1, 89.7% in Group 2). Psychoactive medication use was significantly higher in Group 2 (64.1%) compared to Group 1 (38.5%, p=0.023). Average hospitalisation duration was 3.97 days in Group 1 vs. 5.23 days in Group 2 (p=0.049). Recommendations for psychiatric consultations or inpatient psychiatric care increased from 56.4% (Group 1) to 82.1% (Group 2, p=0.014). These results suggest an increase in psychiatric issues among female patients, necessitating more frequent psychiatric consultations. Hospital stays during the SARS-CoV-2 epidemic were notably longer, likely due to extended waiting times for paediatric psychiatric ward placements. I must stress that no paediatric ward in Poland is adequately equipped to care for children following suicide attempts. In one instance, a boy was brought in by police, for reasons unrelated to a suicide attempt. The officers watched him in his hospital room, but he attempted to take his life in the ward bathroom. Paediatric wards lack features like handle-free doors, creating significant stress for staff. Patients with mental health disorders are particularly challenging for paediatricians, underscoring the need for a robust referral system to psychiatric care centres.

I am pleased that, as of 1 September 2025, health education will be introduced in schools. Without comprehensive education from an early age, we cannot improve the well-being of the Polish population. However, I am concerned about the direction this education will take. Regrettably, paediatricians were not invited to contribute to the curriculum's development. As President of the Polish Paediatric Society, I do not know what the curriculum will entail. This will be a challenging subject to teach, requiring educators with authority and the ability to adapt content to children's and adolescents' needs. Regardless of changes to the school curriculum, prevention will remain a domain of doctors. Obesity is currently a significant health issue, and paediatricians must prioritise patient education in this area. Therefore, paediatricians should place a strong emphasis on educating patients in this area. Another critical element of prevention is the promotion of vaccinations. Unfortunately, vaccination programmes are currently implemented unsatisfactorily, highlighting the critical role that well-prepared health education plays in public health. Reliable and thoughtfully designed health education is essential for success. That is why it is so important that it is reliable and properly prepared.<sup>60</sup>

### Prof. Janusz Heitzman MD PhD

Committee of Clinical Sciences of the Polish Academy of Sciences, Vice-President of the Polish Psychiatric Association

I am very pleased that the Institute for Social Policy Development has prioritised the topic of child and adolescent psychiatry as part of the Polish Presidency of the Council of the European Union's health agenda. I will begin by stating my concern that we are overly medicalising the issue of

<sup>59</sup> Karolina Jankowska-Sasin, Edyta Zawłocka, Teresa Jackowska, "Analiza hospitalizacji dzieci z powodu prób samobójczych w latach 2017–2023 na jednym oddziale pediatrycznym" [Analysis of Hospitalisations of Children Due to Suicide Attempts in 2017–2023 in One Paediatric Ward], Przegl Pediatr 2024; 53 (1): 60–67. DOI: 10.26625/10005, <u>https://</u> przegladpediatryczny.pl/magazine/shownumber/535.

<sup>60 &</sup>quot;Prof. Jackowska: pediatrzy nie zostali włączeni do prac nad programem edukacji zdrowotnej" [Pediatricians not included in the work on the health education curriculum, says Professor Jackowska]. Puls Medycyny. Published on: 15-10-2024, <u>https://pulsmedycyny.pl/medycyna/profilaktyka/prof-jackowska-pediatrzy-nie-zostali-wlaczeni-do-prac-nad-programemedukacji/.</u>



mental health. We focus not on the mental health of children and adolescents but on their mental disorders. We need to reverse this mindset entirely. This shift in thinking is the actual starting point for prevention and for identifying who is responsible for the lack of it. The absence of prevention cannot solely be blamed on schools, mental health clinics, psychiatrists, psychologists, or parents. This is an issue that fits into the context of our entire civilisation. This is a systemic issue tied to broader financial, political, and cultural neglect. We have lost something fundamental, pedagogy, but in fact is simply upbringing. We cannot discuss the mental health of children and adolescents without acknowledging the critical role of the adult world in upbringing, teaching values, communication, and responsibility. Children need to learn what they can and cannot do and where they need the support of adults. Without this guidance, children will continue to feel helpless. The crises we see in paediatric wards, psychiatric wards, and emergency rooms are evidence of systemic failure and, simultaneously, the helplessness of these children. We have not learned how to teach children to take responsibility for themselves or to show co-responsibility for others. There is no sense of accountability for one's peers - no solidarity. Instead, there is this "hate", leading to suicide attempts and suicides. The children who present in emergency situations are often most hurt not by dysfunctional families but by their closest peers. This is the core issue. Relying on health lessons, such as pro-health education, to resolve this is a grave mistake. It is not about children learning what schizophrenia is, only to return home claiming they have it because they recognize the symptoms discussed in class.

For years, I have advocated within the Ministry of Education for the introduction of health education combined with dedicated form time classes. We need to teach children and adolescents how to live healthy lives: how to eat well, the importance of physical activity, why sleep is essential, and why staring at glowing screens late at night is harmful. Alongside health education, there should be two hours of dedicated form time. One hour should focus on addressing discipline – helping children who are habitually late, skipping school, or struggling academically, especially when their parents are disengaged. The second hour should focus on fostering communication and empathy. During this time, children should turn off their phones, learn to talk to each other, and develop sensitivity. Without this, the curriculum-driven educational system will continue to produce fatigue and overall health failures. The lack of a focus on health and upbringing is deeply concerning. There is also the problem of the erosion of authority figures for children, which is related to the fact that we are losing the ability to create such authority. Once, authority might have come from a family member, a teacher, or an older peer. Today, children lack such figures and turn to virtual authorities, which are inherently unstable and always carry hidden dangers. Without a trusted authority, children feel helpless. Children need real-world authority figures, not technology. In Poland and across Europe, we are seeing insufficient support for the upbringing process within families, schools, and public spaces.

### Magdalena Zając

#### **Parents for Climate Coalition**

Parents for Climate is a diverse group of parents promoting intergenerational activism to achieve climate justice. Aware of the three greatest challenges humanity faces this decade – namely the climate crisis, air pollution, and biodiversity loss – we unite to drive urgent political and social changes necessary to ensure that all children can live on a habitable planet. We collaborate with various movements, organisations, and institutions working for climate action on local, national, and global levels. We stand in solidarity with families in countries most affected by the global climate crisis. Our shared motivation stems from a deep concern for the health, future, and safety of our children and grandchildren. Our initiative is grassroots-driven, decentralised, and independent.<sup>61</sup> We believe that fostering the mental health of our children begins at the most fundamental level: engaging with parents and building from the smallest, most crucial social unit – the family. It is often observed that parents require support and treatment more urgently than

<sup>61</sup> Rodzice dla Klimatu [Parents for Climate], https://www.rodzicedlaklimatu.org/.



their children. When parents' issues remain unaddressed, they can manifest as problems in their children. Psychotherapists frequently note that a parent needs therapy, with the child being the next stage in the evolution of the parent's unresolved challenges.

Environmental factors, a frequent focus of Parents for Climate, significantly influence the physical and mental health of children. Research shows that exposure to air pollution leads to increased cases of depression, anxiety, and various health issues among children and adolescents. Another concern is the poor quality of food provided to children, an issue affecting almost every family. We expose our children to foods laden with artificial fertilizers and preservatives – products that should not form part of their diet. Additionally, there is a critical issue of nature deficit disorder, stemming from children being confined indoors and engrossed in electronic devices. As a society and as parents, we fail to ensure that children spend time in natural environments, surrounded by greenery and animals. Children in nature are less prone to mental disorders in adulthood. We can draw inspiration from countries like Finland, which implements initiatives such as "cold schools" and forest schools and kindergartens. Another effective tool is the concept of green prescriptions, widely used in the United Kingdom. These prescriptions, provided in the form of printed guides and resources, promote the therapeutic benefits of exposure to greenery and nature. They have been shown to improve cognitive functions, enhance mindfulness, and provide a calming effect.

### Maciej Karaszewski MD PhD

Director of the Department of Healthcare Services at the Ministry of Health

It is worth asking ourselves the question: What can we proudly highlight during the Polish Presidency of the Council of the European Union, and what should we place further emphasis on? One clear achievement to showcase is the community-based model of psychiatric care for children and adolescents. This is a system developed in Poland that many European countries simply don't have. The level-one psychological and psychotherapeutic care is an innovative solution absent in numerous EU nations. I know this because I was involved in the development process from the very beginning, and there were relatively few models available to inspire the creation of this three-level care framework. The National Health Fund (NFZ) provides extensive resources on its website, including patient guides and an up-to-date list of reference centres at Levels One, Two, and Three. According to NFZ data, as of 7 December 2024, Poland had 492 level-one reference centres, 83 level-two outpatient clinics, 90 level-two outpatient clinics with wards, and 34 inpatient level-three reference centres.<sup>62</sup>

Level-one reference centres provided care to approximately 300,000 children and adolescents. The introduction of the new care system has reduced the percentage of children requiring hospitalization compared to those receiving treatment. All the indicators we closely monitor demonstrate that this system is either functioning effectively or beginning to show promising results. Based on my experience, any reform in the healthcare system requires time to yield visible improvements. Changes don't immediately produce results upon the issuance of a regulation or law. It is a process. The system itself must adapt, learn new ways of delivering care, and coordinate effectively across levels, which inherently takes time. This system simply has to learn a new way of providing services and coordinating between levels. This takes time.

In the area of mental health prevention, we plan to integrate the M-Chat test into primary care facilities as part of the two-year-old health check-up. This screening tool will help identify children at risk of autism spectrum disorder. Concerning substance use, we should focus on reducing alcohol availability, such as by closing all night-time alcohol retail outlets. This, of course, requires broad consensus across various sectors and will not be easy. Another key focus should be promoting prevention during pregnancy by increasing awareness of healthy nutrition and the risks associated with substance abuse.

<sup>62</sup> National Health Fund, Ochrona zdrowia psychicznego dzieci i młodzieży. [Protection of mental health of children and adolescents], <u>https://www.nfz.gov.pl/dla-pacjenta/informacje-o-swiadczeniach/ochrony-zdrowia-psychicznego-dzieci-i-mlodziezy/</u>.



Regarding the Supreme Audit Office report evaluating the state of child and adolescent psychiatry during the 2022 pandemic, it seems that an assessment for 2023 – when the psychiatric care reform began to take effect – might yield significantly different conclusions. Approximately 500 level-one centres have since been established, and the dynamics between children and adolescents have started to change. The reality on the ground differs substantially from the conclusions presented in the report. It is also misleading to state that hospitalisations have increased without noting that the proportion of hospitalised children relative to those receiving treatment has decreased.

### Renata Szredzińska

President of the Board of the Empowering Children Foundation, Member of the Working Team for the Mental Health of Children and Youth at the Ministry of Health

I want to address parents of the youngest children, whether they are preparing for the birth of their child or already caring for an infant. An untapped potential at this stage lies in antenatal classes, which primarily focus on the physiological aspects of childbirth and postpartum recovery, while saying very little about bonding and building early relationships that will benefit the child throughout their childhood and adult life. I agree on the importance of prevention in schools and teaching children communication and mutual responsibility. I am probably part of the last generation that spent its childhood playing outdoors with peers. Back then, large and multi-generational families were common, but demographic changes have resulted in an environment where many children grow up as only children, often self-isolated at home. Today, children are not developing social skills but instead are spending their time "surfing" online.

Today, we are discussing what can be promoted at the European level during the Polish Presidency. Several challenges are common across nations. Poland is no longer a nationally homogeneous country; we have sizable refugee groups, including a large number of children from Ukraine and other countries who have endured the hardships of migration crises. Studies show that 15% of children fleeing war zones develop post-traumatic stress disorder (PTSD) if they do not receive early intervention. Poland is not alone in facing this issue, and schools are not yet fully equipped to support these children through intercultural education.

What Poland can highlight as an achievement is its violence prevention efforts. I refer to child protection standards designed to identify or address early symptoms of both peer and domestic violence. These efforts aim to prevent such problems from escalating. Poland is one of the few EU countries that fully funds two 24/7 helplines for children and adolescents: the 116 111 helpline run by our Empowering Children Foundation, and the 812 12 12 helpline managed by the Ombudsman for Children's Rights. Our helpline operates daily, 24 hours a day, 7 days a week<sup>63</sup> It serves as an initial screening tool for problems, many of which can be addressed early by parents or schools. By calling the helpline, children can talk to a friendly adult who listens and provides assistance.

I also want to highlight the Barnahus model, which provides comprehensive care for children affected by crime in a single location to prevent secondary victimization. Many European countries are adopting the Barnahus model, and Poland should prioritize its implementation. The Empowering Children Foundation currently operates 12 Children's Help Centres based on Barnahus principles in cities such as Warsaw, Gdańsk, and Wrocław. These centres adhere to international standards established in Scandinavian countries in the 1990s (with earlier roots in the Children's Advocacy Centres created in the U.S. in the 1980s). The essence of the Barnahus model is to ensure that a child who has experienced violence receives integrated, multidisciplinary, and professional support in one child-friendly, specially equipped location. This concept is critical because, in Poland, child victims are often dealt with by multiple uncoordinated institutions – courts, prosecutors, police, social services, and healthcare facilities – leading to repeated testimony, significant stress, and secondary victimisation. To mitigate this, each child's case is managed start-to-finish by a dedicated team of specialists from various fields in our Centres. The majority of children we serve are victims

<sup>63 116 111</sup> Helpline for children and adolescents. Empowering Children Foundation, https://116111.pl/.



of sexual abuse by adults. Such experiences have profound negative impacts on their development and physical, emotional, and social functioning, and may also influence their adult lives. Research indicates that individuals who experienced sexual abuse in childhood are more likely to engage in risky sexual behaviours or face re-victimization as adults. Our goal is to provide effective support to prevent this. We offer individual therapy for children and support groups for their parents. Our therapists use diverse therapeutic approaches, with some having over 20 years of experience working with sexually abused children.<sup>64</sup>

### Prof. Barbara Remberk MD PhD

Head of the Department of Child and Adolescents Psychiatry at the Institute of Psychiatry and Neurology in Warsaw, Member of the Working Group for the Mental Health of Children and Adolescents at the Ministry of Health

It is widely acknowledged that the earlier we respond to mental disorders, the higher the chances of recovery. Certainly, how a child feels is profoundly influenced by the functioning of their family. For young children, the family constitutes their primary environment. For teenagers, the family and their peers play a critical role. These factors have an enormous impact. A child who is bullied at school or is in a school environment where they are struggling academically must first persuade their parents of the need to change schools. However, they often remain trapped in such circumstances. Similarly, this applies to dysfunctional family situations. This is why there is unanimous agreement on the fundamental importance of "ground level" interventions in the prevention of mental disorders. However, for some patients, poverty and the level of despair they face make the "ground level" seem entirely abstract. A school may be supportive, but a father who finished a special needs school and a mother struggling with alcohol addiction are unlikely to assist their child through the educational system. If a mother working 12-hour shifts at a store near the border of the Podlaskie and Mazowieckie provinces is support to her children.

When discussing "over-psychiatrisation", we need to remember that it is children from poor families and orphanages who are prescribed the most psychiatric medications – not the children of wealthy parents, who will instead be taken to psychotherapy. This highlights the close relationship between child and adolescent psychiatry and the social welfare system. Various aspects of social support, as well as systemic measures aimed at assisting impoverished and marginalised patients and their families, are crucial.

I would also like to stress that certain psychoses in young people could be prevented if these individuals abstained from smoking marijuana. In the public debate on marijuana legalisation, what is rarely mentioned is the well-documented evidence that marijuana use at a young age, even in relatively small quantities, significantly increases the risk of developing psychosis.

### **Barbara Olszowy**

Chief Specialist in the Health and Social Affairs Team at the Office of the Ombudsman for Children's Rights

In Poland, thanks to the reforms that have been implemented, we are moving in the right direction, focusing on community-based activities and beginning at the "ground level". However, this progress does not always align fully with the implementation of all relevant regulations. It seems crucial to diagnose specific needs and challenges more thoroughly. One example is the introduction of psychologists into schools. Our data reveals who is being employed as school psychologists and the high percentage of individuals who lack the proper qualifications. Even hiring a newly graduated psychologist is a partial solution, let alone hiring volunteers or psychology students,

<sup>64</sup> Empowering Children Foundation, https://fdds.pl/co-robimy/pomagamy-dzieciom-krzywdzonym.html.



which is a complete failure. I get the impression that we still do not treat the mental health problems of children and adolescents with the seriousness they deserve. The prevailing mindset appears to be: "We will hire anyone, as any adult can handle such problems". This approach is fundamentally flawed. It is vital for us to focus on properly implementing the effective solutions we have already developed and built upon.

At the Office of the Ombudsman for Children's Rights, we also receive information that the standards we worked so hard to establish – standards that had a lengthy vacatio legis before their enforcement – are not being implemented. And this is not a matter of isolated non-compliance by individuals; it is an issue with entire institutions failing to adhere to them. For further guidance, I recommend exploring the wealth of information and resources available on our website: https:// brpd.gov.pl/.<sup>65</sup> As a reminder, the Ombudsman for Children's Rights\_Helpline is available 24/7, providing a safe space where children can openly discuss their problems without fear or hesitation.<sup>66</sup>

### Irena Rej

#### President of the Board of the Polish Pharmacy Chamber of Commerce

When problems with e-cigarettes arose, we tried to convey our observations to various authorities, sharing and applying our experience from combating legal highs. We had considerable success in that area, as we effectively eliminated the problem from stores. While it may still exist in underground channels, the scale of the issue is nowhere near what it once was. We proposed that if eliminating e-cigarettes entirely is currently not feasible due to European regulations, we should at least focus on measures we can implement ourselves. What can we do? The Minister of Health can issue a regulation mandating that shops selling e-cigarettes be located at a distance from schools, Similar to the approach taken with alcohol. This is a straightforward solution that requires only appropriate regulations. Stores near schools should not sell e-cigarettes, nor should e-cigarettes be displayed alongside items like candy bars or sweets. These are the simplest, cost-free measures that could be taken. Unfortunately, I encounter a wall of indifference to such issues. The Ombudsman for Children's Rights was the only institution that responded to our appeal. Yet, such proposals need a collective effort. Issuing executive acts alone will not solve the problem. It is actions and people's willingness to drive change that can begin to make a difference.

The situation is similar when it comes to alcohol availability, which can be purchased virtually anywhere and at any time. It is often easier to buy a "miniature" bottle of alcohol than to request a full-sized one. Increasing numbers of young people are turning to alcohol. Why is this happening? Sometimes it stems from curiosity or the desire to try something new, but it can also be an attempt to escape problems. Children do not invent these behaviours themselves; they mimic what they see around them – whether from parents, peers, or influencers. I am pleased that the issue of substance use is a focus of the European Union's initiatives. Denmark, our partner country in the presidency trio, will also continue addressing the mental health of children and adolescents. Meanwhile, the European Union is taking action against e-cigarettes and other substances. All these efforts should align, and that gives me hope. Perhaps only through coordinated EU-wide efforts can we achieve tangible results, beyond the scope of isolated national actions.

In psychiatry, psychotherapy and pharmacotherapy are crucial. We are well aware that psychiatric medications for children face many registration restrictions. Frequently, drugs used for children are based on clinical trials conducted on adults. Therefore, I fully support the Ministry of Health's efforts to reimburse numerous off-label medications used in child and adolescent psychiatry. It is commendable that in 2024, psychiatry saw the highest number of new therapies reimbursed in

<sup>65</sup> Ombudsman for Children's Right, Pomoc psychologiczna dla dzieci i młodzieży. Ważne informacje. [Psychological support for children and adolescents. Important information], 18 September 2024, <u>https://brpd.gov.pl/2024/09/18/pomoc-psychologiczna-dla-dzieci-i-mlodziezy-wazne-informacje/</u>.

<sup>66</sup> Ombudsman for Children's Rights Helpline. https://brpd.gov.pl/dzieciecy-telefon-zaufania-rzecznika-praw-dziecka/.



non-oncological fields – 19 in total.<sup>67</sup> We look forward to further reimbursements for the paediatric population, including off-label medications for conditions such as bipolar disorder (BD) and depression.

### Prof. Dominika Dudek MD PhD

President of the Board of the Polish Psychiatric Association, Head of the Department of Psychiatry and Clinic of Adult Psychiatry, Collegium Medicum, Jagiellonian University in Kraków

I wanted to present the perspective of psychiatrists on the reform of child and adolescent psychiatry. Let us remember that there is a moment when 16-17-year-old patients come to psychiatrists for various reasons. These patients will soon reach adulthood. If we are discussing how to assist young people within the system, I believe it is crucial to develop an effective system for transitioning patients from child and adolescent psychiatry to adult psychiatry. Such a young person is often closely connected with their child and adolescent therapist and psychiatrist, and must face a sense of loss when transitioning to a different and unfamiliar system of care. This transition is further complicated by the fact that the adult psychiatry system, which has also undergone significant reforms in recent years, operates differently and under different principles than the child and adolescent system. Therefore, it is essential to establish models of care that enable this transition to adulthood and the adult psychiatric system to occur smoothly and comprehensively without disrupting treatment. As psychiatrists, we understand that a child's illness is, in essence, a family illness. It is therefore critical that preventive and therapeutic measures encompass the entire family. This involves providing treatment for the child while also supporting the family. Often, families include siblings who, while not currently ill, may be affected by their brother's or sister's illness, Which can influence their development and increase the risk of disorders or behaviours such as turning to alcohol or drugs as an escape from the family's challenging situation.

Prevention during pregnancy, particularly concerning postpartum depression, is also of paramount importance. Why is this so significant for child and adolescent psychiatry? A mother's illness during this period affects bonding and later impacts the child's emotional development. This task often falls to paediatricians. A woman with postpartum depression may not seek help from a psychiatrist or even attend a follow-up appointment with her gynaecologist, but she will bring her child for vaccinations. In such cases, a paediatrician, observing both the child and mother's condition, can refer the mother to a psychiatrist.

### Julia Pupek-Pyzioł MD PhD

Consultant in Child and Adolescent Psychiatry for the Podlaskie province

I am a province-level consultant in child and adolescent psychiatry. My original specialisation was in adult psychiatry, but I currently work primarily with children and adolescents. However, as a psychiatrist, I find it inherently difficult not to view a child who comes to me through the lens of their long-term outcomes and what the future may hold for them. There is no doubt that interventions for children and adolescents should primarily occur at the first level of care. These include therapeutic, community, and psycho-educational activities involving the child, their family, and the broader school environment. The second line of intervention involves medication. As we know, access to this type of support varies significantly across the country and between regions. While first-level care is relatively well-distributed nationwide, the second level – clinics and day wards – is less accessible and poses greater challenges for patients. We also encounter cases where, even if such assistance is available, parental neglect or incapacity prevents children from benefiting from these interventions in their home environment or on an outpatient basis.

<sup>67</sup> Polish Ministry of Health, Polityka lekowa: podsumowanie roku i nowa lista refundacyjna. Kluczowe zmiany dla pacjentów [Drug policy: summary and new reimbursement list. Key changes for patients], December 2024, <u>https://www.gov.pl/web/</u>zdrowie/polityka\_lekowa\_podsumowanie-r.-i-nowa\_lista-refundacyjna-kluczowe-zmiany-dla-pacjentow.



In such situations, hospitalizations should be an option. However, there is a major issue here: the availability of inpatient and therapeutic ward placements is severely limited, with far too few spaces available.

### Karolina Wasielewska

#### **Institute for Social Policy Development**

Child and adolescents psychiatry is one of the health priorities of the Polish Presidency of the Council of the European Union. It is crucial to examine the context in which the mental health of children and young people is debated in Poland and the European Union. In Poland, media discussions intensified around the urgent need to address child and adolescent psychiatry after data from the National Police Headquarters revealed that, by the end of 2023, the number of young people attempting suicide had increased by 150% compared to 2020, with the total number of attempts exceeding 2,000. This means that in 2023, almost six minors attempted suicide every day, with one fatality occurring nearly every other day. Suicide prevention remains one of the key objectives of the World Health Organisation (WHO), which reports that 90% of suicides are committed by individuals in a depressive state or mood. It is vital to ask what specific mental health challenges children and adolescents in Poland face. Are depressive problems and mood disorders the primary issues demanding our attention, or are there other equally serious but lessdiscussed challenges that require urgent intervention? It is also worth reflecting on the positive and negative roles of influencers in social media, who can significantly impact the mental health of children and adolescents. Influencers are individuals engaged in various online activities, enjoying popularity, gathering a community of like-minded followers, and having a substantial influence on them.

Before diagnosing a mental disorder, it is essential to assess the problem at a level that is often entirely non-medical. I remember Deputy Minister Wojciech Konieczny saying in my interview that one of the solutions Poland will propose to Europe involves a "ground level" action, which entails educating teachers, parents, and students on recognising mental health issues in children and adolescents. The sense of threat arising from climate change and the lifestyle of families also contributes to psychological stress among young people. Schools play a crucial role in this process, particularly when children cannot rely on support from their immediate family in addressing mental health challenges. Another critical component of early detection of mental disorders includes check-ups and screening tests for children and adolescents conducted as part of paediatric care. Doctors examining children should also assess the mental state of the parents. In this context, transitional care – ensuring a seamless transition for patients from paediatric care to adult care – is a vital aspect.

The NIK report on the state of child and adolescent psychiatry in Poland, published on 10 September 2024, revealed that the increase in the number of patients and the development of first-level reference care is disproportionate to the capacity to provide assistance at the remaining reference levels, i.e., in mental health clinics, day wards, and third-level inpatient wards. Consequently, only 3.5% of children and adolescents received psychiatric care in 2022. The EZOP II study indicates that up to 14% of children and adolescents in Poland may require such care.

In 2023, the European Commission adopted over 20 initiatives to support the mental health of citizens in Member States, as outlined in the document titled A Comprehensive Approach on Mental Health. This approach is guided by three key principles: adequate and effective prevention, access to high-quality and affordable mental healthcare and treatment, and social reintegration following recovery. In today's discussion on the priorities for the Polish Presidency, these three principles were consistently mentioned. Regarding the mental health of children and adolescents, mental health appears to be comprehensively addressed across various areas within the 20 initiatives mentioned. This includes mental health support for the youngest patients and respect for neurodiverse individuals, whether in workplaces or educational institutions. Neurodiverse



individuals are defined as those whose neurological systems function differently from those of their neurotypical peers. These individuals may have various conditions associated with neurodiversity, such as dyslexia, dyscalculia, autism spectrum disorders, or attention deficit hyperactivity disorder (ADHD).

### Jakub Gierczyński MD PhD, MBA

#### **European Health Network**

According to the World Health Organisation (WHO), mental health is a state of well-being that enables individuals to cope with life's stresses, realize their abilities, learn and work effectively, and contribute to their community. It holds both intrinsic and instrumental value and is an integral part of overall well-being. At any given time, a variety of individual, familial, social, and structural factors can interact to either protect or compromise mental health. While most people demonstrate resilience, those facing adverse circumstances – such as poverty, violence, disability, and inequality – are at greater risk of developing mental health disorders. Many mental disorders are treatable at relatively low cost; however, healthcare systems worldwide remain significantly underfunded, with considerable treatment gaps. When mental health care is provided, it is often of inadequate quality. Additionally, individuals with mental health disorders frequently face stigma, discrimination, and violations of their human rights.<sup>68</sup>

According to a report by the Institute for Social Policy Development (IRSS), between 2011 and January 2025, mental health has been a health priority under eight presidencies of the Council of the European Union.<sup>69</sup> The Polish Presidency's focus on the mental health of children and adolescents aligns with the European Union's mental health strategy, outlined in the document titled *A Comprehensive Approach on Mental Health*.<sup>70</sup> This document was updated and re-adopted on 10 October 2024, during the celebration of World Mental Health Day.<sup>71</sup> It is worth recalling that, on 7 June 2023, the European Commission published the strategy *A Comprehensive Approach on Mental Health*, which is grounded in a holistic approach to mental health. Such an approach is essential for addressing mental health challenges and drives the European Union's key actions in this area. Accordingly, the EU's comprehensive approach to mental health is based on three guiding principles: adequate and effective prevention, access to high-quality and affordable mental healthcare and treatment, and social reintegration following recovery. Given the multifaceted nature of factors affecting mental health, it is crucial to consider these factors across all policy areas. Accordingly, the EU's comprehensive approach to mental health will be broad in scope and encompass efforts aimed at:

- 1. Mainstreaming mental health across all policy areas (including the European Mental Health Capacity Building Initiative)
- 2. Promoting good mental health, prevention, and early intervention for mental health problems (including the European Depression and Suicide Prevention Initiative, the Healthier Together initiative strengthening its Mental Health component, a platform for people experiencing mental health problems, the European Code for Mental Health, and the development of a joint ecosystem for brain research).
- 3. Improving the mental health of children and adolescents (including a child and youth mental health network, Child Health 360: prevention toolkit, the Youth First Flagship, and the *Healthy Screens, Healthy Youth* initiative).

<sup>68</sup> WHO, Mental health, <u>https://www.who.int/health-topics/mental-health#tab=tab\_1</u>.

<sup>69</sup> IRSS, Raport otwarcia. Quo Vadis Trio? 2024. [Quo Vadis, Trio? Opening Report], <u>https://irss.org.pl/wp-content/uploads/2024/02/Raport-otwierajacy-PL-online-1.pdf</u>.

<sup>70</sup> uropean Commission, Directorate-General for Health and Food Safety, A comprehensive approach to mental health, 7 June 2023, <u>https://health.ec.europa.eu/publications/comprehensive-approach-mental-health\_en</u>.

<sup>71</sup> European Commission, A comprehensive approach to Mental Health: Progress so far. Tracking framework for the implementation of the Commission Communication on a comprehensive approach to mental health, 10 October 2024, <a href="https://health.ec.europa.eu/document/download/6317c605-5f5d-4d4f-9c8a-d5c93e869814\_en?filename=ncd\_tracking-framework-mh\_en.pdf">https://health.ec.europa.eu/document/download/6317c605-5f5d-4d4f-9c8a-d5c93e869814\_en?filename=ncd\_tracking-framework-mh\_en.pdf</a>.



- 4. Support for those most in need (including protection for crime victims, the fight against cancer: a platform for young cancer patients and cancer survivors).
- 5. Counteracting psychosocial risks in the workplace (including the EU-level initiative on psychosocial risks and EU workplace campaigns).
- 6. Strengthening mental health systems and improving access to treatment and care (including an initiative for more and better-trained professionals in the EU, technical support for mental health reforms in several sectors, and gathering data on mental health).
- 7. Breaking through stigma (including by tackling stigma and discrimination).
- 8. Fostering mental health globally (including by providing mental health support for Ukraine's displaced and affected people, and supporting the dissemination of the Inter-Agency Standing Committee Minimum Service Package on Mental Health and Psychosocial Support).<sup>72</sup>

According to the 2020 report by the Supreme Audit Office (NIK) titled *Accessibility of Psychiatric Treatment for Children and Adolescents (2017–2019)*, the system for psychiatric care for children and the youth requires reform as it does not provide comprehensive or universally accessible healthcare in this area. Key issues identified include the uneven geographical distribution of medical staff, psychiatric wards, and clinics for minors: In five provinces, no day psychiatric wards existed, and in the Podlaskie province, there was no 24-hour psychiatric ward. In some cases, underage patients were admitted to adult wards. The number of entities offering such services also decreased, and their accessibility depended heavily on the place of residence, being particularly challenging in small towns and rural areas. What is worse, preventive care, which should be a cornerstone of the community-based treatment model – the most effective form of psychiatric care for this population – was insufficiently implemented. NIK's post-inspection recommendations to the Minister of Health include: reducing territorial disparities in access to psychiatric care services for children and adolescents, developing a model for forecasting the demand for specialist physicians, ensuring an equitable distribution of training centres and residency centres, establishing minimum staffing indicators for child and adolescent psychiatrists.<sup>73</sup>

According to the NIK report of 10 September 2024 entitled Psychiatric Care for Children and Young People, the system for psychiatric care for children and adolescents remains inefficient. The health needs of children and adolescents have not been met, despite an increase in the availability of psychological and psychotherapeutic support as part of the reform of child psychiatry that has been underway for over four years. Key issues identified include a persistent shortage of child and adolescent psychiatrists, resulting in longer treatment waiting lists, overcrowded hospitals, with young patients either admitted to adult wards or denied admission due to a lack of available spaces, as well as irregularities in the use or documentation of direct coercion in all audited hospitals. The actions taken by the Minister of Health to address the situation were ineffective, primarily because, prior to introducing the new model of psychiatric care, no comprehensive reform plan was developed. This included the failure to define necessary resources, expected outcomes, or a timeline for implementation. According to NIK, it is necessary to continue the reform of child and adolescent psychiatry and cross-sectoral cooperation, particularly between healthcare, social services and the education system. The NIK report highlights that suicides are the second leading cause of death among adolescents, and the number of suicide attempts by children and adolescents in Poland is steadily rising. According to data from the National Police Headquarters, by the end of 2023, the number of young people attempting suicide had increased by 150% compared to 2020, exceeding 2,100 cases. This equates to almost six minors attempting suicide daily in Poland in 2023, with one fatality occurring approximately every other day. Suicide prevention remains one of the key objectives of the World Health Organisation (WHO), which reports that 90% of suicides are committed by individuals in a depressive state or mood. Some sources estimate

<sup>72</sup> Why should the EU act on mental health?, <u>https://commission.europa.eu/strategy\_and\_policy/priorities\_2019\_2024/</u> promoting\_our\_european\_way\_life/european\_health\_union/comprehensive-approach\_mental\_health\_pl.

<sup>73</sup> Supreme Audit Office, Dostępność lecznictwa psychiatrycznego dla dzieci i młodzieży (w latach 2017–2019) [Accessibility of Psychiatric Treatment for Children and Adolescents (2017–2019)], March 2020. Available at: <u>https://www.nik.gov.pl/plik/id,22730,vp,25429.pdf</u>.



that nearly 1 million children and adolescents in Poland require assistance from psychiatrists, psychologists, psychotherapists, and other specialists. Preventing mental health disorders and expanding psychiatric care for children and adolescents is therefore crucial. From 2020 to 2022, the number of psychiatric services provided to children and adolescents increased from 1.8 million to 3.8 million, with 1 million services recorded in the first quarter of 2023 alone. However, this growth has not met the demand, as waiting lists continue to lengthen. Over the period 2020–Q1 2023, the number of patients waiting for mental health clinic appointments more than doubled (from nearly 10,000 to just under 20,000). Waiting lists for day wards grew by a quarter, while for inpatient wards, they tripled. The time required to access treatment increased, with more than 70% of children and adolescents admitted to hospital wards in emergency situations.<sup>74</sup>

Child and adolescents psychiatry in Poland is facing significant challenges. The crisis in this field is the result of years of neglect and underfunding, exacerbated by the COVID-19 pandemic and the war in Ukraine. In 2022, compared to 2019, there was a 168 percent increase in psychiatric patients aged 13–18 and an 87 percent increase in the group of children under the age of 13. There is a shortage of specialists in child psychiatry, psychologists, and psychotherapists. Therefore, a consistent reform of child and adolescent psychiatry is essential, with its main premise being a shift in the burden of psychiatric care from hospitals to community-based care. The establishment of level one community care centres has secured psychiatric care for paediatric and adolescent patients while alleviating the burden on hospital youth wards. The new mental healthcare system for children and adolescents envisions the creation of a network of centres operating across three reference levels. In practice, 70% of the patients who seek help require only psychological and psychotherapeutic care, while 30% need to be referred to the second level, where the assistance of a psychiatrist or hospital admission is necessary. It is also crucial to increase public expenditure on child psychiatry and psychological and psychiatric care for minors. Over the past four years, funding for psychiatric care for children has quadrupled, rising from approximately 250 million zlotys in 2019 to over one billion zlotys in 2023. Access to reimbursed, effective medications is critical. Between 2021 and 2024, 22 new molecule-indication pairs in psychiatry were reimbursed, including off-label indications, which is particularly important for the paediatric population.<sup>75</sup>

### Digitisation in Health Care as a Priority of the Polish Presidency of the Council of the European Union in 2025

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<sup>74</sup> Supreme Audit Office, Opieka psychiatryczna nad dziećmi i młodzieżą [Psychiatric Care for Children and Young People], September 2024, <u>https://www.nik.gov.pl/plik/id,29673,vp,32532.pdf</u>.

<sup>75</sup> Announcements of the Minister of Health – the list of reimbursed drugs, <u>https://www.gov.pl/web/zdrowie/obwieszczenia-ministra-zdrowia-lista-lekow-refundowanych</u>.



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### Introduction

A conference entitled *Road to the Presidency. Digital Transformation in Medicine and Healthcare* was held at the Medical University of Warsaw on 21 November 2024. The conference was devoted to one of the health priorities of the Polish Presidency of the Council of the European Union, i.e. digitisation in healthcare. In terms of this priority, the Polish Presidency plans to work in the following areas:

- 1. The implementation of the EHDS (European Health Data Space) legislation:
  - a. the architecture of the EHDS system,
  - b. digital transformation vs digital exclusion,
  - c. primary and secondary data management.
- 2. Cybersecurity of medical devices, including:
  - a. collecting experiences and feedback on the implementation of currently applicable,
  - b. draft legal acts, including during the meeting of the Medical Devices Coordination Group (MDCG),
- 3. Cooperation among EU Member States to develop cross-border e-health services.<sup>76</sup>

The conference, organised by the Institute for Social Policy Development, brought together experts in the field of digitisation in medicine. The conference will result in a cross-sectional chapter in the White Paper and a list of "Polish export-worthy products" in the field of digital transformation in healthcare. The conference was funded by the National Institute of Freedom – Centre for the Development of Civil Society under the Governmental Programme NOWEFIO Civic Initiatives Fund for the years 2021-2030.

### Małgorzata Bogusz

President of the Board of the Institute for Social Policy Development, member of the European Economic and Social Committee, member of the Council of Non-Governmental Organisations for the Polish Presidency of the Council of the European Union

On behalf of the Institute for Social Policy Development, we are pleased to invite you to participate in the conference *The Road to the Presidency: Digitisation in the Programme of the Polish Presidency of the Council of the European Union.* Today's debate is part of a series of initiatives led by the Institute for Social Policy Development (IRSS) focusing on the priorities of the Polish

<sup>76</sup> Polish Ministry of Health, Bezpieczeństwo, Europo! Priorytety polskiej prezydencji w obszarze zdrowia [Security, Europe! Health Priorities of the Polish Presidency], <u>https://www.gov.pl/web/zdrowie/bezpieczenstwo-europo-priorytety-polskiej-prezydencji-w-obszarze-zdrowia</u>.



Presidency of the Council of the European Union, which begins on 1 January 2025. The Road to the Presidency series was launched in 2023, and to date, IRSS has organised six such events, bringing together over 100 Polish and international experts. These initiatives aim to establish an expert platform to discuss the Presidency's priorities and develop recommendations in the form of a White Paper. Our discussion today is devoted to the scope of health priorities under the Polish Presidency of the Council of the European Union, commencing on 1 January 2025. As we know, the Polish Ministry of Health has defined four key priorities for Poland's Presidency in the field of health: the digital transformation of healthcare, mental health for children and adolescents, the promotion of preventive measures, and pharmaceutical security.<sup>77</sup> The focus of today's conference is the digitisation of healthcare, one of the most important pillars of Poland's EU Presidency programme. We have invited experts to share their insights from the fields of medicine and social policy to contribute to the development of a catalogue of best practices for the digitisation of healthcare. This catalogue will serve as a resource for Poland to present and share its expertise on the European stage during its Presidency of the Council of the European Union.

As a member of the European Economic and Social Committee (EESC) – an advisory body of the EU comprising 329 members,<sup>78</sup> I witness firsthand how each document prepared by the European Commission is reviewed and debated within our three constituent groups: employers, trade unions, and the non-governmental sector, the latter of which I am honoured to represent.

### Justyna Mieszalska

#### President of the Medical Centre of the Medical University of Warsaw

On behalf of the Medical Centre of the Medical University of Warsaw, I warmly welcome you. Together with the Institute for Social Policy Development, we are delighted to welcome you to the second debate on the road to the Polish Presidency with a focus on digitisation. One more debate on public health still lies ahead. I recall that many years ago, the Centre for Information Systems in Healthcare (CSIOZ) began work on the P1 platform. The COVID-19 pandemic accelerated numerous changes in the digital transformation of healthcare in Poland. The introduction of electronic medical records, e-referrals, e-sick leave certificates, and e-prescriptions significantly facilitated our ability to function during the pandemic. We have become accustomed to these advancements, and it seems unlikely that we will return to previous practices. However, as the head of a medical facility, I must point out our society is not only made up of people over the age of 18 who are comfortable with technological innovations, but also seniors over the age of 65 who are often excluded from many digital benefits. For example, the online patient account (IKP), a flagship project of the National Health Fund and the Ministry of Health, is still underutilised by the over-65s. I recently looked at the results of the PolSenior study for the years 2016–2020, and the data has remained largely unchanged for years. A significant proportion of over 65s are affected by digital exclusion and only 20% of over 80s express an interest in learning how to use a computer or smartphone. PolSenior2 is a nationwide study on the health status, socio-economic situation and quality of life of older Poles, conducted as part of the National Health Programme 2016–2020 and funded by the Ministry of Health.<sup>79</sup> I hope that today's debate on digitisation will place particular emphasis on individuals who are digitally excluded from healthcare services and help us develop strategies to address this issue in Poland.

<sup>77</sup> Polish Ministry of Health, Bezpieczeństwo, Europo! Priorytety polskiej prezydencji w obszarze zdrowia [Security, Europe! Health Priorities of the Polish Presidency], <u>https://www.gov.pl/web/zdrowie/bezpieczenstwo-europo-priorytety-polskiej-prezydencji-w-obszarze-zdrowia</u>.

<sup>78</sup> European Economic and Social Committee (EESC), https://european-union.europa.eu/institutions-law-budget/institutionsand-bodies/search-all-eu-institutions-and-bodies/european-economic-and-social-committee-eesc\_pl.

<sup>79</sup> Projekt PolSenior2. Badanie poszczególnych obszarów stanu zdrowia osób starszych, w tym jakości życia związanej ze zdrowiem [PolSenior Project2. Survey of the health of the elderly, including health-related quality of life.], https://polsenior2.gumed.edu.pl/.



# Sharing is Caring? Challenges related to the secondary use of health data under the EHDS

### Marta Musidłowska

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The European Data Strategy (February 2020) envisages the creation of a single, common European data space comprising individual sectoral and cross-sectoral data spaces – an interoperable framework that defines common standards and practices to facilitate data exchange and joint processing. Among other things, this is intended to support the development of new products and services, scientific research and civil society initiatives. The European Health Data Space (EHDS) will be the first common European data space to be based on a regulatory scheme. It consists of three main components, each of which fulfils a specific purpose to improve the exchange and accessibility of electronic health data.

- 1. Primary use of electronic health data,
- 2. Harmonisation of regulations on the interoperability of electronic health record systems and wellness applications declaring interoperability with electronic health record systems,
- 3. Secondary use of electronic health data,

Reuse of health data for research, innovation, public health, policymaking, regulatory activities, and personalised medicine establishes an "alternative", common mechanism for access to electronic health data for secondary use across the Union, without hindering or replacing existing administrative or contractual arrangements. Under Article 9(4) of the GDPR, Member States may no longer maintain or introduce additional conditions, including restrictions and specific provisions requiring the consent of natural persons, in relation to the processing of personal electronic health data for secondary use under this Regulation. However, they can introduce stricter measures and additional safeguards at national level to protect the sensitivity and value of the data.

Minimum categories of electronic data for secondary use (Article 33 of the EHDS):

- 1. Electronic health data from electronic health records;
- 2. Data impacting on health, including social, environmental behavioural determinants of health;
- 3. Aggregated data on healthcare needs, resources allocated for healthcare, healthcare provision and access, healthcare expenditure, and financing;
- 4. Genomic data, impacting on human health;
- 5. Health-related administrative data, including claims and reimbursement data;
- 6. Human genetic, genomic and proteomic data;
- 7. Other human molecular data such as proteomics, transcriptomics, metabolimics, lipidomics and other omics data;
- 8. Electronic health data generated automatically via medical devices;
- 9. Data from wellness applications;
- 10. Data related to professional status, specialisations, and institutions of healthcare professionals involved in the treatment of individuals;
- 11. Population wide health data registries (public health registries);
- 12. Data from medical registries and death registers;
- 13. Data from clinical trial, biomedical trials and clinical trials (covered by specific regulations);
- 14. Other health data from medical devices;
- 15. Data from registries for medicinal products and medical devices;
- 16. Data from research cohorts, questionnaires and surveys related to health, after the initial publication of the results;
- 17. Health data from biobanks and associated databases.



Entities involved in the process of granting access for the secondary use of electronic health data include: health data holders, health data users, Health Data Access Bodies (HDAB), and natural persons.

The process of secondary use of electronic health data consists of:

- analysis and evaluation of datasets descriptions,
- data access application,
- issuance of the data permit,
- data preparation,
- granting access and data use,
- publication of processing results.

As part of the analysis, assessment and descriptions of the datasets, data holders communicate to the health data access body (HDAB) a general description of the datasets they hold (Article 41 (2) EHDS). HDABs/EC publish descriptions of datasets in national catalogues of datasets/ EU Datasets Catalogue (Art. 55(1), 57 EHDS). Natural/legal persons wishing to access the data browse the dataset catalogues. Subsequently, a health data request (Article 47 EHDS) and a data access application (Article 45 EHDS) are prepared.

The data access application includes:

- the identity of the applicant,
- a determination of the purpose referred purposes referred to in Article 34 of the EHDS the application pertains to,
- a detailed explanation of the intended use and expected benefit of the electronic health data,
- a description of the requested data, including their format, data sources, geographical coverage where data is requested from several Member States,
- an indication whether electronic health data should be made available in a pseudonymised format or an anonymised format (where data is requested in pseudonymised format, the data applicant should explain why this is necessary and why anonymous data would not suffice),
- in this situation, it is also necessary to demonstrate compliance with the GDPR or national provisions on personal data protection.

According to Article 34 of the EHDC, the secondary use of electronic health data is permitted only for public sector bodies or Union institutions where there is a public interest in the area of public and occupational health, where policymaking and regulatory activities in healthcare are required, and for the production of healthcare statistics. The same article allows the secondary use of electronic health data for other entities for the purposes of education and training in health and care sectors, scientific research in health and care sectors – including the development, innovation, training, and testing of algorithms – and to improve care, optimise treatment and ensure the provision of healthcare.

Article 35 of the EHDC prohibits the secondary use of electronic health data for taking decisions that could be detrimental to a natural person or groups of natural persons based on their electronic health data, for taking decisions in relation to a natural person or groups of natural persons in the context of job offers or the provision of less favourable benefits, or for advertising and marketing activities. The secondary use of electronic health data for the development of harmful products or services (e.g., addictive substances or weapons) or in connection with activities that violate ethical regulations under national law is also prohibited.

As part of the next stage – the evaluation of the application and issuance of the data permit, the HDAB verifies whether the applicant meets the specified criteria collectively, including:

- Does the objective described in the application correspond to at least one of the permitted purposes under Article 33 of the EHDS,
- Are the data to which the application relates proportionate, adequate, and necessary to achieve the designated objective,



- The processing complies with Article 6 of the GDPR, particularly when access concerns pseudonymised data,
- Relevant expertise and professional qualifications,
- Appropriate technical and organisational measures that may be demonstrated by the applicant,
- Information on the ethical review (where applicable).

The HDAB should also consider threats to national defence, public security, public order, or risks of compromising sensitive data in government regulatory databases. At the data preparation stage, health data holders provide the data upon request of the HDAB, in connection with the permit granted to the user (the final opportunity to inform about the IP/TS) (Article 41(1) of the EHDS). The HDAB should provide the data to the health data user in a Secure Processing Environment (SPE), applying technical and organisational measures, as well as security and interoperability requirements (Article 37(1)(a) of the EHDS). Access to data should be granted exclusively in a Secure Processing Environment (Article 50 of the EHDS). Data processing is controlled by the HDABs (Article 37(1)(a) of the EHDS). As part of granting access to and use of data, additional restrictions are imposed on users regarding the processing, including a prohibition on attempting to re-identify anonymised or pseudonymised data. Violations are subject to administrative penalties, enforcement measures, and criminal sanctions (where provided by national law) (Articles 41a(2a), 43(4) of the EHDS).

As part of the publication of results based on the secondary use of electronic health data, the User is obliged to make the results publicly available, including information relevant to the provision of healthcare. Competence in the field of health is required to use secondary electronic health data.

The overarching principle is that a proper level of protection of human health must be ensured in all Union policies and actions (Article 168(1) TFEU). Shared competences include the internal market, common safety issues in public health matters, and research and technological development. Supporting competences are the protection and improvement of human health. The exclusive competences of the Member States are the definition of health policy, the organisation and provision of health services and medical care, as well as the management of the healthcare system and the allocation of resources.

The elements implemented ("as is") include priority categories of health data in the electronic health record exchange format, the tasks of HDABs, components of data access applications, elements constituting the quality label and data usability tags, etc. The mandatory elements ("shall") must be implemented, but Member States have the flexibility to refine specific details. This ensures the functionality of the EHDS infrastructure, adapted to the national context: the designation of one or more HDABs, the provision of experts and financial resources for HDABs, the development of training for healthcare professionals, and the promotion of digital health skills and patient education. Optional elements ("may") follow the principle that Member States can decide whether to implement a given solution. These include the introduction of an opt-out option for the primary use of data, the establishment of a mechanism for sharing data subject to an opt-out clause for secondary use, the creation of intermediaries for certain types of data holders, the strengthening of measures and the introduction of additional safeguards for secondary data or the establishment of procedures for obtaining the status of trusted data holder.

The registration of electronic personal health data for primary use is an obligation imposed on Member States. They must ensure that healthcare providers record personal data belonging, in whole or in part, to the priority categories in the electronic health records system. These categories include patient summaries, electronic prescriptions, electronic dispensations, medical imaging analyses, reports on related medical studies, medical examination results (including laboratory results), and discharge reports. As regards the primary use of medical data, the European Union requires Member States to impose this obligation on healthcare providers through national legislation. However, the regulation itself does not directly impose this requirement on healthcare providers. Instead, this obligation must be implemented at national level in all EU Member States



to ensure that at least these priority categories of data are registered electronically. As far as the secondary use of medical data is concerned, there is no strict requirement for data holders to record all other categories of data in electronic form. However, if such data are already stored electronically, there is an interesting legal loophole: data holders who do not want to share their data with potential users may simply argue that they no longer record this information electronically. This is a potential problem, but as far as I know, Belgium has a relatively effective system in place. However, the country faces challenges in the area of healthcare due to the high degree of regional autonomy. In contrast, Finland is considered the model system in Europe when it comes to the secondary use of medical data.

### **Prof. Ryszard Piotrowicz MD PhD**

Committee on Clinical Sciences of the Polish Academy of Sciences, Committee on e-Health, Telemedicine and Artificial Intelligence of the Polish Cardiac Society

Hybrid cardiac telerehabilitation should become the European standard for patients with heart failure.

Heart failure affects 26 million people worldwide, including 12 to 18 million in Europe. In Poland, 1.5 million people have been diagnosed with heart failure. ICD-50 heart failure is becoming a growing societal challenge. At the same time, it is a disease entity with an increasing incidence in terms of incidence. It is also the leading cause of hospitalisation, especially in patients over 65 years of age, and generates the highest hospital costs. However, heart failure can be effectively prevented and treated. It is crucial to integrate evidence-based standards, derived from clinical trials, into routine clinical practice. In this way, these standards will establish a comprehensive and effective heart failure care system.

As part of an effective heart failure healthcare system, effective prevention and treatment can be supported by evidence from clinical trials using telemedicine. Telemedicine makes it possible to monitor biomedical parameters and assess the risk of heart failure, the course of the disease and even exacerbations<sup>80</sup>. The effectiveness of telemedicine in the prevention and treatment of heart failure has been demonstrated in two clinical trials – MONITOR-HF (n=550) and IN-TIME (n=664)<sup>81,82</sup>. The integration of telemedicine into clinical practice for the prevention and treatment of heart failure should be preceded by the establishment of an effective healthcare system. To achieve this, access to healthcare for patients with heart failure must be maximised while minimising regional differences in access. According to data from the National Health Fund (NFZ), the greatest disparities in cardiac rehabilitation are observed in the western and central regions of Poland. Optimising cooperation with the patient on the basis of a partnership is also crucial.

In the guidelines for the diagnosis and treatment of heart failure, the European Society of Cardiology (ESC) provides recommendations for physical rehabilitation in patients with chronic heart failure. Physical exercise is recommended for all patients who are able to perform it to improve exercise capacity, quality of life, and reduce the number of hospitalisations due to heart failure. A supervised, exercise-based cardiac rehabilitation programme should be considered for patients with more severe

<sup>80</sup> European Society of Cardiology (ESC) Working Group on Diagnosis and Treatment of Acute and Chronic Heart Failure, "Wytyczne ESC dotyczące diagnostyki i leczenia ostrej niewydolności serca w 2016 roku. Grupa Robocza Europejskiego Towarzystwa Kardiologicznego (ESC) do spraw diagnostyki i leczenia ostrej i przewlekłej niewydolności serca", Kardiologia Polska 2016; 74, 10: 1037–1147, https://gdansk.ptkardio.pl/files/articles/29/01\_kp\_2016\_10\_wytyczne\_esc\_\_\_ niewydolnośc serca zlinkowany.pdf.

<sup>81</sup> Brugts J.J., Veenis J.F., Radhoe S.P., et. al., "A randomised comparison of the effect of haemodynamic monitoring with CardioMEMS in addition to standard care on quality of life and hospitalisations in patients with chronic heart failure: Design and rationale of the MONITOR HF multicentre randomised clinical trial", Neth Heart J. 2020 Jan;28(1):16-26., https:// pubmed.ncbi.nlm.nih.gov/31776915/.

<sup>82</sup> Hindricks G., Taborsky M., Glikson M., et al., "Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial", https://www.thelancet.com/journals/lancet/article/PIIS0140–6736(14)61176–4/ abstract.



illnesses or concomitant disease<sup>83</sup>. Nevertheless, access to cardiac rehabilitation is unsatisfactory. Of the 673 hospitals surveyed in 43 European countries, only 63% reported implementing heart failure treatment programmes, and only 42% of these included an exercise component. In Europe, less than 20% of people with heart failure participate in cardiac rehabilitation programmes<sup>84</sup>. The most common reasons for the lack of access to adequate cardiac rehabilitation include the lack of legal regulations, an appropriate care system, insufficient funding, staff shortages and the absence of national guidelines and policies in this area. At the same time, socio-economic barriers and psychological factors contribute to patients' inability to access cardiac rehabilitation. One solution to the lack of access is remote cardiac rehabilitation via telemedicine.<sup>85</sup>

The TELEREH-HF clinical trial confirmed the effectiveness of a home-based telemonitored cardiac rehabilitation model based on walking training in patients with heart failure, compared to standard cardiac rehabilitation based on interval training on a bicycle ergometer, carried out in an outpatient setting.<sup>86</sup> Both study groups achieved a significant improvement in quality of life, with no statistically significant differences observed between the two rehabilitation programmes. The home-based cardiac telerehabilitation programme consisted of three training sessions per week and lasted eight weeks. Each session included a 10-minute warm-up, a 30-minute core aerobic workout, and five-minute minutes of cool-down and stretching exercises. The effectiveness of home-based cardiac telerehabilitation was assessed based on changes in NYHA class, peak oxygen consumption, the a six-minute-minute walk test, and the SF-36 quality of life questionnaire.<sup>87,88,89,90</sup>

As a result, a home-based cardiac telerehabilitation model was proposed in Poland for patients with heart failure, acute coronary syndromes, or those who have undergone coronary artery bypass grafting or other cardiac surgery. Home-based cardiac telerehabilitation is recommended as the second stage of rehabilitation, following an initial 2- to 4-week programme of inpatient or outpatient cardiac rehabilitation. Home cardiac telerehabilitation should last eight to 12 weeks or more. The cardiac telerehabilitation programme is supplemented with educational sessions focused on lifestyle changes, including therapeutic and dietary recommended exercises, and the installation and prevention, self-assessment techniques, recommended exercises, and the installation and operation of the monitoring system. Education also includes training planning and conducting initial telerehabilitation sessions. These sessions should be conducted as part of inpatient or outpatient rehabilitation during the initial stage, which includes clinical assessment,

<sup>83</sup> McDonagh T.A., Metra M., Adamo M., et al., "ESC Scientific Document Group. 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure", Eur Heart J. 2021 Sep 21;42(36):3599-3726, https://pubmed.ncbi.nlm.nih. gov/34447992/.

<sup>84</sup> Bjarnason-Wehrens B., McGee H., Zwisler A.D., "Cardiac rehabilitation in Europe: results from the European Cardiac Rehabilitation Inventory Survey", European journal of cardiovascular prevention and rehabilitation, Volume 17, Issue 4, 1 August 2010, 410–418, https://pubmed.ncbi.nlm.nih.gov/20300001/.

<sup>85</sup> Conraads V.M., Deaton C., Piotrowicz E., et al., "Adherence of heart failure patients to exercise: barriers and possible solutions: a position statement of the Study Group on Exercise Training in Heart Failure of the Heart Failure Association of the European Society of Cardiology", Eur J Heart Fail. 2012 May;14(5):451–8, https://pubmed.ncbi.nlm.nih.gov/22499542/.

<sup>86</sup> Applying Telemedicine in a Model of Implementing Cardiac Rehabilitation in Heart Failure Patients (TELEREH–HF), NCT02523560, https://clinicaltrials.gov/study/NCT02523560.

<sup>87</sup> Piotrowicz E., Baranowski R., Bilinska M., et al., "A new model of home-based telemonitored cardiac rehabilitation in patients with heart failure: effectiveness, quality of life, and adherence", Eur J Heart Fail. 2010 Feb;12(2):164–71, https:// pubmed.ncbi.nlm.nih.gov/20042423/.

<sup>88</sup> Piotrowicz E., Stepnowska M., Leszczyńska-Iwanicka K., et al, "Quality of life in heart failure patients undergoing homebased telerehabilitation versus outpatient rehabilitation – a randomized controlled study", Eur J Cardiovasc Nurs. 2015 Jun;14(3): 256-63, https://pubmed.ncbi.nlm.nih.gov/24849304/.

<sup>89</sup> Piotrowicz E., Zieliński T., Bodalski R., Home-based telemonitored Nordic walking training is well accepted, safe, effective and has high adherence among heart failure patients, including those with cardiovascular implantable electronic devices: a randomised controlled study. Eur J Prev Cardiol. 2015 Nov;22(11):1368-77. 2015 Nov;22(11):1368–77, <u>https://pubmed.ncbi.nlm.nih.gov/25261268/</u>.

<sup>90</sup> Piepoli M.F., Conraads V., Corrà U., Piotrowicz E., et al., "Exercise training in heart failure: from theory to practice. A consensus document of the Heart Failure Association and the European Association for Cardiovascular Prevention and Rehabilitation", Eur J Heart Fail. 2011 Apr;13(4):347-57, <u>https://pubmed.ncbi.nlm.nih.gov/21436360/</u>.



therapy optimisation, and physical fitness evaluation<sup>91</sup>. This model was incorporated into the catalogue of guaranteed services as hybrid cardiac telerehabilitation, available in a centre, day ward, or inpatient setting, under the Regulation of the Minister of Health of 16 December 2016, which amended the regulation on guaranteed services in the field of medical rehabilitation<sup>92</sup>,<sup>93</sup>. Home-based cardiac telerehabilitation in patients with heart failure requires a three-lead ECG device capable of recording with a reverse loop of up to five minutes (tele-event Holter) and a system for training management. In addition, the equipment for home cardiac telerehabilitation should include a blood pressure monitor, an electronic scale and a pulse oximeter. The organisation of home-based cardiac telerehabilitation services should be based on an interdisciplinary team consisting of a telerehabilitation centre, comprising a doctor, an ECG technician, a physiotherapist, and a psychologist. This team is responsible for the remote management and monitoring of the effectiveness and safety of the patients' remote training sessions and for responding to emergency situations. Each time, the team at the telerehabilitation centre conducts a remote assessment to evaluate the patient's well-being, including medication taken, body weight, blood pressure, and ECG results. Based on this assessment, the centre confirms whether the patient is able to continue with the exercises. Controlled outdoor exercise (outside the patient's home) and telepsychotherapy sessions with a psychologist can be included as a complement to home cardiac telerehabilitation.

Implemented hybrid cardiac telerehabilitation - whether in an outpatient centre, day ward, or inpatient setting – should be seen as part of a comprehensive, holistic approach to care. It should therefore be developed into a comprehensive hybrid telecare programme for patients with heart failure. The first stage of comprehensive hybrid telecare for heart failure following hospital discharge should be an e-consilium to assess eligibility for remote cardiac telerehabilitation. This service should be provided in an outpatient clinic or within Primary Health Care. Outpatient care should be delivered by nursing staff, with remote supervision from cardiology specialists, following the specialist consultation model used in the AMULET study.<sup>94</sup> Meanwhile, cardiac telerehabilitation within the comprehensive hybrid telecare model for heart failure should be conducted in accordance with the model proposed in the TELEREH-HF study.95 As a complementary component of comprehensive care, continuous telemonitoring of implantable devices, supported by clinical assessment algorithms, should be maintained throughout the entire care period. This includes various telemonitoring components, such as non-invasive telemonitoring using the TIM-HF2 model, non-invasive haemodynamic telemonitoring, telediagnostics using ECG telemonitoring or available mobile applications. Comprehensive care also includes ongoing cardiac care, multidisciplinary support from specialists, including a pulmonologist, a nephrologist, a geriatrician, a dietitian, a psychologist, a physiotherapist, and a pharmacist, as well as the active involvement of caregivers and social support services.

In conclusion, the implemented model of hybrid cardiac telerehabilitation serves as an essential initial stage of cardiac rehabilitation following exacerbations. It delivers tangible clinical benefits

<sup>91</sup> Jankowski P., Niewada M., Bochenek A., "Optymalny Model Kompleksowej Rehabilitacji i Wtórnej Prewencji", Kardiol Pol. 2013;71(9):995-1003, <u>https://pubmed.ncbi.nlm.nih.gov/24065281/</u>.

<sup>92</sup> The Regulation of the Minister of Health of 16 December 2016 amending the Regulation on guaranteed services in the field of medical rehabilitation (Journal of Laws 2016, item 2162) Available at: <u>https://isap.sejm.gov.pl/isap.nsf/DocDetails.</u> <u>xsp?id=WDU20160002162</u>.

<sup>93</sup> Internal directive no. 33/2017/DSOZ of the President of the National Health Fund of 22 May 2017 amending the regulation on determining the conditions for concluding and implementing contracts in the types of medical rehabilitation and health programs in the field of services – treatment of children and adults with coma, <u>https://www.nfz.gov.pl/zarzadzenia\_prezesa/zarzadzenia\_prezesa\_nfz/zarzadzenie-nr-332017dsoz,6575.html</u>.

<sup>94</sup> Krzesiński P., Jankowska E.A., Siebert J., Piotrowicz K., et. al., "Effects of an outpatient intervention comprising nurseled non-invasive assessments, telemedicine support and remote cardiologists' decisions in patients with heart failure (AMULET study): a randomised controlled trial", Eur J Heart Fail. 2022 Mar;24(3):565-577, <u>https://pubmed.ncbi.nlm.nih.</u> gov/34617373/.

<sup>95</sup> Koehler F., Koehler K., Deckwart O., et al., "Telemedical Interventional Management in Heart Failure II (TIM–HF2), a randomised, controlled trial investigating the impact of telemedicine on unplanned cardiovascular hospitalisations and mortality in heart failure patients: study design and description of the intervention", Eur J Heart Fail. 2018 Oct;20(10):1485– 1493, https://pubmed.ncbi.nlm.nih.gov/30230666/.



and reduces healthcare system costs by enabling home-based rehabilitation. However, it remains a fragmented approach that does not account for comprehensive, continuous care, including longterm monitoring and prevention. The benefit of hybrid cardiac telerehabilitation does not last 12 to 24 months after completion. It is therefore crucial to take action to maintain these improvements with the aim of reducing re-hospitalisation rates and reducing mortality in patients with heart failure. This requires viewing the model as part of a broader framework of comprehensive cardiac telecare. Nevertheless, access to cardiac rehabilitation is unsatisfactory. Patients who have suffered an acute heart attack and are covered by the coordinated health programme after a heart attack (KOS-Zawał) have a 33% lower risk of death. However, only one in four patients takes part in the programme. This is mainly due to limited access to rehabilitation centres, regional differences in availability, strict admission criteria for cardiac day rehabilitation wards and the need to set up an intensive care unit within these wards.

### Paweł Kaźmierczyk PhD (Legal Sciences)

Leader of the Health Data Working Group at the Polish Supreme Chamber of Physicians and Dentists

I have the impression that Poland can be proud of its concrete successes in the field of e-health. A study published in the middle of the year shows that Poland ranks fifth in the European Union in terms of digital maturity. We have the Internet Patient Account (IKP), electronic prescriptions, electronic orders and mandatory electronic health records. According to the 8th Study on the Degree of Computerisation of Entities Performing Medical Activities, published by the E-health Centre, approximately 80% of medical entities in Poland have implemented electronic medical records, either fully or partially.<sup>96</sup> In some cases, "partially" may only mean a single document in a large provincial hospital, but the progress is obvious. We have a centralised medical event reporting system and are in the process of building a comprehensive record of patient health information and available medical tests. Currently, about half of healthcare facilities report medical events, while the other half do not – but the percentage of reporting entities continues to grow. Compared other countries, such as Germany and other large EU Member States, Poland performs remarkably well.

I also represent the Telemedicine Working Group Foundation, where we have been actively promoting the development of telemedicine in Poland since 2016.<sup>97</sup> For example, the first regulations for the provision of telemedicine services were introduced in Poland in December 2015. For comparison: Germany adopted similar regulations three years later, in 2018. In most countries of the European Union, these solutions were only implemented at the beginning of the COVID-19 pandemic, when circumstances forced such measures. In February 2021, we published a report entitled *The Use of Telemonitoring of Implantable Devices to Improve the Care of Cardiac Patients*.<sup>98</sup>

The European Health Data Space (EHDS) is to create a Community-wide, European framework for the interpretation and flow of patient status data. Ultimately, this means that if we are travelling to Italy or Spain and need medical care, a local doctor can access our medical data from Poland just as easily as if we were visiting another facility in Kraków, Warsaw or another Polish city. While this vision looks promising at a legislative level, its practical realisation is both fundamental and difficult. It requires significant financial and organisational investment as well as solutions to ensure seamless interoperability. This remains a major challenge – both at national and EU level. To put it simply, we must first ensure that electronic health records are fully implemented in all healthcare organisations. Secondly, we need to create a standardised system for the exchange of medical

<sup>96</sup> E-health Centre, 8th Study on the Degree of computerisation of entities performing medical activities, 2024, <u>https://cez.gov.pl/pl/page/o-nas/aktualnosci/nowe-badanie-poziomu-cyfryzacji-ochrony-zdrowia</u>.

<sup>97</sup> Telemedicine Working Group, <u>http://telemedicine-tmuw.pl/</u>.

<sup>98</sup> Telemedicine Working Group, Wykorzystanie telemonitoringu urządzeń wszczepialnych w celu poprawy opieki nad pacjentami kardiologicznymi [The Use of Telemonitoring of Implantable Devices to Improve the Care of Cardiac Patients], 2021, <u>http://telemedycyna-tmuw.pl/api/file/events/tmuw/Raport proc.20TGR\_full\_ver2.pdf</u>.



data across the European Union. I believe this should be one of the key priorities of the Polish Presidency. Poland has the opportunity to showcase its successful national eHealth initiatives and serve as an example for other EU Member States looking to develop their own digital healthcare systems. This model should be built on a shared interoperability standard. Proper implementation of primary health data processing is critical, as it forms the foundation for joint data utilisation – allowing for advanced analytical, research, and development applications. Additionally, there is a vast potential in leveraging artificial intelligence (AI) systems. Standardised health data processing opens the door to groundbreaking advancements in medical research and innovation.

I would also like to address the data flow model, specifically the "input-output" mixed model, which is an extremely important topic. As part of the activities of the Polish Supreme Chamber of Physicians and Dentists, we published a 2024 report titled Medical Data in a Doctor's Work: Current Status and Desired Changes.<sup>99</sup> The report aims to spark a broad discussion and serve as a roadmap for initiatives in medical data management – bringing benefits to patients, the medical community, employers, and healthcare payers. In the first phase, we focus on the fundamental aspects, including a review of the existing rules for the management of medical data. We are also proposing systemic solutions and advocating for policy changes to improve access to and use of medical data by doctors, while ensuring transparent data protection standards. In the following phases, we plan to develop practical tools and training for physicians and healthcare facilities to improve their ability to collect, report, analyse and use medical data - and ultimately improve the quality of care. Medical data are the backbone of a doctor's work and a fundamental driver of innovation in healthcare. High-quality medical data are crucial for making an accurate diagnosis and determining optimal treatment strategies. With the vast amounts of digital health data now being collected by healthcare institutions and related organisations, new opportunities for medical advancement are emerging. Large-scale data analysis - that can provide insights into populationwide health trends has the potential to influence future clinical guidelines and recommendations. A data-driven approach to medicine not only improves the precision of treatment, but also reduces the burden on medical staff and lowers healthcare costs. By utilising medical data effectively, doctors can focus more on what matters most-treating patients.

### Małgorzata Gałązka-Sobotka PhD (Economics)

Dean of the Centre of Postgraduate Medical Education and Director of the Institute of Healthcare Management at Łazarski University

Both the European Medical Data Space (EHDS)<sup>100</sup> and the Polish Presidency of the Council of the European Union give me hope that we will finally be able to mobilise, integrate and accelerate efforts to make our primary data systems more coherent. Before discussing the value of data for secondary use – something I very much welcome as a researcher – we must first improve the interoperability of internal systems and ensure the collection of reliable data that allow accurate analysis and conclusions to be drawn.

I would like to cite an example that I believe is particularly important for public health today: our national HPV vaccination programme. We can now be proud to have a fully functional dashboard entitled *Human Papillomavirus (HPV) Vaccination Report*.<sup>101</sup> This report is based on data from electronic vaccination cards. From 1 October 2023, healthcare professionals who administer recommended preventive vaccinations (including HPV vaccination) must indicate the vaccination administered together with the qualification assessment in the electronic vaccination

<sup>99</sup> Polish Chamber of Physicians and Dentists, Dane medyczne w pracy lekarza stan obecny i pożądane zmiany [Medical data in the doctor's work, the current state and the desired changes], 2024, <u>https://nil.org.pl/uploaded\_files/art\_1707132900\_</u> raport\_dane-medyczne-w-pracy\_lekarza.pdf.

<sup>100</sup> European Health Data Space, https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space\_pl.

<sup>101</sup> E-health Centre, Raport o szczepieniach przeciwko wirusowi brodawczaka ludzkiego (HPV) [Human Papillomavirus (HPV) Vaccination Report], <u>https://ezdrowie.gov.pl/portal/home/badania-i-dane/raport-o-szczepieniach-przeciwko-wirusowibrodawczaka-ludzkiego-hpv</u>.



card in accordance with Article 19(7) of the Prevention and Control of Infections and Infectious Diseases Act, which applies to recommended vaccinations. A recommended vaccination that was previously documented in a patient's medical records on paper can be entered in the electronic vaccination card as a historical vaccination. A patient is considered vaccinated if at least one of the following conditions is met from 1 January 2019: the patient has been recorded with an appropriate immunisation record (based on the International Classification of Medical Procedures ICD-9, code 99.559), or the patient has received and used a prescription for an HPV vaccine (Gardasil, Gardasil 9 or Cervarix). The report is updated weekly, allowing us to track the number of children who have received the first and second doses of the vaccine. It is accessible to everyone; however, its biggest limitation is that the report only covers vaccination rates within the public programme, excluding children vaccinated through the private healthcare system and local government programmes – of which there are thousands. We can ask ourselves: what will the consequences be? Specifically, when assessing the effectiveness of the preventive vaccination programme, without a complete set of data, we may soon be inclined to conclude that the programme is ineffective – simply because it did not appear to work, as it covered only a very small percentage of eligible children. With such incomplete data, we will draw incorrect conclusions and make flawed recommendations. I do not yet know how to solve this issue - particularly in the context of HPV vaccination - but I am already sounding a strong warning: if we fail to address this gap and do not complete these data, we will be unable to draw accurate conclusions about one of the key programmes included in the National Oncology Strategy. This could lead to questioning the effectiveness of both health policy and possibly even the vaccination programme itself. Such an outcome would be highly detrimental to all of us and, above all, would expose the fact that while we focus on ambitious, large-scale solutions, we still lack a fundamental grasp of essential data and concepts.

Therefore, I repeat that in connection with the EHDS and the Presidency, we may be able to mobilise all our resources to integrate primary data. The European Health Data Space (EHDS) is said to be building a network of data highways. I would very much like us to establish a network of smaller roads – channels for sharing health information – because they will lead us to that highway. Without these pathways, progress will be difficult.

I believe we have yet to reach 50% adverse event reporting in P1. I am concerned that, despite the long-standing legal requirements, there is still a lack of discipline in this area, and the regulator is not enforcing a law that, in my view, is critical for integrating into the EHDS system. The solution is simple: at least in the public sector, reimbursement for services should be conditional on registering events in P1. Such a minor change could have a significant impact in the Polish reality. But I am an optimist – I believe that better access to data lies ahead.

### Paweł Łangowski

#### Chair of the Healthcare Committee, SGI Europe

Much has been said about data interoperability, but as the Chair of the Health Committee, I would like to play the role of a devil's advocate in our discussion. SGI Europe is one of the three European cross-industry social partners (alongside ETUC and BusinessEurope).<sup>102</sup> SGI Europe plays an active role in European social dialogue, engaging in both bilateral negotiations with trade unions and tripartite discussions involving social partners and EU institutions. As a representative of employers, I have the impression that our healthcare systems hold vast amounts of medical data that remain largely underutilised. Discussions on healthcare system reform and health policy development should always be grounded in up-to-date and reliable data.

A good example of the use of medical data in health policy development is the Health Needs Map – Database of Systemic and Implementation Analyses, implemented by the Department of Analysis and Strategy of the Ministry of Health. The project is co-financed by the European Union through the European Social Fund under the Operational Programme Knowledge Education Development.



The Health Needs Maps provide analyses of current data to identify healthcare needs at both regional and national levels. They compile demographic and epidemiological data, information on provided healthcare services, as well as data on the utilisation of human and equipment resources. Based on this information, forecasts are prepared to anticipate future healthcare service needs for individual provinces and the entire country. However, this tool should be continuously updated with new data and enhanced with advanced analytical functions. The transition from PDF documents to an interactive online platform is certainly a step in the right direction.<sup>103</sup>

A second notable example of the digitalisation of healthcare in Poland is the Online Patient Account (IKP). However, at present, the Ministry of Health is unable to determine why people log in to see a doctor. While data is available on the number of registered users and the total number of accounts, it remains unclear how frequently patients log in and whether they do so for reasons other than obtaining a QR code for a prescription. As a result, we have a system with thousands of accounts – many of which were created solely to obtain a COVID certificate. How are we utilising this infrastructure, software, and data? This raises a crucial reflection: sometimes, we develop solutions that sound appealing in theory, but when we examine their practical impact, significant challenges emerge. One major issue concerns medical data reporting. While most hospitals report to the P1 platform, the majority of Primary Care providers – which should serve as the backbone of the entire healthcare system – do not.

Given this reality, the claim that the European Health Data Space (EHDS) will introduce revolutionary solutions is flawed, as medical data is simply not being collected. We lack comprehensive data on patients' underlying medical conditions because there is no mandatory reporting. Healthcare providers face no consequences for failing to report data, and until this issue is addressed, discussions about the EHDS, its implementation, and the scope of primary and secondary data collection will remain moot. Without reliable data, there will be no basis for effective management. Ultimately, the efficiency of healthcare services is directly proportional to the extent of monitoring and reporting – only by knowing what we are doing and for what purpose can we truly improve the system.

A prime example of duplication in healthcare services in Poland is occupational medicine. Not only is this sector decentralised, but it is also not integrated with the P1 platform. As a result, many tests conducted as part of occupational health assessments are later reordered by general practitioners (GPs). The GP is unaware that these tests have already been performed and does not have access to the results, leading to unnecessary repetition of services. Ensuring data interoperability in this area remains a key challenge. However, the greatest gap in the use of medical data is found in school medicine. Every child undergoes a routine health assessment, generating valuable medical data. Many institutions already aggregate this data and have effective solutions, yet despite years of discussion, there seems to be little political will or determination to digitise this sector. We should consolidate this data to enable better analysis of long-term health trends, such as tracking the development of non-advanced chronic diseases from childhood to adulthood.

### Piotr Samel-Kowalik PhD (Health Sciences)

Department of Environmental Hazard Prevention, Allergology and Immunology, Faculty of Health Sciences, Medical University of Warsaw

Currently, we have a vast amount of medical data in the system, yet we struggle to utilise it effectively. The case of school medicine exemplifies how the lack of digitisation in medical care prevents us from obtaining reliable information about population health trends. To conduct meaningful analyses and create effective dashboards, we need high-quality, timely data. The data available in public statistics systems is not inherently bad, but the delay in accessing it – sometimes spanning months or even years – significantly reduces its usefulness. Another challenge is data resolution,

<sup>103</sup> Polish Ministry of Health, *Projekt Mapy Potrzeb Zdrowotnych – Baza Analiz Systemowych i Wdrożeniowych* [Draft Health Needs Map – A Database of Systemic and Implementation Analyses], 2024, <u>https://basiw.mz.gov.pl/</u>.



meaning the level of granularity necessary to draw accurate conclusions. Addressing both issues simultaneously may lead to a solution, but the timeframe for such improvements seems distant, as it requires legislative changes. In Poland, there are two parallel systems for collecting medical data: a digital system and a non-digital system, where data circulates but remains underutilised. From a public health, research, and management perspective, dashboards can provide valuable insights into health challenges. However, if outdated or low-quality data is fed into these tools – data aggregated at too high a level or several years old – it will fail to enhance patient care or optimise the system. Data visualisation plays a crucial role in making health information accessible to a wide audience. Scientists use it to identify trends, decision-makers rely on it for policy development, and the general public benefits from clear, communicative representations. However, visualisation is only as effective as the data behind it. To make rational, evidence-based decisions, we need real-time, high-quality information. If data is inaccurate, outdated, or delayed, decision-making will be ineffective, particularly in a rapidly evolving health landscape.

### Andrzej Haremski

#### Expert in social cybernetics, medical school graduate

As a social cybernetics expert, I would like to examine the digitisation of health care from the perspective of someone focused on the development of civilisation and the structuring of societies. Social cybernetics explores complex social systems composed of individuals, institutions, organisations, and information and communication technologies. Its goal is to understand and enhance the functioning of these systems while developing methods and tools to achieve this. Drawing from diverse disciplines such as computer science, psychology, sociology, economics, political science, and management studies, social cybernetics enables the study and analysis of online behaviour, the societal impact of technology, the formation of social groups, decision-making processes, and communication strategies. In practical terms, social cybernetics is applicable in areas such as organisational management, social marketing, market research, and the design and implementation of new technologies. Many of today's societal challenges, including combating disinformation and mitigating the negative effects of the Internet on mental health, can be addressed through its application.

Currently, civilisational development is accelerating at an unprecedented pace. Changes that once took centuries now unfold within a decade. Digitisation has become the backbone of societal functioning. Naturally, the older generation struggles more in the digital sphere compared to younger people. However, digitalisation is an irreversible aspect of modern civilisation, which is why efforts must be made to reduce digital exclusion. At the same time, the use of medical data for the advancement of medicine and the healthcare system should be accepted, provided it remains under the full supervision of designated institutions and adheres to strict regulatory standards. The option to opt out should not be considered. No one asks whether we want to be assigned a PESEL number, nor whether we wish to be included in key databases of tax authorities, the police, or military reserves. As citizens of a given country, our inclusion in such systems is an inherent aspect of governance. In Poland, digital exclusion affects a significant segment of society, numbering in the millions, who require support in managing and accessing their medical data.

A key aspect of the digitisation of healthcare is ensuring that users can effectively interact with IT systems to create value and drive innovation in medicine. In my work, I conduct research and implementation projects focused on diagnosing neurological disorders in children. For medical projects, we create conditions that enable the safe transformation of ideas into products and services, in compliance with MDR regulations for medical devices incorporating AI. Our expertise lies in developing secure and efficient medical applications based on cutting-edge technologies. By leveraging Computer Vision and machine learning, we assist doctors in diagnostics and process automation, ultimately improving patient care and overall system efficiency.<sup>104</sup>



In conclusion, the sociocybernetic perspective enables us to view human collaboration with artificial intelligence (AI) within both social and technological contexts. Anticipating the behaviours and needs of individuals and societies is crucial in this process. To achieve this, it is essential to assess the social and health-related benefits of AI applications in medicine. This requires balancing the perspectives of the medical community and patients alike. Additionally, it is important to examine the technological aspects of digitalisation in relation to broader civilisational progress and the development of healthcare systems across individual countries and regions, such as the European Union and Europe as a whole.

### Tomasz Imiela MD PhD

#### Member of the Warsaw Regional Chamber of Physicians and Dentists

In 2023, the Strategic Studies Team of the Warsaw Regional Chamber of Physicians and Dentists prepared a report entitled Digitisation of Health in the Public Interest. This document, the result of nearly two years of work, serves as a comprehensive resource on the challenges of digital transformation in healthcare, offering recommendations on how to address them. The ongoing fourth industrial revolution, driven by digital technologies, is profoundly reshaping the healthcare system. Initially, the sector faced difficulties in adopting ICT solutions, but the COVID-19 pandemic drastically accelerated the digitalisation of medical care. In Poland, the rapid rollout of e-prescriptions, e-sick notes, and remote consultations highlighted both the benefits and drawbacks of these technologies. As a result, previously niche topics - such as the immense potential of digital innovations - gained significant public attention. At the same time, the risks associated with e-health solutions became more evident than ever, particularly concerning patient safety and the responsibilities of medical professionals. Digitisation is impacting every aspect of the healthcare system. It alters the patient experience, the work of doctors and other healthcare professionals, the delivery of medical services, hospital and clinic operations, and even the shaping of health policy. The increasing significance of data is reflected in the widespread adoption of electronic medical records and the push to establish medical registries. Additionally, a growing volume of healthrelated data is now generated and stored outside traditional healthcare systems, raising critical questions about access and governance. In the digital age, privacy takes on a new dimension, requiring updated safeguards developed through social dialogue. This is particularly crucial for health data, given its highly sensitive nature. The collection of digital health data unlocks vast opportunities for applications in medicine and healthcare management. The development of digital solutions is leading to integrated, comprehensive system-wide approaches that facilitate patientprovider collaboration, coordinated at either national or local levels.

Digitisation requires public authorities to develop flexible strategies and development plans that can adapt to ever-changing conditions while considering the needs of various stakeholders – above all, prioritising the public interest. This report was created to underscore the significance of this aspect in the design and implementation of e-health initiatives. We live in an information society where digital tools and virtual environments must be factored into social policies. Digital solutions, tested in healthcare systems worldwide, are designed to enhance efficiency and improve the quality of medical services. However, past experiences with e-health implementation suggest that, when introduced without adequate preparation, these tools can have unintended adverse effects. An electronic patient record should not become an additional administrative burden that detracts from the time doctors dedicate to patient care. Likewise, data collection should serve a meaningful purpose rather than becoming an end in itself.

The value of data lies in its application to decision-making, ensuring that it enhances the daily functioning of healthcare, making it more effective and patient- and physician-friendly. When investing in digital infrastructure and software, proper coordination of expenditures and the harmonisation of standards are crucial to guaranteeing security and avoiding dependency on a single provider. Artificial intelligence algorithms trained on biased or incomplete datasets risk deepening existing health inequalities and creating new forms of exclusion and discrimination that



may initially be difficult to detect. This underscores the urgent need for regulations that account for the entirely new context of "non-human" decision-making tools.<sup>105</sup>

### **Jacek Sztajnke**

IT systems architect, member of the Scientific Council for the Rare Diseases Platform project

The Rare Disease Patient Passport and the Rare Disease Platform are two of the six pillars of the Plan for Rare Diseases 2024-2025.<sup>106</sup> The responsibility for determining what data is included in the patient's passport lies with the attending physician at an Expert Centre for Rare Diseases (OECR), where specialised knowledge of individual rare conditions is concentrated. The doctor decides what information should be recorded in the passport. By definition, rare diseases affect a small group of individuals, occurring in no more than five cases per 10,000 people. However, many of the challenges faced by rare disease patients also affect the general population - only in rare diseases, these issues are amplified. At present, the Rare Disease Patient Passport has not yet been integrated into the healthcare system. The Plan for Rare Diseases outlines its implementation by the end of 2025, but there have been delays in rolling out this tool. The passport is intended to contain key medical data, including information on prescribed and contraindicated medications, past procedures, and other essential details. A critical component of the passport is the "emergency card", designed for use in urgent situations. Consider the case of an unconscious patient found on the street. Emergency services arrive, assess the patient, and diagnose a heart attack. The patient is transported to a cardiology department, where it is discovered that they do not have a myocardial infarction but rather an aortic aneurysm due to Marfan syndrome, a rare genetic disorder. If paramedics had access to this patient's rare disease history, the emergency response would have been managed differently from the outset. Three years ago, a pilot programme for the Rare Disease Patient Passport was conducted at the Rare Disease Centre in Gdańsk. A prototype passport was developed, and chip cards were distributed to patients for on-the-go access to their medical data. The initiative was widely praised, and patients are now asking when the system will be fully implemented nationwide.

The Rare Diseases Information Platform is one of the six areas of the Plan for Rare Diseases, developed to address an existing information gap. Recognizing this need, the Minister of Health decided to establish a comprehensive and reliable source of information. The materials and content published on the Platform will be regularly updated by a team of specialists and experts who work daily with individuals suspected or diagnosed with a specific rare disease or a group of rare diseases. The main objective of the Platform is to enhance accessibility and facilitate the exchange of knowledge on rare diseases among all stakeholders in the healthcare system, with a particular focus on doctors and patients. The Rare Diseases Platform brings together patients with rare diseases, their families, and patient organizations. It also includes doctors and other healthcare professionals, such as nurses, midwives, physiotherapists, dietitians, speech therapists, and public health specialists. Medical students specializing in fields like medicine, nursing, physiotherapy, dietetics, medical analytics, medical biotechnology, and public health are also part of the initiative. Teachers, especially those involved in special education, along with students of pedagogy, contribute to the platform, as do healthcare administrators, policymakers, and the general public. This initiative aims to create a centralized knowledge hub, improving awareness, access to expertise, and collaboration across various fields related to rare diseases.<sup>107</sup>

<sup>105</sup> Warsaw Regional Chamber of Physicians and Dentists, Cyfryzacja zdrowia w interesie społecznym [Digitisation of Health in the Public Interest], 2023, https://www.termedia.pl/mz/Cyfryzacja-zdrowia-w-interesie-spolecznym-raport,51506.html.

<sup>106</sup> Rada Ministrów przyjęła Plan dla Chorób Rzadkich na lata 2024–2025 [Council of Ministers adopted the Plan for Rare Diseases 2024-2025], <u>https://www.gov.pl/web/zdrowie/rada-ministrow-przyjela-plan-dla-chorob-rzadkich-na-lata-2024-2025</u>]

<sup>107</sup> Polish Ministry of Health, Platforma Informacyjna Choroby Rzadkie [Rare Diseases Information Platform], <u>https://</u> <u>chorobyrzadkie.gov.pl/pl/aktualnosci/witamy-na-platformie-informacyjnej-choroby-rzadkie</u>.



In the development of the Online Patient Account (IKP), significant emphasis was placed on HL7 integration technology, which facilitates data exchange between medical systems.<sup>108</sup> As an IT systems architect, I find it somewhat surprising that HL7 technology is incorporated into P1, yet not all systems seem to account for it, potentially contributing to integration difficulties. The simplicity of the interface was a key consideration in projects such as the Rare Disease Patient Passport and Doctor.One. The entire system was designed so that the patient does not need to log in manually. Instead, they receive a chip with an access key, and a regular Android phone is sufficient to retrieve information. The process works similarly to contactless payments – by simply bringing the phone close to the chip, the system retrieves the necessary data. This technology is the same as when downloading a digital key, allowing the phone to connect to the database seamlessly. The system displays the document, eliminating the need for manual login. It's a straightforward process that anyone with an Android phone can perform effortlessly.

### **Michał Gontkiewicz MD PhD**

## Leader of the Health Data Working Group at the Polish Supreme Chamber of Physicians and Dentists, member of the Supreme Council of Physicians and Dentists

We have been discussing digitisation in health care for years at various levels, and these topics continue to resurface. The e-Health Centre is currently developing the *Patient Summary Poland* (PS) project, which compiles key health information, including blood type, allergies, current medications, chronic diseases, past surgeries, and implanted medical devices. The PS will assist doctors in developing appropriate treatment plans, reducing potential risks, and overcoming language barriers. The implementation of the Patient Summary, alongside other cross-border e-services, will enhance health security for citizens, particularly those who frequently travel within the EU and EFTA countries. The project is financially supported by the European Health and Digital Executive Agency. It launched on 1 January 2024 and is scheduled for completion on 31 December 2026.<sup>109</sup>

However, we are currently facing challenges related to data access models, which are crucial. The medical data we collect and process is both an invaluable asset and a significant risk. As long as discussions continue on the implementation models, which I must admit I do not fully understand, achieving a workable solution will remain difficult. We already have a proven system, tested multiple times, developed by a well-established organisation – the Polish Insurance Institution (ZUS). This system grants access to sick leave records, and when a doctor needs this information, they do not have to request patient consent each time; they simply retrieve the necessary data. This demonstrates the existence of general access models, where data is securely protected to prevent unauthorised access and ensure that no one can use it anonymously. If the service remains incomplete – for instance, if a sick leave certificate is not issued – the patient receives a notification detailing why, who accessed the data, for what purpose, and at what time. This system has proven effective, and its necessity is clear – without a functional data access model, the entire information exchange system cannot operate efficiently.

In the medical sector, we have many excellent solutions, such as DrOne. However, these solutions do not integrate with one another. The public healthcare system's data infrastructure is practically not implemented in private-sector solutions, even though the private sector is vast. In my field – gynaecology and obstetrics – apart from hospital-based care, nearly the entire market is private. We can ignore this issue, but significant amounts of data, for example, cervical diagnostics from private facilities, are lost. We unnecessarily lose this data simply because we fail to integrate, enforce, or implement a common database. There is also no enforcement of certification for these solutions. In reality, we, as the Polish Supreme Chamber of Physicians and Dentists, in collaboration with AHTAPol, should certify the processes of accessing, obtaining, and editing medical data. We should

<sup>108</sup> E-Health Center, Instrukcja stosowania polskiej krajowej implementacji HL7 CDA [User's Manual for the Polish National Implementation of HL7 CDA], 2019, <u>https://www.cez.gov.pl/fileadmin/user\_upload/hl7/instrukcja\_stosowania\_pik\_hl7\_ cda\_v1\_3\_lu2\_5def850b1cd87.pdf</u>.

<sup>109</sup> E-Health Center, Patient Summary Poland, https://www.cez.gov.pl/pl/page/patient-summary.



also extrapolate this data to other European markets. This is not just a technological or legal issue – it is also a cultural issue. Across EU countries, there are vast differences in approach, levels of knowledge, and degrees of concern regarding such solutions. Without well-standardised methods, we will not bridge this gap, and we will continue to face issues. Even if we standardise the Polish market and introduce secure access to health data, we will still struggle with cross-border utilisation. Despite our strong ambition to improve healthcare systems, we often overlook the patient, who should remain the central focus of our efforts. Medical data should not be processed for the sake of another great scientific study; rather, it should serve to improve diagnosis and treatment processes. We design systems so that they can offer viable solutions, including assessing which innovations can be introduced to the market as reimbursed healthcare services. Ensuring proper access to data is critical for securing treatment options. The certification of standardised solutions is fundamental to ensuring safe and effective implementation. Without it, we will keep going in circles – creating innovative solutions in isolated areas without scaling them for broader use.

### **Tomasz Rudolf**

#### Co-founder and CEO of the medical start-up Doctor.One

Doctor. One is a continuous medical care platform that provides patients with direct physician support, enhancing engagement, adherence to medical recommendations, and treatment effectiveness.<sup>110</sup> When developing Doctor.One, we based our approach on several key assumptions. The first and foremost is that IT systems are primarily used by doctors, not patients. Physicians are required to engage with these systems daily, sometimes for hours, yet many existing solutions fail to streamline their workflow. Modern IT systems have the potential to ease the burden on medical professionals, including doctors and other healthcare staff. By optimising digital tools, we can ensure that they do not have to rely on multiple, fragmented communication channels to provide effective care. For instance, in Brazil, 97% of doctors use WhatsApp to communicate with their patients. In Poland, according to our research and surveys, between 50% and 75% of doctors share their personal phone numbers with patients. Physicians often receive medical documentation via various informal channels – including Instagram, Facebook chat, and SMS – requesting medical consultations. Through Doctor.One, we have established a secure and structured communication platform that protects medical data while improving the efficiency of doctor-patient interactions. Today, several thousand physicians use Doctor. One, benefiting from a more streamlined and secure approach to patient communication.

Today, we collaborate with hospitals and other healthcare institutions that seek to implement an asynchronous telemedicine model – not as a replacement for in-person visits, but as a complementary tool in the management of chronic diseases, introducing new forms of patient care. When discussing telemedicine, it is often narrowly reduced to a simple phone call between a doctor and a patient - a doctor who may not know the patient at all and is conducting a consultation for the first time. Both doctors and patients frequently perceive telemedicine as the "lesser sibling" of in-person consultations and traditional medicine. To change this, we must actively promote diverse, structured methods of medical data collection. Managing chronic disease patients alone accounts for up to 80% of healthcare costs, which means we must rethink how to handle such cases more effectively. One potential solution is discharging patients earlier while ensuring telemedical supervision. However, for patients who do not use digital tools, hybrid models are necessary. These should incorporate care coordinators, nurses, or other professionals who can act as traditional points of contact. We have learned that while digital solutions are highly effective, they are not universally accessible. Even though this issue is marginal in our case, our care coordinators must still have the flexibility to support patients who do not engage with digital tools. For these individuals, traditional methods – such as phone calls or paper-based questionnaires – should remain available, ensuring comprehensive and inclusive patient care.



I believe that the future of healthcare will increasingly belong to telemedicine, as the digital competence of both younger medical staff and patients continues to grow. For new generations of doctors and patients, using chat applications or digital tools for certain tasks will feel more natural. However, telemedicine should not replace traditional doctor visits where they are necessary. Instead, it should serve as a complementary solution, particularly in the face of limited medical staff resources. Where possible, we should delegate specific tasks to technology that can support doctors and nurses, or to support personnel and care coordinators, who – aided by digital tools – can relieve doctors of routine patient monitoring between visits. We can already see this shift when analysing the requirements of drug programmes. Introducing more flexible approaches – instead of requiring patients to visit a clinic every week, every month, or every three months – could allow them to remain under continuous remote supervision, maintaining regular digital contact with their care teams.

We strive to reach digitally excluded patients so we introduce Doctor.One during an in-person visit at the doctor's office. We do not cater to anonymous patients seeking quick consultations or prescriptions – this platform is designed for care teams to extend patient support between visits. We serve a significant number of patients aged 65+, so we remain mindful that both doctors using the interface and patients navigating the system must have clear, legible fonts. In any technology platform, it is crucial that development teams maintain direct interaction with users. For us, an invaluable experience came from spending time at medical conferences, engaging with doctors, observing their workflows, and testing interfaces on their own devices. Seeing the font sizes doctors used on their phones provided key insights, allowing us to refine the system based on real-world use. This user-driven approach is essential. We must continuously observe how people interact with technology and actively incorporate user feedback to enhance Doctor.One. The greatest challenge in system design is not just ensuring that a platform includes all the necessary features – it is making it simple, intuitive, and easy to navigate for every user.

### Karolina Wasielewska

#### **Institute for Social Policy Development**

One of the priorities of the Polish Presidency of the Council of the European Union, which unites everyone present here, is the digital transformation of medicine and health care. Of course, this concept can be interpreted in various ways, including very broadly, as we will see during today's meeting, where a range of topics in this field will be discussed. I am a journalist. For many years, I have run a blog dedicated to the careers of women in the tech industry, Girls Gone Tech.<sup>111</sup> I am also the author of the book *Digital Girls. Female Pioneers of Polish Computer Science*, which, in a way, also tells the history of Polish IT.<sup>112</sup>

The "export-worthy" products that Poland can showcase during its presidency of the Council of the European Union include the Online Patient Account (IKP), which, according to government data, is already used by 48% of Poles.<sup>113</sup> Most commonly, users rely on it for e-prescriptions and e-referrals, while services such as booking vaccinations are used to a lesser extent. Similar systems have been developed in many EU countries, with a significant number emerging during the pandemic, leading to an extraordinary acceleration in digitalization. However, these systems were created independently and often lack interoperability. They do not interact with one another, so while the pandemic has undoubtedly accelerated digitization, it has also resulted in a fragmented approach, with each country operating somewhat in isolation. This raises the question: could the Polish Presidency serve as an opportunity to promote greater interoperability between these systems? Or should we even consider developing a pan-European Online Patient Account, especially as the EU is soon set to introduce the European Digital Identity Wallet, the equivalent of Poland's mObywatel system?

<sup>111</sup> Karolina Wasielewska, Girls Gone Tech, <u>https://www.girlsgonetech.pl/</u>.

<sup>112</sup> Karolina Wasielewska, Cyfrodziewczyny. Pionierki polskiej informatyki, <u>https://www.empik.com/cyfrodziewczyny-pionierki-polskiej-informatyki-wasilewska-karolina,p1239400559,ksiazka-p</u>.

<sup>113</sup> Online Patient Account (Internetowe Konto Pacjenta, IKP), https://pacjent.gov.pl/internetowe-konto-pacjenta.

We aim to promote the use of artificial intelligence (AI) in healthcare. In 2024, the Warsaw School of Economics' Think Tank for Healthcare published a report entitled Artificial Intelligence in Healthcare: Legal Security and Implementation in Poland. The report outlines the benefits and risks associated with integrating AI into everyday clinical practice and the operations of organizations within the health and healthcare sectors. It concludes that AI is becoming an inherent component of the healthcare landscape, and the rapid development of AI- and machine learning-based tools brings hope for improvements in healthcare quality, diagnostic efficiency, and therapeutic effectiveness.<sup>114</sup> Artificial intelligence has also been incorporated into the objectives of the State Digitisation Strategy. Goals for 2035 in a medical context. According to this strategy, approximately 100 disease entities are expected to be jointly diagnosed by AI. The Poland's Digitisation Strategy is the first comprehensive document of its kind in the country's history, intended to serve as a roadmap for digital transformation over the next decade. Its primary goal is to enhance citizens' quality of life through digitisation.<sup>115</sup>

We must remember that Polish hospitals frequently fall victim to cyberattacks, including extortion, blackmail, identity fraud, and system blockades. In 2022, hospitals experienced a threefold increase in cyberattacks, with 43 reported incidents, compared to 13 in 2021. One in three facilities lacks IT architecture specialists, and only 16% have conducted regular cybersecurity training in recent years. It is therefore difficult to claim that Polish hospitals maintain a high standard of IT security.<sup>116</sup>

Before we can fully embrace telemedicine, we must first address digital exclusion. While 48% of citizens use the Online Patient Account (IKP), an impressive figure at first glance, it also means that 52% do not use it at all. Digital exclusion remains a significant issue, particularly affecting seniors. Many individuals face such substantial gaps in IT education that catching up will be extremely challenging. Digital exclusion also stems from limited internet access. In 2020, as many as 3.8 million people in Poland experienced primary digital exclusion, defined as not using the internet due to a lack of need, skills, equipment, connection, or financial resources. Of those affected, 96% were aged 45–74, and half of this age group lacked even basic digital skills.<sup>117</sup> A recently published report by the Orange Foundation, Social and Digital Exclusion in Poland, clearly indicates that education is the most effective way to combat digital exclusion.<sup>118</sup>

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<sup>114</sup> Warsaw School of Economics, Sztuczna inteligencja w zdrowiu. Bezpieczeństwo prawne i wykorzystanie w Polsce [Artificial Intelligence in Healthcare: Legal Security and Implementation in Poland], 2024, <u>https://gazeta.sgh.waw.pl/</u> meritum/raport\_sztuczna\_inteligencja\_w\_zdrowiu\_bezpieczenstwo\_prawne-i\_wykorzystanie-w\_polsce.

<sup>115</sup> Polish Ministry of Digital Affairs, Strategia Cyfryzacji Polski do 2035 roku [State Digitisation Strategy. Goals for 2035], https://www.gov.pl/web/cyfryzacja/strategia\_cyfryzacji\_polski\_do\_2035\_r.

<sup>116</sup> Gazeta Prawna, "Niebezpieczny e-wirus. Rośnie liczba cyberataków na szpitale" [Dangerous e-Virus: Rising Number of Cyberattacks on Hospitals], <u>https://serwisy.gazetaprawna.pl/nowe-technologie/artykuly/8639283,cyberbezpieczenstwocyberataki-szpitale-wirusy.html</u>.

<sup>117</sup> Polish Ministry of Digital Affairs, Wykluczenie cyfrowe [Digital Exclusion], <u>https://www.gov.pl/web/cyfryzacja/kluby-rozwoju-cyfrowego-odpowiedzia-na-wykluczenie-cyfrowe</u>.

<sup>118</sup> Orange Foundation, Wykluczenie społeczno-cyfrowe w Polsce [Social and Digital Exclusion in Poland], 2021, https://fundacja.orange.pl/strefa-wiedzy/post/wykluczenie-spoleczno-cyfrowe-w-polsce-2021.



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#### Prevention and Public Health as a Priority of the Polish Presidency of the Council of the European Union in 2025

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# Introduction

A conference entitled *Road to the Presidency: Prevention and Public Health* took place at the Medical University of Warsaw on 13 December 2024. The event focused on one of the health priorities of the Polish Presidency of the Council of the European Union – health prevention. In this regard, the Polish Presidency plans to undertake the following actions:

- 1. Assessing the effectiveness of health prevention strategies and programmes implemented across European Union Member States;
- 2. Compiling a catalogue of best practices, solutions, and policy proposals at both national and EU levels;



- 3. Evaluating the effectiveness of public policies and prevention efforts in relation to key health risk factors;
- 4. Promoting an integrated approach to prevention and education, with an emphasis on interdisciplinary learning.<sup>119</sup>

The event, organised by the Institute for Social Policy Development, brought together numerous experts in public health and prevention, alongside specialists from various medical fields and representatives of non-governmental organisations. As an outcome of the conference, a cross-sectional chapter will be included in the White Paper, along with a list of "Polish export-worthy products" in the field of preventive healthcare. The conference was funded by the National Institute for Freedom – Centre for the Development of Civil Society under the NOWEFIO Civic Initiatives Fund Government Programme for 2021-2030, as well as through scientific grants from GSK, Medicover, MSD, and Novo Nordisk.

#### Małgorzata Bogusz

President of the Institute for Social Policy Development, Member of the European Economic and Social Committee, Member of the Council of Non-Governmental Organisations for the Polish Presidency of the Council of the European Union

On behalf of the Institute for Social Policy Development, we are pleased to invite you to participate in the conference The Road to the Presidency: Prevention and Public Health in the Programme of the Polish Presidency of the Council of the European Union. The conference is held under the auspices of the European Economic and Social Committee, the Committee of Clinical Sciences of the Polish Academy of Sciences, the Lech Wałęsa Institute, the THINKTANK Center, and the Polish Promotional Emblem Poland Now Foundation. In addition, the Institute for Social Policy Development has applied for the sponsorship of the Polish Presidency of the Council of the European Union and the Public Health Committee of the Polish Academy of Sciences.

As a member of the European Economic and Social Committee (EESC) – an advisory body of the EU comprising 329 members<sup>120</sup> I witness firsthand how each document prepared by the European Commission is reviewed and debated within our three constituent groups: employers, trade unions, and the non-governmental sector, the latter of which I am honoured to represent.

Today's debate is part of a series of initiatives led by the Institute for Social Policy Development (IRSS) focusing on the priorities of the Polish Presidency of the Council of the European Union, which begins on 1 January 2025. The *Road to the Presidency* series was launched in 2023, and to date, IRSS has organised six such events, bringing together over one hundred Polish and international experts. These initiatives aim to establish an expert platform to discuss the Presidency's priorities and develop recommendations in the form of a White Paper.

Our discussion today is devoted to the scope of health priorities under the Polish Presidency of the Council of the European Union, commencing on 1 January 2025. As we know, the Polish Ministry of Health has defined four key priorities for Poland's Presidency in the field of health: the digital transformation of healthcare, mental health for children and adolescents, the promotion of preventive measures, and pharmaceutical security.<sup>121</sup> The agenda of today's conference will focus on prevention in health care and health security as one of the pillars of the Polish Presidency of the Council of the European Union.

<sup>119</sup> Polish Ministry of Health, Bezpieczeństwo, Europo! Priorytety polskiej prezydencji w obszarze zdrowia [Security, Europe! Health Priorities of the Polish Presidency], https://www.gov.pl/web/zdrowie/bezpieczenstwo-europo-priorytety-polskiejprezydencji-w-obszarze-zdrowia.

<sup>120</sup> European Economic and Social Committee (EESC), European Economic and Social Committee (EESC), https://europeanunion.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/europeaneconomic-and-social-committee-eesc\_pl.

<sup>121</sup> Polish Ministry of Health, Bezpieczeństwo, Europo! Priorytety polskiej prezydencji w obszarze zdrowia [Security, Europe! Health Priorities of the Polish Presidency], https://www.gov.pl/web/zdrowie/bezpieczenstwo-europo-priorytety-polskiej-prezydencji-w-obszarze-zdrowia.



We have invited over 40 distinguished experts to participate in today's event, sharing their experiences across various fields of medicine and social life. Their contributions will help create a catalogue of best practices that Poland can showcase on the European stage during its Presidency of the Council of the EU.

#### Justyna Mieszalska

#### President of the Medical Centre of the Medical University of Warsaw

On behalf of the Medical Centre of the Medical University of Warsaw, I extend a warm welcome to you all. Thanks to the courtesy of the Honourable Rector of the Medical University of Warsaw, we are once again able to take part in the Road to the Presidency conference series. Today's conference, titled Prevention and Public Health in the Programme of the Polish Presidency of the Council of the European Union, highlights an area that has been central to my professional career for the past twenty-four years. I had the privilege of overseeing public health at the Ministry of Health, and in 2015, I co-developed Poland's first National Health Programme. Its strategic goals were to extend healthy life expectancy, improve health-related quality of life, and reduce social inequalities in health.<sup>122</sup> That same year marked another milestone with the adoption of the Public Health Act, designed to counteract negative epidemiological trends and mitigate key health risk factors affecting the well-being of Polish citizens.<sup>123</sup> Today, I am keen to hear your proposals regarding public health and prevention programmes for the coming years. I hope that clinicians, governmental and non-governmental organisations will actively participate in implementing public health policies, ensuring that health inequalities are reduced. We must raise awareness that obesity, overweight, alcohol consumption, substance use, and air pollution contribute significantly to disease development and mortality in Poland. Public health efforts should prioritise those living in smaller towns and rural areas. I strongly believe that health education from an early age must be our focus. We are ready and willing to assist the Ministry of Health in developing the next National Health Programme, ensuring that the collective expertise of all involved is put to good use. I sincerely hope that today marks another milestone on the road to Poland's Presidency of the Council of the European Union.

#### The Importance of Prevention in Medical Sciences

#### Prof. Rafał Krenke MD PhD

#### Rector of the Medical University of Warsaw

On behalf of the Medical University of Warsaw, I would like to express our great pleasure and privilege in hosting you today – and I extend this invitation for the future as well. This event has been made possible thanks to the dedicated efforts of President Małgorzata Bogusz, President Justyna Mieszalska, and Professor Bolesław Samoliński. I would like to take a moment to highlight Professor Samoliński's extensive experience in EU public health policymaking. As Chair of the Public Health Priorities Subcommittee during Poland's 2011 Presidency of the Council of the European Union, he played a key role in shaping EU health priorities. At that time, the Medical University of Warsaw hosted two major conferences: one on the prevention of brain diseases, including neurodegenerative conditions, and another – equally important – on the prevention, early diagnosis, and treatment of chronic respiratory diseases in children. Notably, the latter was adopted as an EU priority and formally included in the Council of the European Union's conclusions. I sincerely hope that we will be equally engaged and proactive during this Presidency.

Today's meeting is a working session. We are all acutely aware of the importance of preventive

<sup>122</sup> Rozporządzenie Rady Ministrów z dnia 4 sierpnia 2016 r. w sprawie Narodowego Programu Zdrowia na lata 2016–2020 [Regulation of the Council of Ministers of 4 August 2016 on the National Health Programme for 2016-2020], Journal of Laws of 2016, item 1492, https://www.gov.pl/web/zdrowie/npz–2016–2020.

<sup>123</sup> Ustawa o zdrowiu publicznym [Public Health Act], https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu20150001916.



medicine, and during the COVID-19 pandemic, Poland's spending in this area rose dramatically – by approximately 88%. However, significant disparities persist across the European Union. For instance, Austria allocates 1.25% of GDP to preventive medicine, while Poland dedicates only 0.14%. A broader analysis of European countries shows that 14 nations spend more than EUR 100 per capita annually on preventive healthcare, while 13 others fall below this threshold. These discrepancies are highly significant and must be addressed. I believe that many European countries face similar challenges, and we must advocate for a proportionate and balanced increase in preventive health funding across the EU. We look forward to the report from today's discussions and, most importantly, to seeing concrete actions taken in response – particularly during Poland's EU Presidency from January to June 2025.

# Public Health and Prevention in the Polish Presidency of the Council of the European Union

#### **Wojciech Konieczny**

Secretary of State, Ministry of Health

The priority of the Polish Presidency is security, understood in seven dimensions, including, of course, health security. The entire health-related agenda of the presidency at the Ministry of Health is overseen by Minister Katarzyna Kacperczyk, who supervises the Department of International Cooperation, the unit responsible for coordinating the presidency.

The health priorities of the Polish Presidency are directly linked to public health. In the field of prevention, the focus is on promoting multidirectional health prevention, whose effectiveness at the population level depends on broad implementation and promotion. Some EU countries have achieved remarkable health outcomes in areas where Poland still struggles – such as overweight and obesity, alcohol consumption, and tobacco and nicotine use. This is why preventive health promotion has been elevated to the status of a presidency priority.

The approach to prevention can be viewed in two ways. On the one hand, prevention itself remains unchanged, continuing to be a core focus of public health efforts. However, the way it is implemented and prioritised is evolving. On the other hand, certain recent events have shifted the role of prevention in ensuring health security. These include the COVID-19 pandemic, the war in Ukraine, and the rise of digital technology, which introduces new cybersecurity threats to healthcare systems.

The National Health Programme for 2021-2025 is set to conclude in 2025, requiring the development of a new five-year programme.<sup>124</sup> This must be approached in a structured manner. The Public Health Act, which has now been in force for ten years, also needs revision.<sup>125</sup> **Many of the initiatives pursued during the Polish Presidency will contribute to shaping the next National Health Programme and revising public health legislation.** The current act, originally drafted by the Ministry of Health and a Senate-appointed team led by Senator Beata Małecka-Libera, has served as a solid foundation, but needs updates to align with long-term objectives. We have good material that we need to change for certain goals that we want to achieve in the long run. The Public Health Act of 2015 was designed with a 10-year horizon. The changes introduced now will define public health policy for the next decade. Given its significance, this legal framework must be developed with the utmost diligence and **must align with the evolving health needs of the Polish population. Funding for these initiatives is critical**, and **expert input will play a key role in shaping future policies.** The Polish healthcare system has significant potential, making it one of the most distinctive systems in Europe.

<sup>124</sup> Polish Ministry of Health, National Health Programme 2021-2025, https://www.gov.pl/web/zdrowie/npz-2021-2025.

<sup>125</sup> Ustawa o zdrowiu publicznym [Public Health Act], https://www.gov.pl/web/zdrowie/ustawa-o-zdrowiu-publicznym.



# Health Priorities of the Polish Presidency of the Council of the European Union

#### Katarzyna Kacperczyk

Undersecretary of State, Ministry of Health

From 1 January 2025, Poland will assume the Presidency of the Council of the European Union under the slogan "Security, Europe!". The Polish Presidency will support initiatives aimed at strengthening European security across multiple dimensions, including external, internal, information, economic, energy, food, and health security. **Health has become one of the most critical areas of cooperation among EU Member States**, and our goal is to reinforce this collaboration across Europe. The Polish Presidency presents a unique opportunity to drive meaningful change within EU health systems and improve the quality of life for all citizens. **The key health priorities of the Polish Presidency are:** 

- 1. Mental health of children and adolescents;
- 2. Health promotion and disease prevention;
- 3. Digital transformation of healthcare;
- 4. Pharmaceutical security.

Throughout our Presidency of the Council of the European Union that starts in January 2025, Poland will showcase the strengths of its healthcare system. While we often focus on its shortcomings, we must acknowledge the many effective solutions and dedicated professionals within it. Over the past decades, Poland has built considerable expertise in medical sciences, clinical practice, and health research. This Presidency will be an opportunity to highlight these achievements and adopt a more positive, forward-thinking approach to the future of European healthcare.

The digital transformation of healthcare, which includes the digitisation of health systems and services, is the first health priority of the Polish Presidency of the Council of the European Union. During the Belgian Presidency, a legislative package on the European Health Data Space (EHDS) was adopted.<sup>126</sup> The Polish Presidency will oversee its implementation both at the national and EU levels. Poland has extensive experience in digital healthcare and aims to play a key role in shaping how these regulations are applied across the EU and within Poland. Cybersecurity in hospitals is a crucial part of these digital priorities. This initiative, discussed with the European Commission, will focus on strengthening hospitals' ability to implement cybersecurity safeguards and digital tools. The Polish Presidency will support these efforts using funds from the National Recovery Plan (KPO), With a competition for hospitals set to launch in early 2025. Another key focus is the growing role of artificial intelligence in healthcare. In June 2024, the Artificial Intelligence Act was adopted, establishing a common framework for the use and deployment of AI systems across the European Union. The Polish Presidency will contribute to discussions on how AI can enhance healthcare while ensuring patient safety and ethical considerations.<sup>127</sup>

**The second health priority of the Polish Presidency is prevention and health promotion.** Prevention is a key element of the umbrella initiative led by the European Commission as part of the European Union for Health (EU for Health)<sup>128</sup> and is also a core component of Europe's Beating Cancer Plan.<sup>129</sup> Poland welcomes the growing participation of stakeholders in these EU-wide

<sup>126</sup> European Health Data Space (EHDS), https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space\_pl.

<sup>127</sup> Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act), lex.europa.eu/legal–content/PL/TXT/?uri=CELEX:32024R1689.

<sup>128</sup> EU4Health programme 2021-2027 – a vision for a healthier European Union, https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union\_pl.

<sup>129</sup> Europe's Beating Cancer Plan, https://commission.europa.eu/strategy\_and\_policy/priorities\_2019\_2024/promoting\_oureuropean\_way\_life/european\_health\_union/cancer\_plan\_europe\_pl.

initiatives and the financial resources allocated to them. In the area of cancer and cardiovascular disease prevention, the Council of the European Union, at the end of the Hungarian Presidency, adopted a conclusion mandating the European Commission to develop a concrete action plan in this field. The Polish Presidency is in close contact with the Commission and hopes that such a strategic document will be prepared. If this initiative appears on the agenda during Poland's term, Poland will actively support and facilitate its implementation. Poland aims to initiate a discussion and conduct an assessment of the effectiveness of prevention programs and public policy instruments related to prevention and public health across EU Member States. The Polish Presidency seeks to review and evaluate existing EU programs and instruments to identify the most effective approaches and recommend their broader implementation. As part of this effort, the Polish Presidency will analyze educational and information campaigns, as well as primary and secondary prevention programmes. Furthermore, in coordination with the European Commission, a Council of the European Union debate will be organized to address the growing risks of cancer and cardiovascular diseases and explore strategies for strengthening prevention measures across the EU.

I acknowledge that the organisation and financing of healthcare systems remain the exclusive competence of EU Member States. Apart from pharmaceutical regulations, most aspects of health policy at the EU level are not subject to direct regulation. For many years, healthcare was not a priority on the European Commission's agenda, but following the COVID-19 pandemic, it has gained prominence both within the EU institutions and among Member States. This presents a new dynamic – on the one hand, the European Commission lacks the legal competence and necessary instruments to intervene in the healthcare systems of Member States. On the other hand, there has been a growing number of initiatives, particularly within the European Health Union framework, demonstrating increased EU activity in health-related areas. As part of our Presidency of the Council of the European Union, we intend to initiate a discussion on where health currently stands on the EU policy agenda and where it should be positioned in the future. From my previous experience working on climate change policy, I have seen how it evolved into a cross-cutting issue that now influences multiple sectoral policies. Similarly, health policy is now gaining broader cross-sectoral relevance. A current example is the EU legislative proposal to restrict access to nicotine-free e-cigarettes for children, an initiative that affects various sectors of public policy and governance across EU Member States.

The third priority, which is of great significance for Poland and all EU Member States, is the mental health of children and adolescents. Until now, mental health issues have been rarely addressed – if at all – within EU policy discussions. Specifically, the mental well-being of children and young people has not been a focus of attention, nor has there been a structured approach to tackling risks associated with new technologies and social media. Poland has been engaging in discussions on youth mental health with the Directorate-General for Health since January 2024. With the new European Commission and new European Parliament, we have been able to shape the four-year agenda of the Commission, successfully securing the inclusion of mental health for children and adolescents as a key topic. Furthermore, this issue has been recognised as one of the priorities of Commission President Ursula von der Leyen, underlining its importance at the highest level of EU policymaking. Moreover, the topic was considered so important that it was chosen among the priorities of Commission President von der Leyen. Mental health challenges among children and adolescents are prevalent across all EU Member States, and there is strong interest in developing recommendations and implementing effective actions. As part of the Polish Presidency, we aim to prepare a comprehensive report in collaboration with the European Commission, the World Health Organization, and Member States. This report, to be presented in April 2025, will provide a detailed assessment of the mental health status of children and adolescents across the EU and outline policy recommendations. Additionally, we intend to propose Council Conclusions on this issue, seeking formal adoption by the Council of the European Union in June 2025.

The fourth priority of the Polish Presidency in the field of health is pharmaceutical security within the European Union. Since the Belgian Presidency, work has been underway



to revise the EU pharmaceutical legislation.<sup>130</sup> This revision covers a regulation and a directive, amounting to several hundred pages of complex legal text. The pharmaceutical framework has not been updated in two decades, and the process is highly intricate, as it must balance the diverse interests of numerous stakeholders while accounting for the specificities of national markets and reimbursement systems across EU Member States. A key objective will be to establish a position for the Council of the European Union, which will guide further negotiations on this reform. It is important to recall that every legislative act undergoes a trilateral negotiation process involving the European Parliament, the European Commission, and the Council of the European Union. In these negotiations, the Presidency represents the Council and, by extension, the Member States. While the European Parliament already adopted its position on the pharmaceutical package during its previous term, the Council and the Member States have not yet finalised their stance. Poland will hold the Presidency for six months, but Denmark and Cyprus will carry forward the agenda as part of the Trio Presidency. This 18-month programme ensures continuity in key policy areas, with the priorities set during Poland's term serving as the foundation for the subsequent Presidencies. The Danish government has expressed its intention to finalise the pharmaceutical package during its term, and Poland will play a key role in shaping this process. Additionally, it has been agreed that work on a biotechnology strategy, expected to take the form of the Biotech Act, will be a logical follow-up to the initiatives launched under the Polish Presidency.<sup>131</sup>

We must not forget that innovation and competitiveness in the pharmaceutical sector are essential for patient health and drug security. Our goal is to ensure both market availability and reimbursement of medicines in every EU Member State. However, there are numerous instances where pharmaceutical companies do not apply for reimbursement of innovative medicines, limiting patient access in some countries. Our challenge is to find a balanced compromise that guarantees health security through real access to therapies. Mario Draghi's report, The Future of European Competitiveness, recommends supporting the production of innovative medicines while strengthening the financial capacity of national health systems and reimbursement mechanisms.<sup>132</sup> In addressing health-related risks, we are working closely with the Health Emergency Preparedness and Response Authority (HERA)<sup>133</sup> and the new Commissioner for Health, Oliver Várhelyi. The Critical Medicines Act is one of the key legislative initiatives on the agenda of Poland's Presidency.<sup>134</sup> The pharmaceutical package cannot be discussed in isolation from real health needs and risks. We must ensure patients not only have access to medicines on the market but also through reimbursement systems. The European Union cannot afford shortages in medicine supply. Currently, most Active Pharmaceutical Ingredient (API) production is outsourced to Asia, which poses a strategic risk. While some larger EU Member States still produce APIs, a sustainable strategy is needed to strengthen Europe's pharmaceutical security at both the EU and national levels. Strengthening Europe's pharmaceutical sector, including both innovative and generic medicines, is a challenging but necessary task. This goal aligns with the Biotech Act, which will enhance support mechanisms and clinical research for new medicines in Europe. We aim to develop a comprehensive approach, ensuring security for both innovators and the generic sector while establishing robust instruments and funding to enhance pharmaceutical security. Promoting competitiveness within the EU's pharmaceutical industry is crucial for maintaining Europe's strategic advantage. However, we need to promote a human dimension of competitiveness, which must serve patients. It is unlikely that we will reach a consensus on joint procurement of high-

<sup>130</sup> Reform of the EU pharmaceutical legislation, https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategyeurope/reform-eu-pharmaceutical-legislation\_en.

<sup>131</sup> Von der Leyen confirms Critical Medicines, Biotech Acts in pipeline, https://www.euronews.com/health/2024/07/19/vonder-leyen-confirms-critical-medicines-biotech-acts-in-pipeline.

<sup>132</sup> Mario Draghi, The future of European competitiveness, https://commission.europa.eu/topics/strengthening-europeancompetitiveness/eu-competitiveness-looking-ahead\_en#paragraph\_47059.

<sup>133</sup> Health Emergency Preparedness and Response (HERA), https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera\_en.

<sup>134</sup> A Critical Medicines Act to secure Europe's pharmaceutical independence, https://commission.europa.eu/topics/ strengthening-european-competitiveness/eu-competitiveness-looking-ahead\_en#paragraph\_47059.

cost medicines while ensuring equal access across Member States. This debate is just beginning. It is also essential to thoroughly assess past joint procurement experiences, particularly regarding COVID-19 vaccines. Without a detailed evaluation of previous EU-wide purchasing mechanisms, led by DG Health and later HERA, future procurement models cannot be properly designed. Additionally, medicine stockpiling has emerged as a priority on the EU agenda. Any potential solidarity-based joint procurement mechanisms to prevent medicine shortages would require an effective storage strategy to ensure supply security across the EU.

I am also pleased with the initiative of the ORPHAN National Forum, Minister Urszula Demkow, and members of the European Economic and Social Committee to organise regular conferences on rare diseases. Poland is a leader in the diagnosis and treatment of rare diseases within the European Union, with certain solutions – such as the diagnosis and treatment of spinal muscular atrophy (SMA) and the Neonatal Screening Programme – placing us among the top-performing countries in this field.

# The Experience of the Polish Presidency in 2011 in Building Public Health Programmes

#### Prof. Bolesław Samoliński MD PhD

Chair of the Subcommittee on Health Priorities during the Polish Presidency of the Council of the European Union 2011, Head of the Department of Environmental Hazard Prevention, Allergology, and Immunology at the Medical University of Warsaw, Chair of the Council of the Discipline of Health Sciences, Medical University of Warsaw

The first Polish Presidency of the Council of the European Union in 2011 was a major milestone. In the field of health care, Poland was the only EU country to entrust the preparation and implementation of its health priorities to the scientific community. As a result, the Polish Presidency was widely regarded as the most effective EU Presidency following the Treaty of Lisbon in 2007. Fourteen years later, we are preparing for Poland's second Presidency of the Council of the European Union, which will take place from January to June 2025. A comparison of health priorities from fourteen years ago highlights how much the surrounding environment and our lifestyles have changed, bringing new challenges. Digitisation, in particular, has become a complex issue with multiple dimensions. The COVID-19 pandemic, combined with digitalisation, has led certain groups – especially those in early developmental stages – to retreat into the digital and telecommunications space, distancing themselves from society and contributing to an increase in mental health disorders among young people. Despite these changes, some priorities remain the same. We continue efforts to reduce health disparities, prevent brain diseases, promote preventive healthcare, facilitate early diagnosis of respiratory diseases, improve early detection and treatment of communication disorders, and support structured initiatives for promoting healthy lifestyles. However, public health must now evolve to meet the realities of today's world. As part of the Public Health 2.0 project, the Public Health Committee of the Polish Academy of Sciences has developed several expert reports that comprehensively examine these challenges. A key aspect of modern public health is the increasing role of health awareness and education. Awareness is fundamental to driving action and regulation. During a discussion with a prominent politician, I was asked whether legal regulation or education should come first. My response was: How do you determine what is good and what is harmful? In the 19th century, cigarettes were considered beneficial to health – so we must base policy on scientific evidence. This is the core responsibility of the scientific community. At the same time, we are facing a crisis of trust in public messaging, which stems from a broader crisis of trust in political leadership. This has profound consequences for the standing of public health. Poland's upcoming Presidency of the Council of the European Union presents an opportunity to highlight the need for thorough analysis and evidence-based conclusions in shaping effective health policies.



**Health education in schools should be promoted across the European Union.** I firmly believe that it should be recognised as a key component of the EU's health promotion and policy framework. However, the primary challenge lies in determining who should be responsible for delivering health education in schools. I am strongly opposed to assigning this task to teachers. In Poland, we have approximately 20,000 public health specialists who are well-prepared for this role but are unable to teach because they do not meet the formal criteria required for educators. It is crucial to address this issue by ensuring that public health graduates meet the qualifications set by the Ministry of National Education for school employment. The role of a school health promoter extends beyond simply providing health education to students. It also involves fostering a broader pro-health culture within the school environment. To facilitate this, pedagogy should be incorporated as a subject within public health degree programmes.

A crucial aspect of public health policy is anti-smoking education combined with legislative measures to limit access to tobacco products. Nicotine addiction remains a significant public health challenge. Currently, we are losing the battle against disposable cigarettes, as there is little control over their availability. It may be time to consider policy measures already implemented in other parts of the world, such as Europe and New Zealand, and introduce an EU-wide directive mandating national restrictions on cigarette sales. Such a directive would ensure that individual member states incorporate tobacco access limitations into their national policies. Poland faces unique challenges due to the economic impact of tobacco production, with around 20,000 families depending on this industry. However, when comparing the immense harm caused by nicotine addiction to the financial benefits gained by specific social groups, the case for stricter regulations is overwhelmingly clear. Gradual measures must be implemented to restrict access to tobacco products. One approach could be raising the minimum legal age for purchasing cigarettes over time. For example, in the UK, individuals born after 2009 will never legally be able to buy cigarettes. Another potential strategy is to regulate the points of sale, reducing widespread availability in kiosks, petrol stations, and convenience stores and limiting sales to designated locations.

**Overweight and obesity are further significant public health challenges.** It has even been suggested that obesity could lead to a form of civilizational regression. This is undeniably a major health issue and a pressing challenge for the European Union. There is an alarming increase in disability among children and adolescents, largely due to excess weight and the lack of physical activity. These two interconnected risk factors contribute to the early onset of metabolic diseases, which are now developing at increasingly younger ages.

In the field of public health, the European Union needs a comprehensive strategy that clearly defines the path forward, systematically addressing identified challenges. It would be beneficial during our presidency not only to discuss effective health programmes but also to explore ways of creating a structured roadmap for their implementation, ensuring that the European Commission has the necessary competencies to support this process. The European Union should actively engage Member States in fulfilling specific public health objectives. A key priority should be integrating EU-level health policy with national policies in individual countries.

#### Prof. Wojciech Hanke MD PhD

Chair of the Public Health Committee of the Polish Academy of Sciences

Making key decisions in health policy requires practical analyses and studies on public health in the country. Over the past decades, political discussions on health and healthcare have largely focused on fragmented, media-driven issues, often detached from a broader context. Addressing this gap, the *Polish Health 2.0* project was launched. A team of specialists has prepared eighteen expert assessments covering selected aspects of Poland's health system, with a particular focus on public health, its connections with restorative medicine, the social environment, and the economy. These assessments, presented as concise policy briefs, outline key issues and propose essential policy changes. The project is led by the Public Health Committee



of the Polish Academy of Sciences, operating within the Academy's Fifth Faculty of Medical Sciences.<sup>135</sup> The assessments are structured into three main modules: the Polish health system, public health, and restorative medicine, along with supplementary materials. The public health module includes six expert reports.

The first expert report, entitled *Fundamental Strengthening of Public Health*, describes the public health system in Poland. It emphasizes the need for decisive action to build a robust and effective public health system that can consistently implement the state's health-promoting policies. Within the field of public health, experts highlight the necessity of changing the state's approach to health promotion across six key areas:

- 1. Conducting state health and health-promotion policies based on scientific evidence and best practices from other countries, with a particular focus on representative epidemiological and economic data to assess the economic and social consequences of health loss and disability.
- 2. Integrating restorative medicine, public health, and social policy.
- 3. Continuously monitoring health inequalities, the health and social situation of vulnerable groups, including older adults, and environmental risks.
- 4. Treating health education and mental health as priorities, particularly among children, adolescents, and the elderly.
- 5. Implementing an effective information policy and building genuine leadership to gain the public trust necessary for the acceptance of state health policies.
- 6. Establishing a modern, institutionalized expert base for scientific research to evaluate the effectiveness of the state's health policy and support its implementation.<sup>136</sup>

The second expert report, entitled Improving Physical Activity Among All Generations of Poles, highlights that **physical activity is one of the most important factors influencing human health, quality of life, and longevity**. Regular movement plays a key role in preventing cardiovascular diseases and contributes to reducing premature mortality and overall mortality. The authors propose a list of the most urgent actions that can help improve physical activity levels nationwide. They include:

- 1. Integrating content emphasising the health benefits of regular physical activity into educational programmes in schools and universities.
- 2. Introducing systematic monitoring of activity levels and physical fitness among Poles within the National Health Programme.
- 3. Improving the infrastructure and attractiveness of school sports facilities, adapting them to the needs of modern children and adolescents.
- 4. Increasing the accessibility, quality, and safety of cycling routes is also essential.
- 5. Conducting original Polish research on the health effects and the social and economic costs of insufficient physical activity and sedentary lifestyles is another key action point.
- 6. Finally, a nationwide campaign promoting physical activity should be organised to raise awareness and encourage active lifestyles across all age groups.<sup>137</sup>

The third expert report, entitled *Building Trust in Preventive Vaccination*, asserts that vaccination is one of the greatest achievements in public health. The authors outline six key recommendations.

- 1. Strengthening efforts to monitor the epidemiological situation, including the occurrence of infectious diseases and the implementation of vaccination programmes.
- 2. Building trust in vaccinations through primary healthcare.
- 3. Integrating education on vaccinations and infectious diseases into school curricula.

<sup>135</sup> Public Health Committee of the Polish Academy of Sciences, Polskie Zdrowie 2.0, 2024, https://pan.pl/polskie-zdrowie/.

<sup>136</sup> Polish Academy of Sciences, Public Health Committee, Zasadnicze wzmocnienie zdrowia publicznego [Fundamental

strengthening of public health], https://pan.pl/wp-content/uploads/2023/03/Polskie-zdrowie-2.0\_Brief-nr-II.1\_Zasadnicze-wzmocnienie-zdrowia-publicznego-1.pdf.

<sup>137</sup> Polish Academy of Sciences, Public Health Committee, Poprawa aktywności fizycznej wśród wszystkich pokoleń Polaków [Improving Physical Activity Among All Generations of Poles], https://pan.pl/wp-content/uploads/2023/12/Rekomendacje\_ II\_4\_do\_publikacji.pdf.



- 4. A well-designed communication strategy to promote vaccination.
- 5. Combatting the spread of misinformation and vaccine-related falsehoods.
- 6. Amendments to legal regulations governing the organisation of the vaccination system.<sup>138</sup>

The fourth expert report, entitled Reducing Cigarette Smoking and E-Cigarette Use, Particularly Among the Younger Generation of Poles, presents a **set of recommendations aimed at significantly lowering nicotine addiction** in society, including the following seven:

- 1. An effective tax policy that increases the price of tobacco products to reduce their economic accessibility.
- 2. Stricter regulations on nicotine product sales to limit their availability.
- 3. A ban on the advertising and promotion of nicotine products through amendments to antismoking legislation.
- 4. Targeted health education to prevent smoking initiation and reduce nicotine consumption.
- 5. Launching a support programme for individuals addicted to nicotine, including minors.
- 6. Monitoring the market for nicotine products, their usage patterns, and the effectiveness of preventive measures.
- 7. Restricting the tobacco industry's influence on decision-making processes, including those related to harm reduction policies.<sup>139</sup>

The fifth expert report, entitled *Alcohol at the Turn of the Century*, states that **the most effective** strategy for reducing alcohol consumption includes limiting its economic availability, restricting its physical accessibility, and banning alcohol advertising and promotion.<sup>140</sup>

The sixth expert report, entitled *Socio-economic Inequalities in Health*, confirms that multidisciplinary efforts to address social inequalities are crucial. The most important tasks in this area fall within the scope of a population-based approach to health and disease prevention.<sup>141</sup>

#### **Prof. Cezary Włodarczyk PhD**

Member of the Presidium of the Public Health Committee of the Polish Academy of Sciences, former Director of the Institute of Public Health

**Health promotion and disease prevention are instrumental in realising the priority of the Polish Presidency of the Council of the European Union, namely prevention and public health.** The Public Health Committee of the Polish Academy of Sciences, in its expert opinion titled *Fundamental Strengthening of Public Health*, recommended that the state's health and health-promoting policies be conducted based on scientific evidence and the best practices of other countries, as well as implementing an appropriate information policy and building genuine leadership to achieve public trust.<sup>142</sup> Additionally, Brownson et al. (2009), in the publication *Evidence-Based Public Health: A Fundamental Concept for Public Health Practice*, argued that **evidence-based public health** is the activity of developing, implementing, and evaluating effective public health programmes through the use of scientific reasoning principles, including the systematic use of data and information systems,

<sup>138</sup> Polish Academy of Sciences, Public Health Committee, Budowanie zaufania do szczepień ochronnych [Building Trust in Preventive Vaccination], https://pan.pl/wp-content/uploads/2023/12/Rekomedacje\_II\_5.pdf.

<sup>139</sup> Polish Academy of Sciences, Public Health Committee, Redukcja palenia papierosów i używania e-papierosów, w szczególności wśród młodego pokolenia Polaków [Reducing Cigarette Smoking and E-Cigarette Use, Particularly Among the Younger Generation of Poles], https://pan.pl/ograniczenie-palenia-wsrod-polakow-rekomendacje-ekspertow/.

<sup>140</sup> Polish Academy of Sciences, Public Health Committee, Alkohol na przełomie wieków [Alcohol at the Turn of the Century], https://pan.pl/wp-content/uploads/2024/09/II\_2\_B.pdf.

<sup>141</sup> Polish Academy of Sciences, Public Health Committee, Społeczno-ekonomiczne nierówności w zdrowiu [Socio-economic Inequalities in Health], https://pan.pl/wp-content/uploads/2024/05/Rekomendacje\_II\_6.pdf.

<sup>142</sup> Polish Academy of Sciences, Public Health Committee, Zasadnicze wzmocnienie zdrowia publicznego [Fundamental strengthening of public health], https://pan.pl/wp-content/uploads/2023/03/Polskie-zdrowie-2.0\_Brief-nr-II.1\_Zasadnicze-wzmocnienie-zdrowia-publicznego-1.pdf.

and the appropriate use of programme planning models.<sup>143</sup>

An example where evidence-based public health has been widely discussed is the effectiveness of COVID-19 vaccines and the mortality rates among vaccinated individuals. According to Yun Lu et al. (2024), the efficacy of the two-dose COVID-19 vaccine in preventing deaths was 69.8% in the pre-Delta period and decreased to 55.7% during the Delta period due to viral mutations. A significant decline in efficacy over time was observed, from 65.1% within six months of receiving the second dose to 45.2% beyond six months. Three doses provided 88.7% efficacy in preventing death, with an additional benefit of three doses over two doses amounting to 74.6%. Among individuals with previous COVID-19 infections, the effectiveness of the three-dose regimen in preventing death was 78.6%, with an additional protective effect of 70.0% compared to two doses.<sup>144</sup> The ECDC 2023 report also provided aggregated estimates of COVID-19 vaccine effectiveness for the first, second, and third booster doses in preventing hospitalisation and COVID-19-related mortality among individuals aged 50 and above.<sup>145</sup> According to Wells (2024), vaccine effectiveness declined over time. The incidence of severe cases increased from 5.2% within 90 days of vaccination to 8.3% between 181 and 240 days and reached 15% in individuals vaccinated more than 240 days earlier. The incidence of severe pneumonia followed a linear increase, rising from 18% within the first 90 days to 32% between 180 and 240 days and remaining at 31% beyond 240 days post-vaccination.<sup>146</sup> Weir reported a decline in vaccine effectiveness against the Omicron variant, with peak efficacy observed approximately four weeks after administration, followed by a steady decline. The vaccine was also less effective against the JN.1 subvariant.<sup>147</sup> Shrestha (2024) examined 48,210 individuals during a 17-week follow-up period at the Cleveland Clinic, identifying COVID-19 infections in 2,462 cases (5.1%). The estimated vaccine effectiveness was 42% before JN.1 became dominant and dropped to 19% after its spread. The risk of COVID-19 infection was lower among individuals previously infected with the XBB variant or more recent strains but increased with the number of vaccine doses received.148

All in all, the COVID-19 vaccines were expected to be highly effective. Their efficacy was greater in preventing deaths and hospitalisations than in preventing infections. The vaccine did not fully protect against infection, and its effectiveness waned over time. From an evidence-based public health perspective, this raises a critical question: how should such dilemmas be communicated when initial messaging framed the vaccines as a success? The Emergency Task Force (ETF) of the European Medicines Agency (EMA) has recommended updating COVID-19 vaccines to enhance their effectiveness against the new JN.1 variant of the SARS-CoV-2 virus, ensuring preparedness for vaccination campaigns in 2024/2025.<sup>149</sup>

In practice, there is often a departure from evidence-based public health policies. Instead, decision-making frequently relies on justifying pre-existing political priorities rather than allowing evidence to guide policy. This "policy-based evidence" approach is the inverse of "evidence-based policy". A decision-maker determines a course of action first and then seeks supporting evidence, often relying on ideological or political arguments. A significant increase

<sup>143</sup> Brownson R.C., Fielding J.E., Maylahn C.M., "Evidence-based public health: a fundamental concept for public health practice", Annu Rev Public Health. 2009; 30:175-201, doi: 10.1146/annurev.publhealth.031308.100134. PMID: 19296775, https://pubmed.ncbi.nlm.nih.gov/19296775/.

<sup>144</sup> Yun Lu et al., "Real–world Effectiveness of mRNA COVID-19 Vaccines Among US Nursing Home Residents Aged ≥65 Years in the Pre-Delta and High Delta Periods", Op.For.Inf.Dis, January 2024.

<sup>145</sup> ECDC, Interim analysis of COVID-19 vaccine effectiveness against hospitalisation and death, https://www.ecdc.europa.eu/en/publications\_data/interim\_analysis\_Covid-19-vaccine-effectiveness\_against\_hospitalisation\_and\_death.

<sup>146</sup> Wells A.U., "COVID-19 Vaccine Efficacy Over Time: Severe Disease in Hospitalized Patients", Radiology. 2024 Jan;310(1): e233340. doi: 10.1148/radiol.233340. PMID: 38259212, https://pubmed.ncbi.nlm.nih.gov/38259212/.

<sup>147</sup> J. Weir, Considerations and Recommendations for the 2024–2025 COVID-19 Vaccine.

<sup>148</sup> Shrestha N.K., Burke P.C., Nowacki A.S., Gordon S.M., "Effectiveness of the 2023–2024 Formulation of the COVID-19 Messenger RNA Vaccine", Clin Infect Dis. 2024 Aug 16;79(2):405-411. doi: 10.1093/cid/ciae132. PMID: 38465901.

<sup>149</sup> European Medicines Agency. ETF recommends updating COVID-19 vaccines to target new JN.1 variant, 30 April 2024.



in such practices was observed during the COVID-19 pandemic.<sup>150</sup> While pandemics naturally generate a demand for reliable evidence, the COVID-19 crisis exposed features of a "post-truth" world, where the authority of science diminished and misinformation spread. Disinformation, defined as "information contradicting the epistemic consensus of the scientific community", became widespread. Conspiracy theories and hostile narratives, such as the stigmatisation of Chinese communities, emerged. **This phenomenon has been termed the "infodemic"**.<sup>151</sup>

According to Islam et al. (2021), a social media study conducted from 31 December 2019 to 30 November 2020 showed that out of 637 publications on COVID-19 vaccination, 83% (528/637) were false, 10% (66/637) were misleading, 5% (30/637) were true, and 2% (13/637) were exaggerated.<sup>152</sup> Robert F. Kennedy Jr. in his book titled *The Real Anthony Fauci. Bill Gates, Big Pharma and the Global War on Democracy and Public Health* stated that by funding and putting pressure on the media, scientific journals, government agencies and scientists, Fauci and Gates are ruthlessly censoring the opposition.<sup>153</sup>

Referring to the previously cited data, I can conclude that anti-science is becoming mainstream, and infodemic – a public health dilemma.

According to the Royal Society (2022), governments and social media platforms should address the issue of scientific disinformation online. The market, as demonstrated by the pandemic, is a poor arbiter of truth. COVID-19 has shown that falsehoods can be harmful and, at times, deadly. In specific cases, governments should have the authority to censor deliberate lies and misinformation. The assessment of such misinformation should consider the intent of the perpetrator, the scale and likelihood of harm, and the timing of its impact. A falsehood that does not result in harm would not justify censorship, whereas deliberate deception posing an immediate, certain, and serious threat should prompt action. Deliberate lying, which threatened inevitable, certain and serious harm, requires action.<sup>154</sup> According to Browson et al. (2024), public health has always been politicised. However, during the pandemic, public health became more politicised than ever before, and this growing politicisation has contributed to a broader decline in trust in both government and science. The politicisation of public health is closely linked to electoral polarisation. This occurs when sections of the population adopt increasingly divergent views on political parties and their members (affective polarisation) or on ideologies and policies (ideological polarisation). Both polarisation and politicisation fuel the infodemic.<sup>155</sup> Political leadership plays a critical role in shaping public health messaging in the media. Some leaders exhibit strong leadership, characterised by clear communication, empathy, and alignment between scientific findings and political decisions - for example, the statements of New Zealand's Prime Minister Jacinda Ardern or Germany's Chancellor Angela Merkel. In contrast, opportunistic leadership may involve deliberate misinformation, as seen in statements by US President Donald Trump or Brazil's former president Jair Bolsonaro. Another significant challenge is the media's tendency to favour sensationalist,

<sup>150</sup> Brownson R.C., Erwin P.C., "Revisiting The Future of Public Health: The Good, the Bad, and the Ugly", Am J Public Health, 2024 May; 114(5):479-485. doi: 10.2105/AJPH.2023.307558. Epub 2024 Mar 15. PMID: 38489498; PMCID: PMC11008290, https://pubmed.ncbi.nlm.nih.gov/38489498/.

<sup>151</sup> Brownson R.C., Burke T.A., Colditz G.A., Samet J.M., "Reimagining Public Health in the Aftermath of a Pandemic", Am J Public Health, 2020 Nov; 110(11):1605-1610. doi: 10.2105/AJPH.2020.305861. Epub 2020 Aug 20. PMID: 32816552; PMCID: PMC7542265.

<sup>152</sup> M. Islam et al., COVID-19 vaccine rumors and conspiracy theories: The need for cognitive inoculation against misinformation to improve vaccine adherence, Plos One 2021, https://pubmed.ncbi.nlm.nih.gov/33979412/.

<sup>153</sup> Robert F. Kennedy Jr., The Real Anthony Fauci: Bill Gates, Big Pharma, and the Global War on Democracy and Public Health [Polish edition: Prawdziwy Anthony Fauci. Bill Gates, Big Pharma i globalna wojna przeciwko demokracji i zdrowiu publicznemu, Empik].

<sup>154</sup> Horton R., "Offline: A lie at the heart of public health", Lancet, 2022 Feb 19;399(10326):704. doi: 10.1016/S0140-6736(22)00312-9. PMID: 35183286, https://pubmed.ncbi.nlm.nih.gov/35183286/.

<sup>155</sup> Brownson R.C., Erwin P.C., "Revisiting The Future of Public Health: The Good, the Bad, and the Ugly", Am J Public Health, 2024 May; 114(5):479-485. doi: 10.2105/AJPH.2023.307558. Epub 2024 Mar 15. PMID: 38489498; PMCID: PMC11008290, https://pubmed.ncbi.nlm.nih.gov/38489498/.

rapid news coverage over carefully formulated, balanced scientific communication.<sup>156</sup> According to Loner et al. (2023), research into political discourse has highlighted how different leaders have framed science in their messaging. UK Prime Minister Boris Johnson declared that representing science is an element of national pride. We will build on the experience and originality of our scientists, who have enabled the UK to contribute more to the global fight against COVID-19 than any other comparable country. Italy's President Sergio Mattarella emphasised the ethical representation of science. He said that the invention of the vaccine was the result of bold choices, scientific progress, conscientious behaviour, a widespread sense of civic responsibility, and the convergence of institutions and citizens. European Commission President Ursula von der Leyen emphasized that science plays a crucial role in fostering European integration, highlighting how the combination of financial investment and scientific progress can drive innovation and bring new products to the market.<sup>157</sup>

In conclusion, the Public Health Committee of the Polish Academy of Sciences recommends that national health and pro-health policies be based on scientific evidence and best practices from other countries. It advocates for effective public information strategies and the development of strong political leadership to foster public trust. The institutionalised cooperation of politicians with expert scientific bodies is also recommended, provided that goodwill is maintained on both sides. However, it is ultimately political decision-making that determines success in public health policy.

#### Prof. Marek Krawczyk MD PhD, Dr. h.c. mult.

Full Member of the Polish Academy of Sciences and Dean of the 5th Division of Medical Sciences of the Polish Academy of Sciences

The project Polish Health. Evaluation of Selected Elements of the Health System in Poland Based on Scientific Evidence and Good Practices of Other Countries was launched in 2022 on the initiative of the Public Health Committee of the Polish Academy of Sciences. Sixty-four Polish experts were invited to contribute to 14 expert reports. The project focuses on the analysis of public health, its connection with restorative medicine, the social environment, and the economy. The main objective is to promote education and the dissemination of science. The target audience includes Polish policymakers, journalists, and all health professionals, while also aiming to reach the wider public. The ultimate goal is to incorporate the project's recommendations into national health policy programs. Only genuine leadership and public trust in state health policy can make the healthcare system more efficient and enable the implementation of fully effective programs and interventions. Long-term, best-practice strategies and projects – particularly in public health – are crucial to improving the overall health of society. Modern healthcare systems focus on preventive healthcare, restorative and supportive care, and health promotion. Effective planning and implementation of health policy require the coordination of initiatives across different levels of state and local government. It is essential that various branches of public authority work together rather than hinder one another. The successful coordination of health policy efforts demands a clear division of responsibilities and appropriate legal frameworks.<sup>158</sup>

On behalf of the Presidium of the Polish Academy of Sciences, and based on the findings of *Polish Health 2.0*, we prepared a statement on public health in Poland, which was submitted to the Prime Minister and the Minister of Health. Unfortunately, we have received no response. Additionally, we compiled a report highlighting the rising prevalence of obesity, diabetes, and even strokes

<sup>156</sup> The Lancet – Editorial, August 2020.

<sup>157</sup> Loner E., Fattorini E., Bucchi M., "The role of science in a crisis: Talks by political leaders during the COVID-19 pandemic", PLoS One, 2023 Mar 24;18(3): e0282529. doi: 10.1371/journal.pone.0282529. PMID: 36961803; PMCID: PMC10038249, https://pmc.ncbi.nlm.nih.gov/articles/PMC10038249/.

<sup>158</sup> Polish Academy of Sciences. Public Health Committee, Ważne obszary dla poprawy systemu ochrony zdrowia w Polsce – głos naukowców PAN i zaproszonych ekspertów [Important areas for improving the health care system in Poland – the voice of PAN scientists and invited experts], https://pan.pl/wazne-obszary\_dla\_poprawy\_systemu\_ochrony\_zdrowia\_w\_polsceglos\_naukowcow\_pan\_i\_zaproszonych\_ekspertow/.



among Polish children, attributing these issues in part to the absence of physical education in schools. This is yet another example of how policymakers react – or rather, fail to react. We sent letters to the President of the Republic of Poland and the Prime Minister outlining precisely the concerns that are being discussed here today. Once again, there was no response. If this expert body manages not only to bring the Minister to the opening session but also to ensure that they listen to the debates and take concrete action, then we will have achieved a real success.

#### The Impact of the Pandemic and War on Population Health Security – The Role of Public Services

#### Paweł Grzesiowski MD PhD

#### **Chief Sanitary Inspector**

Today, I return from a meeting of the World Health Organization (WHO) on public health security and measures aimed at safeguarding populations from various threats, extending beyond infectious diseases. This gives me the opportunity to share with you the most up-to-date concepts in this field.

Before I do so, however, I would like to highlight several key aspects that, in my view, are crucial to our efforts. One fundamental point – which we are all aware of, but often take it for granted – is that **today, we live at least 2.5 times longer than we did 120 years ago**. In the 1950s, the average life expectancy was approximately 40 years, so let us reflect on the diseases that posed a challenge then, compared to those we face today. As life expectancy increases, it inevitably brings new and additional health challenges. We are no longer primarily concerned with accidents or acute infections – issues that plagued humanity in the aftermath of World War II. Back then, infectious diseases linked to living conditions and food quality were among the most pressing concerns. Today, however, we are dealing with entirely new health challenges related to ageing populations, as more people reach an advanced age and require medical support in a variety of contexts. **In the European Union, the average life expectancy is now nearly 78 years for men and 83 years for women.** Why do I say "nearly"? Because the past two years have had a profound impact on these statistics. This brings me to a key point in my upcoming presentation before the Council of the European Union: **The COVID-19 pandemic was the most significant disruption to the steady increase in global life expectancy in over a century.** 

The pandemic has reduced life expectancy by as much as 6-7 years in some countries. This decline is primarily due to the fact that the virus predominantly affected the elderly, significantly shortening overall life expectancy. And for this reason, the average life expectancy has been shortened. However, we must also consider other health risks. A natural process associated with ageing is the increase in body fat and the consumption of highly processed foods. These factors contribute to chronic inflammation, which can, in turn, trigger severe immune responses, as seen in COVID-19. Similar effects are also linked to smoking, substance use, and environmental factors such as air pollution (smog) and toxic compounds, all of which contribute to declining public health. And we are talking here about the context of mass impact, i.e. public health. Another critical factor is global mobility. People travel extensively, which increases the risk of importing diseases uncommon in their home countries, such as malaria and dengue fever. Each pandemic follows its own trajectory, and many of you may be following the evolution of the H5N1 virus - commonly known as avian influenza. However, it increasingly appears to be a mammalian virus. At present, we are in the first phase, where the virus circulates among animals. The virus is getting closer to humans, as evidenced by the outbreak among cows in the United States, which has already resulted in human transmission. The key question is when and how the virus might mutate to enable sustained human-to-human transmission. At this stage, we are in the first or second phase, but the virus continues to evolve, and human cases are increasing. This virus could become the next pandemic threat. Are we prepared for a surge in serious illnesses and complications? This is an open question – one I leave for discussion. We were not prepared for COVID-19, as the first two years of the pandemic clearly demonstrated.



Those two years resulted in seven million confirmed deaths, but the real number is estimated to be five times higher. In total, around 30 million people died within just two years. This level of mortality due to a single infectious disease has not been seen since the 1918 Spanish flu pandemic. Let's not forget that the 1918 influenza outbreak, caused by the H1N1 virus, spread worldwide, infecting one-third of the global population and causing tens of millions of deaths. It remains one of the most tragic events in the history of medicine. Let us remember that excess mortality due to COVID-19 primarily affected the elderly. In 172 countries, life expectancy declined by up to six years, whereas in only 32 countries did it increase. In Europe, countries like Norway and Denmark successfully mitigated the impact by implementing early and stringent containment measures. Poland paid a high price for prematurely declaring in May 2020 that the virus had been defeated. The assumption that mass outbreaks would not occur proved incorrect, as demonstrated by the autumn 2020 wave. Let us remember that since the emergence of the Omicron variant, COVID-19 has been regarded as a milder disease. Severe acute complications are now rare. However, the virus continues to have a significant impact on the endocrine, immune, and nervous systems, leading to long-term health disruptions. We are exposed to a virus with a high potential for causing lasting, chronic health issues, leading to long-term health consequences. At present, it is estimated that approximately 10–15% of COVID-19 survivors develop post-COVID syndrome. In adults, post-COVID syndrome (often referred to as long COVID) refers to chronic health consequences resulting from infection with the SARS-CoV-2 virus. It can occur in individuals who experienced severe illness, but also in those with mild or asymptomatic cases of COVID-19. Symptoms of long COVID can persist for several months and significantly impact daily life. The higher the number of COVID-19 infections a person experiences, the greater their risk of developing long-term complications. Given the current high incidence rates and low public interest in vaccination, we must consider the potential consequences: a significant portion of the population – especially young, working-age individuals – may develop long **COVID.** This will lead to increased absenteeism from work, family responsibilities, and social life, further straining public health systems and economic productivity. Vaccination remains crucial in preventing long-term complications of COVID-19. While vaccines do not prevent infection, they significantly reduce the risk of long COVID. This is very important, although we know that the vaccine will not prevent us from getting sick, but it actually reduces the risk of postcovid syndrome. A critical question remains: Have we learned from our pandemic experience? One innovative approach involves wastewater surveillance, a method used by the National Institute of Public Health (NIZP-PZH) in collaboration with the Sanitary Inspection and municipal utilities. This technique allows early detection of infection waves - typically two or three weeks in advance. We can also assess vaccination trends, which remain concerning. In 2021, challenges included high infection rates and limited vaccine access, A trend that persisted into 2023. While the situation has improved slightly, preventive healthcare has lost momentum since the pandemic. A notable example is the resurgence of pertussis (whooping cough), with cases currently at an alarmingly high level in Poland. This is not just a Polish issue - the entire European region is experiencing a surge. While some speculate this may be part of the expected five-year epidemic cycle, the scale of the outbreak has exceeded expectations.

The second major public health challenge is armed conflicts. Human history has been shaped by continuous migration, and every war results in mass displacement. Wherever conflicts occur, civilians flee, creating large populations of migrants. Each of these mass migration crises leaves long-term public health consequences. Historically, wars have been accompanied by devastating disease outbreaks, such as Spanish flu, cholera, smallpox, and the plague. Today, as armed conflicts unfold on the borders of the European Union, we see a resurgence of infectious diseases in war-affected regions. This includes diphtheria, enteric bacteria (e.g., Salmonella), and typhoid fever. A particularly concerning issue is tuberculosis (TB), which remains significantly more prevalent in Asia and Africa than in Europe. As a result, migration flows from these regions increase the risk of TB transmission across Europe. The World Health Organization (WHO) has observed a shift in the global TB burden, as populations with high TB prevalence relocate to new regions. This trend is not limited to Ukraine and Belarus – the primary and closest sources of recent migration



- but also extends to countries such as the Philippines, Indonesia, and several African nations. Currently, the largest outbreaks of tuberculosis - including multidrug-resistant TB (MDR-TB) are concentrated in Southeast Asia (India, the Philippines) and Africa. Another significant risk tied to conflict is the interruption of routine vaccination programmes. Measles, for example, remains a potential epidemic threat, particularly in war-torn regions where immunisation rates have dropped. Fortunately, in many European countries, population immunity remains high, but low vaccination rates in conflict zones could lead to future outbreaks. Fortunately, here we have a much higher population immunity and measles is not an epidemic problem at the moment, but potentially a danger. Beyond infectious diseases, migrants fleeing war zones face a range of serious health challenges. Injuries and trauma resulting from conflict-related violence and accidents often require urgent medical attention. The interruption of treatment for chronic diseases, such as cancer, forces many patients to seek medical care in host countries after hospitals in their home regions have been destroyed. Poor living conditions in refugee settings exacerbate the spread and severity of infectious diseases, further complicating public health responses. Mental health disorders, including post-traumatic stress disorder, anxiety, depression, and substance abuse, are prevalent among displaced populations who have endured the psychological impact of war and forced migration. Maternal and child health risks, particularly pregnancy complications, increase significantly in conditions of displacement, where access to prenatal and postnatal care is limited. And with this, we must also be aware that the world is already facing this challenge and will continue to do so. Cross-border data exchange is crucial in the migration context. Without it, effective public health management becomes nearly impossible. As Poland has welcomed over a million migrants from Ukraine, it is essential to understand the health challenges of this population, to cooperate, and to ensure the continuity of medical treatment, as in the case of tuberculosis or HIV/AIDS. These health concerns do not disappear simply because an individual has crossed a border. The World Health Organization (WHO), the European Centre for Disease Prevention and Control (ECDC), and the United Nations Children's Fund (UNICEF) strongly advocate for the implementation of Early Warning and Response Systems. A comprehensive network of monitoring systems must be established to provide data before an outbreak occurs, before an epidemic or pandemic fully develops. Only through such early intervention can we take timely action and, at the very least, mitigate the impact of such events.

The third challenge for public health is the growing resistance of microorganisms to drugs. It is important to recognize that the countries from which refugees or war victims originate have different antibiotic usage practices than those in developed nations. Consequently, we observe a significantly higher prevalence of multidrug-resistant bacteria.

To summarize, what do we currently have to offer in terms of public health services? We must acknowledge that the traditional method of passive case recording by doctors in hospitals or primary care units is no longer adequate for addressing contemporary challenges. We need to enhance event-based monitoring, meaning that when an incident occurs, even if it is not yet identified as a disease, it should activate public health mechanisms. Syndromic surveillance is key, focusing not just on identifying specific bacteria or viruses but on detecting trends such as an increase in pneumonia or diarrheal cases. Monitoring excess mortality is also crucial, as the officially recorded cause of death often does not reflect the underlying condition that led to the severe health deterioration. These are the situations that we must address with urgency and refine our approach towards. Monitoring must be proactive, meaning that we actively seek out cases and analyse the data within the healthcare system rather than passively waiting for doctors to report cases via standardized forms such as the ZKZL, B, or others. We strive for close collaboration with the Centre for e-Health and the National Health Fund, both of which collect essential data on disease diagnoses. By utilizing syndromic diagnostics - focused on identifying patterns of symptoms rather than waiting for confirmed biological causes – we can detect potential health events at an early stage. This approach allows us to intervene before a full outbreak occurs. The next step is to analyse the data and then make informed decisions. Rapid response teams must be operational, not only to swiftly diagnose emerging issues but also to implement effective solutions. These teams should be



equipped to develop tailored response strategies for each specific case, ensuring that public health interventions are both timely and efficient. A relevant example is the current health crisis in the Democratic Republic of the Congo, where hundreds of people are suffering from an unidentified illness with excess deaths being recorded. A team of international experts is already on-site, and the World Health Organization is actively supporting local authorities in managing medical care. The precise cause remains unknown, but given that the majority of victims are children, potential explanations include a combination of malnutrition, malaria, inadequate medical care, or seasonal climate conditions. The significance of this event lies not only in the disease itself but in the global response – prompt international action ensures that if this outbreak involves an infectious agent, transmission can be contained before spreading further. A final critical aspect is data analysis and decision-making in public health. This remains an area in which Poland has yet to develop sufficient precision and efficiency. The World Health Organization has been investing in opensource intelligence, meaning the systematic monitoring of digital networks, radio, television, print media, and even informal conversations among individuals. In some regions, information spreads primarily through word-of-mouth, making these early signals a crucial tool in detecting emerging health threats. While such methods may not be as applicable in highly digitalized environments, in many parts of the world, these indirect reports serve as the first indicator that a serious public health event may be unfolding, warranting further verification and investigation.

The European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Environment Agency (EEA), the European Chemicals Agency (ECHA), and the European Centre for Disease Prevention and Control (ECDC) have pledged to collaborate under the One Health initiative. Their joint statement was signed during the conference *One Health – One Health for All, All for One Health*, which took place on 13 November 2023 in Luxembourg. In light of the continuously emerging threats to public health in Europe, it has become increasingly evident that human health is intrinsically linked to the health of animals, plants, and well-functioning ecosystems. The One Health approach appears to be a crucial response to these threats, emphasizing the necessity of interdisciplinary and cross-sectoral cooperation across various fields. Key issues addressed within the One Health framework include chemical pollution, food safety, antimicrobial resistance in pathogenic bacteria, zoonotic and re-emerging infectious diseases, climate change, land use, and biodiversity loss.

Poland is not a leader in public health, but we can highlight certain areas where our monitoring systems are highly developed. One such area is potable water safety. We have mapped all water supply systems in Poland, and this sector functions without significant problems. The severe flood, which posed an extreme challenge to water supply management, proved that the system is effective. Another positive example is food safety. Every year, we conduct hundreds of thousands of food tests within the national sanitary inspection network. We have border sanitary and epidemiological stations through which all food products entering the country must pass. No one can bring food products into Poland without proper testing. We also have well-equipped foreign stations prepared for food testing, including food transported under cold chain conditions. Another area where we have made significant progress is chemical supervision. This is a relatively new and highly complex field, but thanks to the codification of virtually all so-called precursors, we have effectively eliminated problems with designer drugs. Over the past few years, we have established a system that ensures any new product with potential psychoactive effects is quickly withdrawn. A recent example is the regulation of products derived from Amanita muscaria (fly agaric mushroom). Within just a month and a half of the first reports that fly agaric was being used as a psychoactive substance, we successfully banned its sale, closing a legal loophole that had previously been exploited. These cases demonstrate that the system under the Chief Sanitary Inspectorate functions effectively in preventing incidents that could pose a threat to public health. However, infectious diseases remain an area where Poland has significant room for improvement. The Polish system relies on passive monitoring, meaning we wait for reports from doctors before responding to potential epidemic threats. In my opinion, this approach requires optimization to ensure more proactive disease surveillance and early intervention.



In conclusion, during our Polish Presidency of the Council of the European Union, we can highlight the safety of drinking water and food, as well as the supervision of chemicals. These areas form part of strategic health security, which is one of the seven priorities of the Polish Presidency announced by the current government. However, despite high vaccination coverage – exceeding 90 percent in some areas – Poland still relies on a paper-based vaccination system rather than a digital one. A recent audit by the Supreme Audit Office exposed numerous deficiencies in this system. Efforts are underway to improve vaccination record-keeping, with the development of an electronic vaccination card template. From January 2025, a nationwide census of vaccinated children in Poland will begin. A total of 7.5 million children, from birth to the age of 19, will be assessed by inspectors from the Chief Sanitary Inspectorate. Inspectors will visit vaccination centres to verify the number of vaccinated children and identify those who have not been immunised.

### Prof. Małgorzata Myśliwiec MD PhD

Provincial Consultant in Paediatric Endocrinology and Diabetology, Head of the Department and Clinic of Paediatrics, Diabetology and Endocrinology of the Medical University of Gdańsk, Plenipotentiary of the Board of the Polish Diabetes Association for Cooperation with the Ministry of Health and the Parliament

In the field of paediatric diabetology and endocrinology, Poland ranks among the world's leaders. Real World Evidence (RWE) data, presented in 2021 at the EASD, ATTD, and ISPAD congresses, demonstrated outcomes from over a dozen countries between August 2020 and July 2021, involving approximately 13,000 patients treated with modern insulin pumps integrated with continuous glucose monitoring (CGM) systems. The real-world data confirmed that Polish patients are among the most metabolically well-controlled, achieving an average Time in Range (TIR) - the period within normoglycaemic levels - of 81.2% (with the standard target TIR >70%). Among children under 15 years of age with type 1 diabetes, Poland achieved the best metabolic control, with a TIR of 82.3%. Additionally, findings published by Polish diabetology experts in 2021 in the journal Diabetes Technology & Therapeutics provided the first comprehensive analysis of RWE data for Polish diabetes patients. These results confirmed that Polish patients use CGM scanning (FGM) more effectively than the global average, with 21.4 scans per day compared to the worldwide average of 13.4 scans. This allows them to achieve superior glycaemic control. These outcomes highlight how well Polish patients utilise advanced diabetes technologies. Modern insulin formulations, insulin delivery systems, and CGM significantly reduce the risk of acute complications, including hypoglycaemia, and improve glycaemic control. Such innovations enhance the quality of life for children and adolescents with type 1 diabetes, granting them greater freedom and relief from the burdens of intensive disease management.

Poland can share several "export-ready" solutions in the field of health prevention with other EU Member States:

The first such initiative is the introduction of the health care service Screening for familial hypercholesterolaemia (FH) as part of the health balance examination conducted during the annual mandatory pre-school preparation as a guaranteed benefit under primary health care. Ultimately, screening for FH will be incorporated into the six-year-old's health check-up, including lipid parameter assessment: total cholesterol, HDL cholesterol, non-HDL cholesterol, LDL cholesterol, and triglycerides.<sup>159</sup>

The second flagship initiative is the launch of a pilot programme in the Mazowieckie Province for screening the early detection of type 1 diabetes, covering 20,000 children. Every child

<sup>159</sup> Recommendation No. 133/2024 of 22 November 2024 of the President of the Agency for Health Technology Assessment and Tariff System on the justification for the qualification of the health care service *Screening for familial hypercholesterolemia as part of the health balance examination conducted during the mandatory annual pre-school preparation* as a guaranteed health care service, https://bip.aotm.gov.pl/assets/files/zlecenia\_mz/2024/167/REK/RP\_133\_2024\_hipercholesterolemia proc.20rodzinna\_BIP.pdf.

participating in the programme will have capillary blood collected via a simple finger prick. The blood sample will be tested for autoantibodies typical of type 1 diabetes (GADA, IA-2A, ZnT8). The presence of these autoantibodies indicates inflammation of insulin-producing pancreatic beta cells and can be detected years before the onset of clinical symptoms. Parents of children aged 2–17 years without a prior diabetes diagnosis can enrol in the programme. Early detection of type 1 diabetes provides multiple benefits, including a reduction in the risk of life-threatening diabetic ketoacidosis, improving patients' quality of life as an early diagnosis enables better initial outcomes and a smoother transition into disease management, and lower stress levels for both patients and families. Identifying genetic predispositions and environmental triggers will also support the development of preventive strategies for type 1 diabetes.

The third initiative highlights Poland's status as the best-performing country among 53 European nations in achieving optimal metabolic control in type 1 diabetes patients since **2020.** The most effective diabetes management comes from automated insulin delivery systems, often referred to as an "artificial pancreas" or "closed-loop systems," which integrate insulin pumps with continuous glucose monitoring (CGM) technology. During Poland's first EU Presidency in 2011, then-Minister of Health Ewa Kopacz introduced full public reimbursement for insulin pumps for children and young adults up to the age of 26. Since then, paediatric diabetologists have maximised the potential of this therapy, ensuring that Polish children and adolescents with type 1 diabetes achieve the best possible treatment outcomes. This achievement is consistently recognised at major international diabetology conferences hosted by the American and European Diabetes Associations. However, Poland remains one of only four EU countries – alongside Latvia, Estonia, and Bulgaria - that do not provide public reimbursement for insulin pumps for adults over 26. The success of the paediatric insulin pump programme clearly demonstrates the value of investing in these technologies. Poland's EU Presidency presents a crucial opportunity to align with the rest of the European Union, ensuring comprehensive reimbursement for insulin pump therapy and reinforcing its commitment to advanced diabetes care and improved public health outcomes.

#### **Prof. Maciej Banach MD PhD**

President of the Polish Lipid Association, Undersecretary of State at the Ministry of Science and Higher Education (2010-2012), Vice-Rector for the Medical College of the John Paul II Catholic University of Lublin, and Assistant Professor at the Johns Hopkins University School of Medicine, Baltimore, USA

The latest World Health Organization (WHO) report, *Action on Salt and Hypertension: Reducing the Cardiovascular Disease Burden in the WHO European Region*, highlights that cardiovascular diseases (CVDs) are the leading cause of disability and premature death in the WHO European Region, which encompasses 53 countries across Europe and parts of Asia. These diseases account for 42.5% of all deaths, equating to approximately 10,000 fatalities per day.<sup>160</sup> I would like to stress that in Poland, approximately 180,000 people die each year due to cardiovascular diseases. Therefore, during the Polish Presidency of the Council of the European Union, I call for a dedicated EU budget to comprehensively address heart and vascular diseases, which remain the leading cause of mortality. In April 2025, as part of the Polish Presidency, we will announce the *European Plan for Prevention*, which will showcase existing tools and best practices from Central and Eastern European countries, with the aim of developing a comprehensive EU-wide strategy to combat cardiovascular diseases through a strong focus on prevention.<sup>161</sup> On this occasion, Poland can contribute by sharing proven public health and prevention strategies that have already been implemented or are on the verge of introduction. I believe that the following initiatives represent best practices that Poland can showcase during its Presidency as models for the EU.

<sup>160</sup> WHO, Action on salt and hypertension: reducing cardiovascular disease burden in the WHO European Region, 2024, https://bip.aotm.gov.pl/assets/files/zlecenia\_mz/2024/167/REK/RP\_133\_2024\_hipercholesterolemia proc.20rodzinna\_BIP.pdf.

<sup>161</sup> Co będzie zawierać Europejski Plan dla Prewencji? O inicjatywie mówi prof. Maciej Banach [What will the European Prevention Plan include? Prof. Maciej Banach talks about the initiative], https://ptlipid.pl/blog/2024/09/09/co-bedzie-zawierac-europejski-plan-dla-prewencji-o-inicjatywie-mowi-prof-maciej-banach/.



The first "export-worthy product" of the Polish Presidency is the introduction of health education as a compulsory subject in primary schools from 1 September 2025. This is the culmination of two decades of work by leading experts and stakeholders. If implemented effectively, it has the potential to become a game changer in disease prevention and health promotion. It can be a game changer when it comes to prevention.

The second initiative is the introduction of coordinated care for primary prevention within the Prevention 40+ Programme. This programme enables comprehensive screening, which could subsequently be integrated into a coordinated care model within the primary healthcare system. In Poland, most patients present multiple overlapping risk factors, and thus, a coordinated approach to primary prevention cannot focus solely on a single risk factor. The integration of primary prevention into coordinated PHC, including consultations with cardiologists, would provide high-quality care for at-risk patients. Developing a structured and harmonised approach to primary prevention at the EU level should be a priority for the Polish Presidency, particularly as we already have strong foundations based on existing national programmes.

The third key initiative that Poland can take pride in is the fact that we have 700 certified lipidologists – specialists dedicated to managing the most common cardiovascular risk factor: lipid disorders. Poland has developed a Network of Lipid Centres, which focuses on diagnosing and treating patients with lipid disorders. These centres are certified as Centres of Excellence for the Treatment of Lipid Disorders under the Polish Lipid Society (PTL) and are integrated into the European Atherosclerosis Society (EAS) Network of Lipid Centres.<sup>162</sup>

# Prof. Piotr Szymański MD PhD

Chair of the Regulatory Committee of the European Society of Cardiology, Head of the Centre for Clinical Cardiology and Rare Cardiovascular Diseases at the State Medical Institute (PIM) of the Ministry of the Interior and Administration in Warsaw

The top priority of the Polish Presidency is to secure the adoption of a European Union Cardiovascular Health Plan, modelled on Poland's National Cardiovascular Disease Programme 2022-2032. In 2023, the European Society of Cardiology (ESC) – the world's largest cardiology society – organised a conference at the European Parliament. A year later, in December 2024, the Council of the European Union included the EU Cardiovascular Health Plan<sup>163</sup> in its conclusions. I would like to emphasise that every day, 4,000 people in Europe die from cardiovascular diseases. Heart disease accounts for more deaths than all cancers combined. This is why the European Society of Cardiology and the Polish Society of Cardiology have consistently called for prioritising cardiovascular Health Plan as its flagship programme for the upcoming parliamentary term. We call on the Polish Presidency to facilitate the adoption of this plan, ensuring it is appropriately funded. The European cardiology community has high expectations for the Polish Presidency in this regard. The National Cardiovascular Strategies in the European Union in Cardiovascular Strategies in the European Union.<sup>164</sup>

The second "export product" Poland can proudly showcase at the EU level is the programme for the care of pregnant women with heart disease. Cardiovascular diseases are the leading cause of death among women, surpassing male mortality rates. Therefore, prevention in this area is not only a healthcare priority but also an essential measure in addressing gender-based health inequalities. There is significant potential for action in this field at both the national and European levels, supported by expert recommendations and policy frameworks. Furthermore, in the broader

<sup>162</sup> Polish Lipid Society, Sieć Centrów Lipidowych [Network of Lipid Centres], https://ptlipid.pl/siec-centrow-lipidowych/.

<sup>163</sup> European Commission announces EU Cardiovascular Health Plan, https://www.escardio.org/The-ESC/Press-Office/Press-releases/eu-health-ministers-adopt-landmark-council-conclusions-on-cardiovascular-health.

<sup>164</sup> Narodowy Program Chorób Układu Krążenia na lata 2022–2032 [National Cardiovascular Disease Programme 2022–2032], https://www.gov.pl/web/zdrowie/narodowy–program–chorob–ukladu–krazenia2.



context of reproductive health, we propose a comprehensive programme for the care of pregnant women with cardiovascular disease. This is a critical element in ensuring maternal and neonatal health and safety, as cardiovascular disease during pregnancy remains one of the leading causes of maternal mortality.

Recently, we had a meeting with the President of the U.S. Food and Drug Administration (FDA), who raised concerns over the diminishing influence of scientific experts on public opinion. The decline in public trust in scientific authorities has led to a situation where public perception is increasingly shaped by social media influencers and celebrities, rather than qualified specialists.

### Prof. Janina Stępińska MD PhD

Director of the National Institute of Cardiology, Chair of the National Council for Cardiology

The European Society of Cardiology classifies Poland as a high-risk country for cardiovascular disease. Poles have shorter life expectancy than Western Europeans, and cardiovascular diseases remain the leading cause of death. Poland can contribute innovative solutions in the field of cardiovascular prevention to the European Union.

The first "export-worthy product", or a key initiative to be highlighted during the Polish Presidency, is an integrated approach to cardiovascular and oncological prevention, focusing on the elimination of shared risk factors. Cardiovascular diseases and cancers share both modifiable and non-modifiable risk factors. Optimising lifestyle-related cardiovascular risk factors – including smoking cessation, reducing alcohol consumption, maintaining adequate physical activity, and promoting a healthy diet – is of critical importance.

The second major initiative is the National Cardiovascular Disease Programme 2022-2032 (NPChUK). This programme addresses both the current and projected increase in cardiovascular disease (CVD) incidence and its consequences, including high mortality rates. The NPChUK aims to reduce morbidity and mortality from CVD and align key health indicators (life expectancy, mortality rates, and disease prevalence) with EU averages; minimise regional disparities in CVD incidence and mortality, particularly those related to healthcare accessibility; lower the prevalence of classic CVD risk factors such as hypertension, smoking, dyslipidaemia, obesity, and diabetes; improve the organisation of cardiology research and enhance the capacity for scientific research and innovation, particularly in identifying high-risk populations, understanding key causes of CVD, and developing advanced diagnostic and therapeutic solutions. The NPChUK encompasses actions in five key areas: human resources, education, prevention and lifestyle, patient care, scientific research and innovation, and improvements in the cardiology care system.<sup>165</sup>

The third key initiative is KOS-Zawał (Coordinated Care Programme for Patients After Myocardial Infarction). Since 2017, this programme has provided patients with comprehensive post-infarction care, including diagnosis, acute-phase treatment, a follow-up visit within 14 days after hospital discharge, access to cardiac rehabilitation, and specialist care. If necessary, patients receive advanced electrotherapy, including the implantation of cardiac support devices. Data from the National Health Fund (Narodowy Fundusz Zdrowia – NFZ) demonstrate that participation in the KOS-Zawał programme significantly reduces post-infarction mortality rates, while cardiac rehabilitation lowers the risk of heart failure following a myocardial infarction.<sup>166</sup>

<sup>165</sup> IKARD, Narodowy Program Chorób Układu Krążenia na lata 2022–2032 [National Cardiovascular Disease Programme 2022-2032], https://www.ikard.pl/narodowy-program-chorob-ukladu-krazenia/informacje.html.

<sup>166</sup> National Health Fund (NFZ), Funkcjonowanie programu KOS-zawał [Coordinated Care Programme for Patients After Myocardial Infarction], https://ezdrowie.gov.pl/portal/home/badania\_i\_dane/zdrowe-dane/raporty/kos-zawal.



#### Prof. Marek Postuła MD PhD

Head of the Pharmacogenomics Unit at the Medical University of Warsaw

I represent the Medical University of Warsaw as well as the Polish Society for Longevity Medicine. The Society's primary aim is to extend the lifespan of Polish citizens while maintaining full health. It also conducts scientific research to enhance our understanding of the ageing process and how to promote healthy ageing. The Society focuses on prevention not only from a population-based perspective but, above all, through a personalised approach.

The first key initiative and an "export-worthy" product for the Polish Presidency is genetic testing, available as part of the *Prevention 40*+ programme. These tests allow for the assessment of genetic predisposition to cancers such as breast, prostate, and colorectal cancer. The package of preventive health examinations under the *Prevention 40*+ programme is accessible to all citizens over the age of 40.

**The second priority should be nicotine prevention.** In terms of nicotine prevention policies, we should observe global best practices. The only effective method to combat nicotine addiction across different age groups is to reduce and ultimately eliminate exposure to nicotine products. In Poland, a wide range of nicotine-containing products is readily available, with no comprehensive legal regulations governing their composition, quality, and accessibility. Furthermore, taxation policies are highly inconsistent, as these products often benefit from significantly lower tax rates. Sweden remains the only EU country to have successfully reduced adult smoking prevalence to the targeted 5% level. In contrast, Poland's smoking rate stands at approximately 30% among the adult population. The European Society of Cardiology has repeatedly emphasised in its guidelines that economic measures – particularly taxation – are the most effective means of encouraging people to quit smoking.

#### **Prof. Ryszard Piotrowicz MD PhD**

Member of the Committee on Clinical Sciences of the Polish Academy of Sciences, Committee on e-Health, Telemedicine and Artificial Intelligence of the Polish Cardiac Society

Preventive healthcare and public health are concerns for the entire population, particularly in the context of cardiovascular diseases. Digital solutions play a crucial role in complementing and integrating all types and levels of healthcare services within the health system.

**One of the flagship initiatives that Poland can showcase during its Presidency of the Council of the European Union is hybrid cardiac telerehabilitation**. Comprehensive cardiac rehabilitation (CR) is a cornerstone of secondary prevention in cardiovascular disease (CVD). According to the guidelines of the European Society of Cardiology, CR holds the highest class of recommendation and the strongest level of scientific evidence as an effective treatment for patients with ST-segment elevation myocardial infarction, those who have undergone myocardial revascularisation, individuals with chronic coronary syndrome, as well as patients with heart failure. The Section of Cardiac Rehabilitation and Exercise Physiology of the Polish Cardiac Society has published an expert opinion outlining the benefits of CR, its target groups, clinical indications, service organisation, and implementation methods. The report also discusses psychosocial risk factors that influence the effectiveness of CR and secondary prevention of CVD in patients undergoing rehabilitation. Comprehensive CR is a continuous process that should be initiated as soon as possible, carried out without interruption, and structured into multiple stages. Furthermore, it must be tailored to each patient's clinical condition and supported by their family, friends, and caregivers.<sup>167</sup> In Poland, health outcomes within the first 30 days following an acute cardiac event are comparable to those

<sup>167</sup> Jegier A., Szalewska D., Mawlichanów A., et al., "Comprehensive cardiac rehabilitation as the keystone in the secondary prevention of cardio-vascular disease", Kardiol Pol 2021; 79(7–8): 901–916, doi: 10.33963/KP.a2021.0066, https://journals. viamedica.pl/polish\_heart\_journal/article/view/85931/64152.

observed in leading European countries. However, within a year, we see a substantial loss of these patients due to the lack of implementation of secondary prevention measures, particularly cardiac rehabilitation. This situation highlights a major gap in post-hospital management. Based on evidence-based medicine (EBM), the omission of comprehensive cardiac rehabilitation as a standard post-discharge intervention constitutes a medical error. Currently, access to cardiac rehabilitation in Poland is alarmingly low, covering only 20% of eligible cardiac patients, meaning that 80% do not receive the rehabilitation they need. Moreover, there are significant regional disparities, with access rates ranging from as low as 1% in some areas to 40% in others. The issue of inadequate cardiac rehabilitation access is not limited to Poland – it remains a major challenge across Europe. European policymakers are actively seeking solutions to improve access and effectiveness. At present, no European country has implemented a cardiac rehabilitation system based on advanced digital technologies. Poland stands as a global pioneer, having introduced statefunded comprehensive hybrid cardiac rehabilitation in 2019.<sup>168</sup> This innovation enables remote delivery of cardiac rehabilitation to high-risk patients in their homes, ensuring that they receive continuous monitoring and support through a structured system. This initiative has significantly improved accessibility and helped mitigate regional inequalities in healthcare provision. The hybrid cardiac telerehabilitation system enables long-term telemanagement of patients following acute cardiac incidents, ensuring a full year of structured medical oversight. Implementing this approach could reduce post-myocardial infarction mortality rates by 20–30% within a year.

#### **Bernard Waśko MD PhD**

Director of the Polish National Institute of Public Health of the National Institute of Hygiene – National Research Institute

In the area of public health, there should be a political consensus and alignment among different groups to achieve long-term public health objectives. In Poland, there are significant disparities in health status between various social and economic groups. Preventive healthcare and public health require digitalisation.

The first initiative Poland can showcase during its Presidency of the Council of the European Union is the Online Patient Account (Internetowe Konto Pacjenta, IKP).<sup>169</sup> This is not only a platform for accessing certain existing healthcare services but also a database for collecting citizens' health data. It has the potential to serve as a monitoring tool for all preventive health activities and to address the issue of data silos, as mentioned by Professor Banach. Furthermore, it facilitates the integration of various population health risks, which are shared across different disease categories, as highlighted by Dr. Stępińska. This tool was introduced a few years ago, but it continues to be developed and enhanced with new functionalities. E-prescriptions, e-referrals, the ability to request prescriptions online, and SMS appointment reminders are among its key features. Let me remind you that all adult Polish citizens with a PESEL number automatically have an Online Patient Account (IKP), even if they are unaware of it or have never accessed it. Various records of provided healthcare services are continuously stored in the system. Currently, there are approximately 19 million registered users, with over one million actively using the IKP online application. And what can be found there? The platform includes functionalities such as physical activity tracking, dietary recommendations, hydration reminders, and risk assessment surveys related to lifestyle and health factors. This provides a foundation for expanding the system to comprehensively monitor participation in preventive healthcare, this is a solid foundation for expanding these functions to include monitoring all events related to participation in preventive healthcare, particularly in primary prevention. This would encompass infectious disease prevention, including all vaccinations – both mandatory and recommended – as well as health check-ups

<sup>168</sup> Internal directive no. 13/2019/DSOZ of the President of the National Health Fund of 6 February 2019, https://www.nfz.gov. pl/zarzadzenia-prezesa/zarzadzenia-prezesa-nfz/zarzadzenie-nr-132019dsoz,6878.html.

<sup>169</sup> Polish Ministry of Health, Online Patient Account (Internetowe Konto Pacjenta, IKP), https://pacjent.gov.pl/internetowe-konto-pacjenta.



conducted at different stages of life. For instance, these health balances take place in early childhood (ages 0–6) and later during the school years (ages 7–18). The system could integrate and track all relevant data, providing a comprehensive overview of the population's health status. This would facilitate evidence-based health policymaking and improve the effectiveness of public health interventions. For institutions like the National Institute of Public Health, access to such data and real-time analysis would enable the development of evidence-based health policies and facilitate the assessment of the effectiveness and efficiency of preventive interventions. The IKP could serve as a central knowledge hub – not only providing services to users but also integrating prevention-related data, breaking down silos, consolidating risk factor assessments, and enhancing population health monitoring. That would be the solution, without a doubt. It would eliminate silos, integrate various risk factors, and, most importantly, enhance the ability to effectively analyse the health status of the population.

# The second major initiative consists of projects developed by the National Institute of Public Health – National Institute of Hygiene (NIZP-PZH), including:

- 1. **The ProfiBaza system**, a digital platform providing public access to data on the health status of the population and the implementation of health programmes aimed at disease prevention and health promotion in Poland.<sup>170</sup>
- 2. **Publications by NIZP-PZH in the field of public health and preventive healthcare,** including the Knowledge Base on Health Inequalities, the Szczepienia.info (Vaccination Information) portal, epidemiological reports, and the biennial report Polish Population Health Situation and Its Determinants a comprehensive overview of the state of public health in Poland.<sup>171</sup>

# Igor Radziewicz-Winnicki MD PhD

President of the Management Board of PZU Zdrowie S.A, Undersecretary of State, Ministry of Health (2012–2015)

Today, I speak in a dual capacity. On one hand, I represent Powszechny Zakład Ubezpieczeń Spółka Akcyjna (PZU), the largest capital group in this part of Europe and the leading Polish insurer. On the other, I represent PZU Zdrowie, one of the largest nationwide medical operators. Our medical network consists of approximately 130 proprietary facilities, including imaging diagnostic laboratories, and 2,4 partner facilities across 600 cities in Poland. On the other hand, I represent PZU Zdrowie, which is one of the largest nationwide medical operators. Our medical network includes about 130 own facilities, including imaging diagnostic laboratories and 2,400 partner facilities in 600 cities in Poland.<sup>172</sup>

The first strategic priority, and an "export product," for the Polish Presidency is the digitisation of medical services, particularly in the domain of preventive healthcare. PZU Zdrowie is committed to advancing the digital transformation of its operational tools. However, Poland is still lacking a modern analytical database system that can comprehensively store and integrate health data. This is not just about accumulating information on the Online Patient Account (IKP). It is imperative that every laboratory test, imaging result, and medical consultation be systematically entered into a centralised medical information system. Currently, electronic medical records are scattered among different healthcare providers, with no unified access, which limits their efficiency. From my perspective, PZU is fully prepared to be a key partner in building such a system. We possess not only financial capital but also intellectual resources and expertise necessary for its development. There is a critical need to create a fully integrated database that consolidates and structures electronic medical records into a single repository. Furthermore, by leveraging artificial

<sup>170</sup> National Institute of Public Health – National Institute of Hygiene (NIZP-PZH), ProfiBaza, https://profibaza.pzh.gov.pl/node/161.

<sup>171</sup> National Institute of Public Health – National Institute of Hygiene, Sytuacja zdrowotna ludności Polski i jej uwarunkowania [Polish population health situation and its determinants] (a report), https://www.pzh.gov.pl/raport\_sytuacja-zdrowotna-ludnosci-polski-i-jej-uwarunkowania/.

<sup>172</sup> PZU Zdrowie, https://zdrowie.pzu.pl/.



intelligence and machine learning algorithms, we can unlock immense potential for predictive analytics, early disease detection, and more effective public health interventions. Large datasets hold extraordinary value for precision medicine and personalized healthcare solutions, which could significantly improve Poland's healthcare landscape.

The second strategic priority for the Polish Presidency is the humanisation of medicine, particularly in the context of preventive healthcare and public health policies. The low uptake of vaccinations in Poland is no longer a medical issue – it is a social communication crisis. Addressing this requires the involvement of not only healthcare professionals but also experts in anthropology, sociology, and cultural studies. The challenge is no longer about vaccine availability or medical knowledge but about how healthcare messages are communicated to the public. A case in point is the HPV vaccination programme. As an executor of a contract with the National Health Fund (NFZ), PZU Zdrowie dispatched a medical team to a school in Płock to vaccinate students aged 9-16 against HPV. The fact that parents actively resisted vaccination efforts despite clear medical evidence highlights a profound issue in public perception and trust. This shows that without a structured and specialised social communication strategy, even the best-designed health initiatives may fail to achieve their intended outcomes.

#### Artur Białkowski

Vice-President of the Management Board, Managing Director for Business Services, Medicover sp. z o.o.

For 29 years, Medicover's operations in Poland have focused on a broad spectrum of services, ranging from healthcare to wellbeing. Its portfolio includes preventive and outpatient care, specialist healthcare, innovative dental services, advanced in vitro procedures, and wellbeing solutions, including extensive sports and dietary offerings.<sup>173</sup> In the area of preventive healthcare and public health, Poland can leverage Medicover's experience in proprietary preventive healthcare programmes during its EU Presidency. These are ready-to-implement solutions that can be exported while also delivering measurable health outcomes within Poland.

The first initiative that Poland can showcase is the Lifestyle Change and Physical Activity Programme, designed to improve the health of patients with obesity who originally faced serious health risks. The programme organises structured physical activity for obese patients. While the goal is to make it accessible to the entire Polish population, it can also serve as a model for other European Union countries.

The second "export-worthy" initiative is the SMS Programme, an electronic school medicine system that enables easy registration of students' health assessments and generates reports for teachers, school principals, local governments, and parents, along with clear recommendations for improvement.

The third initiative is the Fit School Programme, which introduces innovative and engaging approaches to physical education (PE) classes to encourage students to participate actively. The programme is designed to support teachers in making lessons more engaging and motivating for children. It also includes instructional videos that parents can use to exercise with their children at home.

The fourth initiative is the Integration of Preventive Healthcare within Occupational Medicine. Through the provision of health services and employer-financed preventive healthcare programmes, Medicover plays a role in improving the health of the working-age population. Occupational medicine can serve as an effective tool for implementing both primary and secondary preventive measures.

<sup>173</sup> Medicover, https://www.medicover.pl/uslugi-medicover/poznaj-nas/.



#### **Justin Gandy**

Managing Director, MSD Polska

MSD has extensive experience in the field of vaccines and preventive health programmes.<sup>174</sup>

A key initiative that Poland can showcase during its EU Presidency as a model for the dynamic implementation of health prevention measures is the Universal HPV Vaccination **Programme**. This programme aligns with the objectives of the National Oncology Strategy for 2020-2030, complementing the existing free immunisation programme for children and adolescents by offering protection against diseases caused by HPV. From 1 September 2024, vaccinations under this universal programme will be available to children aged 9 to 14, including school-based vaccinations.<sup>175</sup> Poland can serve as an example of how clinical expertise and strong policymaking can drive the rapid expansion of HPV vaccination programmes. The country has already undergone significant growth and transformation in this field, and further milestones lie ahead. The key question now is how best to utilise this momentum – with high expectations and a fully operational platform for action. To ensure the programme's long-term success, we must prioritise data collection, digital health solutions, and monitoring tools that track vaccination coverage rates. These investments will strengthen public health, enhance disease prevention efforts, and ultimately benefit society as a whole. Comprehensive engagement is essential, with a strong foundation built on education and quality-of-life improvements. This is an opportunity to educate and empower society, even drawing on historical traditions of public health to highlight the importance of prevention. This discussion is not only about medical interventions but also about investing in the future - creating a robust policy framework, ensuring long-term financial sustainability, and developing lasting solutions that improve health outcomes both today and for future generations. In the area of prevention, we must embrace the concept of a "second life" by introducing progressive changes and innovations that will drive sustainable development and help achieve key public health goals. Ultimately, the time has come to implement everything we have been preparing for – to make Poland a true "jewel in the crown of Europe" in the field of preventive healthcare.

#### Prof. Brygida Kwiatkowska MD PhD

National Consultant in Rheumatology, Head of the Early Arthritis Clinic, Deputy Clinical Affairs Director of the National Institute of Geriatrics, Rheumatology and Rehabilitation in Warsaw

**Rheumatology requires a multidisciplinary approach.** A crucial aspect of treatment is the measurement of "remission value", where **remission is defined as the resolution or reduction of disease progression**. In immunologically mediated chronic inflammatory diseases such as rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), and axial spondyloarthritis (axSpA), **early diagnosis and effective treatment within the therapeutic window can halt disease progression and enable patients to maintain normal functionality**. Clinical remission has been shown to enhance disease control, resulting in significant economic benefits.<sup>176</sup> The EULAR 2024-2029 European Manifesto, published in 2024, aims to **promote a European response to the health and socio-economic challenges posed by rheumatic and musculoskeletal diseases** (RMDs).<sup>177</sup> EULAR highlights that over 200 RMDs affect approximately 120 million people – one in five Europeans. Virtually every EU citizen is likely to experience the physical, mental, economic, or social effects of RMDs, either personally or through family

<sup>174</sup> MSD, https://www.msd.pl/drugs-and-vaccines/.

<sup>175</sup> HPV vaccination, https://www.gov.pl/web/zdrowie/hpv.

<sup>176</sup> Ostor A.J., Sawant R., Qi C.Z., Wu A., Nagy O., Betts K.A., "Value of Remission in Patients with Rheumatoid Arthritis: A Targeted Review", Adv Ther. 2022 Jan;39(1):75-93. doi: 10.1007/s12325-021-01946-w. Epub 2021 Nov 17, PMID: 34787822; PMCID: PMC8799574, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8799574/.

<sup>177</sup> EULAR 2024 – 2029 European Manifesto, https://www.eular.org/eular.



members, friends, or colleagues. RMDs are the leading cause of physical disability in the EU, accounting for over 50% of years lived with disability (YLDs) in Europe. They represent 38% of all occupational diseases and are responsible for approximately 60% of workplace health issues. The economic burden of RMDs is estimated at EUR 240 billion per year, with direct healthcare costs amounting to 2% of the EU's GDP. Over the past few decades, significant advancements have been made in RMD treatment. The development of anti-inflammatory, immunomodulatory, and immunosuppressive therapies has enabled cost-effective, outpatient, and multidisciplinary treatment models across European healthcare systems. Consequently, fewer patients require hospitalisation, and more individuals can actively participate in social and professional life. **EULAR calls for comprehensive European and national RMD strategies, focusing on** the quality of care (improving prevention, early diagnosis, treatment, and rehabilitation), social policies (mitigating the impact of RMDs on quality of life, education, and employment), recognition of RMDs as a major cause of disability, ensuring adequate social support and mental health services, and research and innovation (developing improved strategies for prevention and treatment).

The first "export product", or a priority for the Polish Presidency is the Pilot Programme for Comprehensive Care for Patients with Early Arthritis (KOWZS).<sup>178</sup> This integrated healthcare model provides early arthritis patients with a coordinated approach, including outpatient specialist care, one-day inpatient treatment and therapeutic rehabilitation, psychological and dietary consultations – essential for high-quality multidisciplinary care. The KOWZS pilot programme aims to evaluate the organisation, quality, and effectiveness of care while developing national medical guidelines and electronic medical record standards. It also promotes an "inverted pyramid" model, shifting patient care from hospital-based treatment to ambulatory settings, with care assistants supporting doctors in care coordination. A digital database will be established, based on standardised medical documentation, allowing for comparative analysis with EU-wide data.

The second priority is lifestyle modification and routine vaccination among rheumatology patients. Studies show that primary prevention measures, including smoking cessation, weight management, physical activity, and a balanced diet, can reduce the risk of developing RMDs by 30-40%.

The third priority is addressing the osteoporosis epidemic. Poland has developed a national osteoporosis risk calculator, which, when combined with ultrasound screening, can serve as a cost-effective and repeatable method for early osteoporosis detection. The test is highly accessible and can be performed in any medical practice.

#### **Prof. Robert Flisiak MD PhD**

Head of the Clinic of Infectious Diseases and Hepatology at the Medical University of Bialystok, president of the Polish Association of Epidemiologists and Infectiologists

**Poland can take pride in the European Union in its highly effective health policy programme,** *Antiretroviral Treatment of People Living with HIV in Poland.* Thanks to the implementation of this programme, HIV is diagnosed and approximately 20,000 patients receive treatment, leading to improved quality of life and life expectancy for people living with HIV and AIDS. This enables individuals to lead as comfortable a life as possible within society and their families.<sup>179</sup>

A priority measure that should be urgently introduced in Poland is the National Programme for the Elimination of Hepatotropic Infections as a Strategy to Prevent Cirrhosis and Liver Cancer. While there is no vaccine for hepatitis C virus (HCV), effective antiviral therapies are available through the NHF drug programme, providing nearly 100% cure rates within 8 to

<sup>178</sup> Draft regulation of the Minister of Health amending the regulation on the pilot program in the field of comprehensive care for patients with early arthritis. Proposal of 27 June 2024, RCL. Minister of Health 15.07.2024, https://legislacja.gov.pl/projekt/12387252/katalog/13070409#13070409.

<sup>179</sup> Government Health Policy Programme for the Antiretroviral Treatment of People Living with HIV in Poland, https://www.gov.pl/web/zdrowie/rzadowy-program-polityki-zdrowotnej-leczenie-antyretrowirusowe-osob-zyjacych-z-wirusem-hiv-w-polsce-na-lata-2022-2026.



12 weeks. The key to successful treatment is early detection of HCV infections – estimated at approximately 130,000 cases in Poland – and swift referral to therapy. Current HCV screening efforts in Poland rely on ad hoc initiatives and pilot schemes, or an ineffective Ministry of Health/ NHF programme based on a 'delegated budget', which fails to provide a systemic solution. The consequences of this fragmented approach are evident in declining treatment rates and a persistently high number of undiagnosed cases. These individuals continue to spread infections, strain healthcare budgets with the long-term costs of cirrhosis and liver cancer treatment, and diminish economic productivity due to premature workforce exit. Many countries, in line with WHO recommendations to eliminate HCV infections by 2030, have established national HCV elimination programmes. A comprehensive strategy in Poland would require relatively modest financial investment but yield substantial benefits, including reduced healthcare costs related to cirrhosis, liver cancer, and liver transplants; increased economic productivity due to prolonged workforce participation; achievement of WHO-mandated HCV reduction targets by 2030; and enhanced national and international reputation, with potential political gains, particularly during Poland's EU Presidency.

#### Prof. Iwona Paradowska-Stankiewicz MD PhD

National Consultant in Epidemiology, Head of the Epidemiology of Vaccine-Preventable Diseases Unit at the Department of Epidemiology of the National Institute of Public Health – National Institute of Hygiene

"Vaccination throughout life" is the slogan that encapsulates the World Health Organization's strategy, reflecting shifting demographics, global travel, and migration patterns. These factors underscore the importance of vaccination not only for children and adolescents but also for adults throughout their lifetime. Our public awareness campaigns, such as European Immunisation Week and Long Life for All, emphasise that lifelong vaccination plays a crucial role in preventing diseases such as influenza, pneumococcal pneumonia, hepatitis B, tetanus, shingles, and pertussis. It is essential to actively promote vaccination and highlight its role in preventing diseases, complications, and mortality. A highly recommended source of up-to-date, reliable, and comprehensive information on vaccinations is the Szczepienia.info portal, established in October 2007 by the National Institute of Public Health - National Institute of Hygiene, in collaboration with the Polish Society of Vaccinology. The portal was developed in line with the WHO's initiative to create a Vaccine Safety Network across multiple European languages. It is WHO-accredited and has been included on the list of trusted websites providing reliable vaccination information. The portal is also referenced as a credible source on the European Vaccination Information Portal, an initiative of the European Commission, the European Centre for Disease Prevention and Control (ECDC), and the European Medicines Agency.<sup>180</sup>

A key priority is the expansion of the national immunisation programme (PSO) to include additional vaccinations and broader population coverage. The PSO is updated annually, outlining vaccination schedules for children and adults at high risk of infection, including timing, dosage intervals, vaccine types, and administration methods. It covers both mandatory (statefunded) and recommended (privately funded) vaccinations. To ensure greater vaccine accessibility, public reimbursement for immunisations is critical – without it, progress will be significantly delayed or even unattainable. Poland's historical success in immunisation is evident, as mandatory vaccinations have been in place since 1960, effectively eliminating or significantly reducing the prevalence of many diseases. Today, we take pride in the fact that for many years there have been no reported cases of poliomyelitis (Heine-Medin disease) or diphtheria. Moreover, one of the greatest global immunisation successes has been the world-wide eradication of smallpox.

<sup>180</sup> NIZP-PZH, szczepienia.info portal, https://szczepienia.pzh.gov.pl/.



#### Prof. Violetta Skrzypulec-Plinta MD PhD

Head of the Department of Women's Health and the Department of Reproductive Health and Sexology at the Medical University of Silesia in Katowice

Poland still has a long way to go in aligning its reproductive health policies with those of the European Union.

A network of specialised clinics dedicated to contraceptive counselling and sex education should be established, and contraception should be made freely available to individuals up to the age of 25. For many years, Poland has ranked lowest in Europe in terms of access to contraception and comprehensive sex education. In October 2024, the Right to Contraception declaration was introduced, initiating a national discussion on contraception. The Right to Contraception Coalition was formed to raise awareness and advocate for the public reimbursement of modern contraceptive methods. This coalition brings together representatives from medical communities and non-governmental organisations, leading educational campaigns on this issue. According to the report Discovering Contraceptive Awareness, 38% of surveyed Polish women and men admit they lack sufficient knowledge about contraception, only 20% are aware of methods beyond condoms, and 23% consider contraception a taboo topic – the highest percentage in Europe.<sup>181</sup> In Poland, there is a shortage of both systemic solutions and public awareness. Young people face significant financial barriers in accessing modern contraceptive methods, which is why public reimbursement should be introduced, as is the case in many EU countries.

**One of the notable achievements in this field was the introduction of public reimbursement for the In Vitro Programme from 1 June 2024**. The government-funded IVF programme provides comprehensive infertility treatment, psychological support, and covers up to six assisted reproduction procedures. The programme also includes cancer patients, enabling them to freeze embryos before or during treatment. The IVF programme, along with oncofertility initiatives and universal access to non-invasive prenatal testing for all pregnant women, forms part of the Ministry of Health's Safe, Conscious Me project. In May 2024, the Minister of Health established a dedicated Task Force for Improving Women's Health Security, marking a significant step towards addressing reproductive health challenges in Poland.

#### Wiesława Rybicka-Bogusz

President of the Mazovia Regional Branch of the Women at the Centre Association

The first achievement we can highlight and "export" abroad is the fact that the Senate of the Republic of Poland has declared 2025 the Year of Health Education and Preventive Healthcare. This demonstrates that health education and prevention are recognised as national priorities in Poland.

The second key initiative is the work of the Women at the Centre Association<sup>182</sup>, which organises over one hundred events annually, focusing on preventive healthcare and health education for women living in small towns and rural areas. We welcome the fact that health security is a priority of the Polish Presidency, as this is precisely what Polish women expect. Women's health should be of paramount concern, as women's well-being directly impacts the health of families and society as a whole. Women fulfil multiple social roles – as mothers, wives, caregivers for children with disabilities, and carers for the elderly. It is often women who encourage their partners to seek medical check-ups, reminding them: "Go, get yourself checked". A notable example of this is the ProstaTaHistoria (ProstateStory) campaign, conducted in collaboration with the OnkoCafe Foundation. This educational initiative aims to raise awareness about the diagnosis and treatment of prostate cancer while ensuring that patients have access to oncological consultations.<sup>183</sup>

<sup>181</sup> Odkrywanie świadomości antykoncepcyjnej [Discovering Contraceptive Awareness] (a Kantar survey), European Parliamentary Forum on Sexual and Reproductive Rights (EPF), 2024, https://www.pap.pl/mediaroom/badanie-kantar-38proc-polakow-nie-ma-wystarczajacej-wiedzy-na-temat-antykoncepcji.

<sup>182</sup> Stowarzyszenia Kobiety w Centrum [Women at the Centre Association], https://kobietywcentrum.org.pl/.

<sup>183</sup> Prostatahistoria (ProstateStory), https://prostatahistoria.biuroprasowe.pl/.



#### Prof. Marzena Dominiak MD PhD

Head of the Department and Department of Dental Surgery at the Medical University of Wrocław, Vice-Rector for Internationalization at the Medical University of Wrocław, President of the Polish Dental Society (PTS), Member of the Women Dentist Worldwide Section of the FDI World Dental Federation

The first "export product", a key initiative that should be highlighted during Poland's Presidency of the Council of the European Union, is the education of medical professionals in the field of preventive healthcare. In this context, medical universities play a crucial role. During medical studies, we focus extensively on teaching students how to treat diseases that have already developed, but we do not sufficiently address how to prevent them in the first place. Public health has increasingly focused on obesity as a major issue. As academic institutions, we seek to play a more significant role in presenting a holistic perspective on this topic, aiming to prevent the growing incidence of overweight and obesity in Poland. We are currently preparing a conference entitled Let's Be Healthy, which will address six fundamental aspects of public health: health, diet, physical activity, responsibility, knowledge, and inspiration. However, in order to effectively address these issues, we must first revise the educational standards for medical professions. Dietetics should be integrated into specific medical specialisations, ensuring that healthcare professionals are equipped to address nutrition-related health issues. In the field of public health, there is also growing recognition of the role of health prevention specialists. We should focus on training educators who can effectively teach children and adolescents within the framework of health education in schools.

**The second priority for the Polish Presidency should be oral health prevention.** As the President of the Polish Dental Society and a long-standing member of the World Dental Federation, I would like to highlight the importance of preventive oral health care. The World Health Organization (WHO) has stated that oral health is a mirror of overall health – what happens in the body is often reflected in the condition of the mouth. If we are to discuss prevention in its broadest sense, we must also focus on oral health. Tooth decay does not result solely from a lack of tooth brushing; it is often a consequence of an unhealthy diet, particularly excessive consumption of sugar and unhealthy fats.

#### Kamila Kadzidłowska

#### Co-founder and Vice-President of the Board of the Parents for Climate Foundation

Parents for Climate is a diverse group of parents promoting intergenerational activism to achieve climate justice. Aware of the three greatest challenges humanity faces this decade – namely the climate crisis, air pollution, and biodiversity loss – we unite to drive urgent political and social changes necessary to ensure that all children can live on a habitable planet. We collaborate with various movements, organisations, and institutions working for climate action on local, national, and global levels. We stand in solidarity with families in countries most affected by the global climate crisis. Our shared motivation stems from a deep concern for the health, future, and safety of our children and grandchildren. Our initiative is grassroots-driven, decentralised, and independent.<sup>184</sup>

The wide range of contemporary health issues affecting children and adolescents in Poland stems from the cumulative impact of environmental factors and unhealthy lifestyles. Key environmental concerns include air pollution (high concentrations of PM2.5 and PM10, nitrogen oxides), excessive use of pesticides and artificial fertilisers, and the presence of antibiotics and toxic substances in food and water. In terms of lifestyle-related risks, the main challenges are excessive consumption of highly processed foods, contributing to diet-related diseases such as obesity, type 2 diabetes, and cardiovascular conditions; insufficient physical activity, leading to

<sup>184</sup> Rodzice dla Klimatu [Parents for Climate], https://www.rodzicedlaklimatu.org/.



postural defects, a weakened immune system, and developmental issues; overexposure to digital devices, which can result in digital addiction, mental health deterioration (anxiety, depression), and sleep deficits; and health misinformation, which limits parental and child awareness of disease prevention. Further compounding these issues is climate change, which exacerbates heatwaves, the degradation of water quality and ecosystems, and the spread of vector-borne diseases. Consequently, the prevalence of non-communicable diseases among children and adolescents is on the rise, including asthma, allergies, chronic respiratory conditions, neurological disorders, metabolic diseases (obesity, diabetes), and mental health disorders such as depression, anxiety, and behavioural problems. Given the scale and urgency of these challenges, coordinated, multi-sectoral action is essential. This must address both the elimination of harmful environmental factors and the promotion of healthier lifestyles. In the context of Poland's Presidency of the Council of the European Union, we propose the following priority actions:

**Establishing the European Coalition for Children's Health – EU4KidsHealth**. We propose introducing the EU principle "Children's Health First/EU4KidsHealth", modelled on the "polluter pays" principle. This principle would require EU legislators to systematically assess the impact of all new regulations on the health and development of children and adolescents.

**Strengthening EU Programmes and Legislative Measures to Advance Child and adolescents** with a particular focus on the following key areas:

**Transposition of the Ambient Air Quality Directive (AAQD)** – measures must prioritise child protection, as children are the most vulnerable to the adverse effects of air pollution. Reducing nitrogen oxides (NOx) and particulate matter (PM) emissions will significantly lower the risk of respiratory infections, asthma, cardiovascular diseases, cancer, neurodegenerative conditions, and developmental and behavioural disorders.

The **Farm to Fork Strategy** should focus on Reducing antibiotic use in animal husbandry and limiting fertiliser and pesticide application, eliminating harmful substances in food contact materials, and enhancing food labelling to ensure consumers have clear information on the health and environmental impact of products.

- a. In the context of the **Green Claims Directive**, it is necessary to introduce transparent and verifiable standards for environmental declarations, ensuring protection against misleading claims that could influence consumer health and dietary choices.
- b. The European Strategy for Climate Change Adaptation must include developing and implementing regulations to reduce greenhouse gas emissions, establishing green zones in urban areas and around educational institutions to shield children from extreme weather events, and supporting education campaigns on the health consequences of climate change and adaptation strategies.
- c. The Packaging and Packaging Waste Directive
- d. A strategy must be developed to protect children from digital addiction, creating regulations to curb excessive screen time among children and adolescents.

#### **Overview of Preventive Programmes from EU Countries**

It is essential to develop and implement best practices from European countries in the field of child and adolescent health, effectively addressing contemporary health challenges arising from both environmental factors and unhealthy lifestyles. The following are examples of programmes that deserve particular attention.

- **Denmark's** *Green Schoolyards* initiative and green zones around schools involve transforming spaces around educational institutions into green areas that serve as protective buffers against air pollution, noise, and the effects of climate change, such as heatwaves. This initiative promotes physical activity and regular contact with nature, which significantly benefits both mental and physical health while improving concentration and educational outcomes.
- Finland's *Healthy Kids of Finland* is an educational programme that integrates healthy nutrition, physical activity, and digital hygiene into the compulsory school curriculum. Schools



implement daily physical activities and educational programmes that teach children responsible use of electronic devices to counteract digital addiction.

- France has implemented 50% Organic Food in Canteens, a regulation requiring that at least 50% of food in school canteens must come from local, organic, or sustainable sources. This initiative promotes healthy eating habits, reduces pesticide use in food production, and supports local organic farming, contributing to a reduction in obesity and diet-related diseases among children.
- Sweden's *Bättre luft i skolan* (Better Air in Schools) aims to improve air quality in and around schools. The programme includes the implementation of modern ventilation systems and urban planning solutions, such as traffic-free zones. Improving air quality significantly reduces the incidence of asthma, allergies, and respiratory infections in children.
- Germany's Be Smart Don't Start is a school-based anti-smoking educational programme supported by teachers and public health specialists. It targets young people to prevent addiction, including smoking and e-cigarette use, promotes a healthy lifestyle, and provides psychological tools to support informed decision-making.
- The Netherlands' JOGG (Gezonde Jeugd, Gezonde Toekomst Healthy Youth, Healthy Future) focuses on combating childhood obesity through integrated initiatives, including the promotion of healthy eating, encouragement of daily physical activity, and health education for both children and parents.
- Spain's Programa de Alimentación Saludable (Healthy Nutrition Programme) is a schoolbased initiative aimed at reducing the consumption of sugar, salt, and saturated fats in children's diets. It also introduces regular health screenings to prevent obesity and other metabolic diseases.
- France and Germany have introduced *Car-Free School Zones*, promoting active transport options such as walking and cycling to school. Investments in infrastructure, including pavements, cycle paths, and bicycle racks, are combined with measures to restrict car traffic around educational institutions. This approach significantly lowers exposure to harmful emissions and noise pollution while also supporting efforts to prevent obesity and mental health disorders such as depression.

Adaptation of the Green Prescriptions Programme, implemented in the United Kingdom as part of public healthcare. This programme promotes the concept of green prescriptions, whereby medical professionals recommend outdoor activities as a method of supporting the treatment of mental health issues (such as stress and depression) and improving physical health.

A strategic partnership with Denmark, which has long been successfully implementing public health prevention programmes, particularly those targeting children, and is recognised as a leader in sustainable development and policies aimed at reducing emissions harmful to both human health and the climate.

Continuation of the initiatives launched during Poland's first Presidency of the Council of the European Union in 2011, led by Prof. B. Samoliński's team, which focused on the prevention of neurodegenerative and respiratory diseases in children, while taking into account the impact of climate and environmental conditions on health.

We would also like to emphasise that Poland has **a number of outstanding initiatives and programmes** with export potential, which could play a key role in promoting the Polish Presidency of the Council of the European Union from January to June 2025.

1. **Introduction of** *Health Education* as a subject in the primary school curriculum. This subject should cover key issues related to the impact of air quality, food, and environmental factors on children's health and development. Particular emphasis should be placed on combatting health misinformation and raising public awareness in the areas of environmental and climate protection. These efforts should support the depoliticisation of climate change by treating it as a matter of environmental quality, which directly affects public health and the security of the European Union.



- 2. The position statement of the Public Health Council on inter-ministerial actions for public health in the context of reducing the impact of air pollution and climate change on health. This document, signed by Minister Wojciech Konieczny in September 2024, provides a strong foundation for coordinated policies in the health and environmental sectors.
- 3. *The NeuroSmog research programme*, conducted by a consortium led by the Jagiellonian University in collaboration with the Institute of Environmental Protection National Research Institute (IOŚ-PIB), is an innovative scientific initiative investigating the impact of air pollution (particularly PM2.5 and PM10 particulate matter) on children's brain development, including cognitive abilities and the prevalence of neurological disorders. The findings could serve as an important argument in shaping EU health and environmental policies.
- 4. The nationwide public awareness campaign, *Better to Prevent than to Cure*, is an example of a large-scale educational initiative conducted in collaboration with healthcare experts, NGOs such as Parents for Climate and HEAL Polska, with potential cooperation with local government authorities. The campaign aims to educate parents about the impact of environmental factors on children's health.
- 5. The guidebook *Schools for Health and Climate*, developed by Parents for Climate in the pre-election period, provides practical solutions for educational institutions to improve air quality and outdoor spaces around schools. Key recommendations include the creation of green protective buffers around educational institutions, the promotion of healthy nutrition in school canteens, the development of blue-green infrastructure to support children's outdoor physical activity, and the implementation of educational initiatives on climate and health protection.

We appreciate the opportunity to contribute to discussions on prevention and public health, particularly in relation to children and adolescents, within the context of the priority initiatives of the Ministry of Health and the upcoming Polish Presidency of the Council of the European Union. Collective action to safeguard children's health, by eliminating environmental risk factors and promoting a healthy lifestyle, represents an investment that will yield long-term benefits in the form of a healthier population, reduced healthcare costs, and increased resilience to future challenges.

## Irena Rej

#### President of the Board of the Polish Pharmacy Chamber of Commerce

Many years ago, at the Ministry of Health on Miodowa Street, a plaque was placed at the main entrance by Minister Jacek Żochowski, bearing the inscription in golden letters: "No politics beyond this point". In today's reality, however, there can be no optimisation or development of the healthcare system without the engagement and understanding of politicians.

The first key priority and an "export product" for the Polish Presidency should be preventive healthcare, an essential element of public health policy. Prevention must come first, as it significantly reduces the need for treatment later.

The second flagship initiative to showcase at the EU level is the digitisation of the healthcare system, particularly e-referrals, e-prescriptions, the Internet Patient Account (IKP), and the Integrated System for Monitoring the Trade in Medicinal Products (ZSMOPL). Poland has a highly advanced and export-worthy solution that combines digitalisation with pharmaceutical security – the ZSMOPL system. The Integrated System for Monitoring Trade in Medicinal Products is an ICT-based system designed to process data submitted by entities involved in the trade of medicinal products. It supports public administration authorities, including the Medicines Management Policy and Pharmacy Department and Pharmacy at the Ministry of Health, the Main Pharmaceutical Inspectorate, the Provincial Pharmaceutical Inspectorates, and the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products. These bodies rely on ZSMOPL to analyse sales volumes and market structures for medicinal products. The system became mandatory on 1 April 2019, requiring pharmacies, hospital pharmacy departments,



pharmaceutical wholesalers, and manufacturers to report trade data. Data submission occurs at the level of individual business locations (MPD) rather than company-wide, ensuring accurate monitoring of stock movements and availability. The reporting entity is therefore an economic entity, but in the case of pharmacies and wholesalers, reporting takes place from the level of a specific place of business (MPD).<sup>185</sup>

The third strategic priority for the Polish Presidency should be pharmaceutical security not just for Poland but for the entire European Union. Medicine security means ensuring the availability of essential medicines and medical devices for patients, as well as quality control of medicines, efficient adverse drug reaction (ADR) reporting systems, counteracting counterfeit medicines, and rationalising and optimising pharmacotherapy. It also requires crisis preparedness, through the creation of emergency reserves, optimised distribution mechanisms, and stronger EU-wide coordination. A noteworthy milestone has been the publication of the National List of Critical Medicines by the Minister of Health, comprising 301 active pharmaceutical ingredients (APIs).<sup>186</sup> This list will be regularly updated to reflect market fluctuations and supply chain vulnerabilities. It is crucial to develop incentives and provide targeted support for the industry to ensure tangible results in initiating or sustaining the production of critical medicines in Poland and across the European Union. Currently, up to 80% of APIs used in Europe and approximately 40% of finished medicinal products originate from China and India. This high level of dependency poses a serious risk to the health and safety of European patients. The EU, including Poland, must regain control over its pharmaceutical supply chains to ensure safe, sustainable, and autonomous access to essential medicines. Pharmaceutical security is a matter of national interest, and a challenge for governments – it should not be viewed solely as the responsibility of the pharmaceutical industry. However, as manufacturers and distributors, we remain committed to cooperation and dialogue, as demonstrated during the COVID-19 pandemic, when Poland successfully ensured uninterrupted access to medicines and medical devices despite global disruptions.

## Lech Pilawski

Member of the European Economic and Social Committee, advisor to the President of the Lewiatan Confederation

The European Economic and Social Committee (EESC) is an EU advisory body representing workers' and employers' organisations as well as other interest groups. The EESC issues opinions on EU matters addressed to the European Commission, the Council of the EU, and the European Parliament, serving as a bridge between EU decision-makers and citizens.<sup>187</sup> The Lewiatan Confederation is a highly influential Polish business organisation, bringing together over 4,100 companies employing more than one million people. Through its activities, the Confederation enables companies to influence legislation, engage in dialogue with public administration, and access tools to support business growth. Lewiatan represents Polish employers at both the national and European levels, maintaining a permanent presence in Brussels, and is the only Polish organisation affiliated with BusinessEurope, the largest European business federation. It is also a member of Business at OECD, an international business network.<sup>188</sup>

An "export product" of the Polish Presidency in the area of prevention and public health should be pharmaceutical security, particularly the availability of critical medicines. The issue of pharmaceutical security has been under discussion within the European Commission and the European Parliament for some time. Previous EU Presidencies have also highlighted

<sup>185</sup> Integrated System for Monitoring Trade in Medicinal Products (ZSMOPL), https://zsmopl.ezdrowie.gov.pl/.

<sup>186</sup> Polish Ministry of Health, National List of Critical Medicines, https://www.gov.pl/web/zdrowie/krajowa-lista-lekow-krytycznych.

<sup>187</sup> European Economic and Social Committee (EESC), European Economic and Social Committee (EESC), https://europeanunion.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/europeaneconomic-and-social-committee-eesc\_pl.

<sup>188</sup> Konfederacja Lewiatan, https://www.gov.pl/web/zdrowie/krajowa-lista-lekow-krytycznych.



this challenge, and the European Economic and Social Committee (EESC) initiated the Critical Medicines Act<sup>189</sup> – a legislative proposal on which I served as rapporteur, with pharmaceutical industry experts providing advisory input. This led to subsequent work on developing a list of critical medicines, although we have substantial reservations about the current approach. The Polish Presidency will need to continue working on this issue, ensuring it remains a priority on the EU agenda. Importantly, Poland can play a key role in shaping this initiative, as the Critical Medicines Alliance, of which I am a member, will publish a strategic report on pharmaceutical security in April 2025. The Critical Medicines Alliance, established in January 2024, serves as a consultative platform bringing together stakeholders from EU Member States, key industries, civil society, and the scientific community. The Alliance's primary objectives include identifying critical areas for action, proposing solutions to enhance the EU's supply of essential medicines, and intensifying efforts to prevent and mitigate medicine shortages.<sup>190</sup>

Another priority for the Polish Presidency should be the European Health Data Space (EHDS).<sup>191</sup> During its work on rare diseases, the EESC underscored significant challenges related to health data management across Europe. The lack of a common data-sharing platform, as well as unclear definitions regarding data standards, creates serious obstacles. Additionally, patient data protection remains a complex regulatory issue. However, this topic has already received widespread recognition at the EU level, and Poland should push for regulatory action to establish a unified European health data platform. I strongly encourage the Polish Presidency to prioritise and champion this initiative.

## Aleksandra Sienkiewicz

Director of the Health Forum, Union of Entrepreneurs and Employers

The Union of Entrepreneurs and Employers (Związek Przedsiębiorców i Pracodawców, ZPP) is one of Poland's largest business organisations, representing over 21,000 companies that collectively employ around one million people.<sup>192</sup> From the perspective of an organisation representing employers, health prevention is fundamental to ensuring the health and productivity of employees. Through preventive healthcare, including primary and secondary prevention, individuals can remain professionally active and maintain a high quality of life.

The first "export product" of the Polish Presidency is health education from an early age. We are increasingly hearing reports that patients are getting younger, with childhood obesity on the rise and mental health disorders among adolescents becoming more prevalent. As entrepreneurs and employers, we face a future where we may simply not have a healthy workforce, as young people affected by preventable diseases could become unable to work and reliant on incapacity benefits. This is why health education must be prioritised. We live in the 21st century, with modern medicine at an advanced level – yet education remains key. It must be integrated across multiple settings: schools, workplaces, and digital platforms such as smartphones and computers. I hope that the introduction of health education in schools from 1 September 2025 will become a point of pride for Poland on the European stage. In the long term, it should deliver tangible results, equipping young people with the knowledge and habits needed to lead long, healthy, and active lives.

The second critical priority is adherence, which means shared responsibility for one's health. This includes maintaining a healthy diet, engaging in physical activity, taking prescribed medications, and following medical recommendations. It cannot be the case that a patient receives a diagnosis and the doctor believes in it more than the patient does. If the patient takes no action, treatment outcomes will be ineffective. Therefore, a holistic and collaborative approach to health is essential.

<sup>189</sup> A Critical Medicines Act to secure Europe's pharmaceutical independence, https://www.eesc.europa.eu/en/news-media/ news/critical-medicines-act-secure-europes-pharmaceutical-independence.

<sup>190</sup> Critical Medicines Alliance, https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/overview/ critical-medicines-alliance\_en.

<sup>191</sup> European Health Data Space, https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space\_pl.

<sup>192</sup> Union of Entrepreneurs and Employers, https://zpp.net.pl/.



## Prof. Teresa Jackowska MD PhD

President of the Polish Paediatric Society, Head of the Paediatrics Clinic at the Centre of Postgraduate Medical Education, Head of the Clinical Department of Paediatrics at the Bielany Hospital

Looking at the three priorities of the Polish Presidency in the field of health – prevention, digitisation, and child and adolescent psychiatry – all of them are directly relevant to paediatric patients.

**Polish paediatrics can take pride in its nationwide screening programmes.** The most significant of these is the Neonatal Screening Programme, which currently covers 30 rare diseases, including spinal muscular atrophy, phenylketonuria, hypothyroidism, cystic fibrosis, congenital adrenal hyperplasia, and biotinidase deficiency. These screening tests allow for early diagnosis, enabling the implementation of targeted dietary interventions, treatment, and specialised care. Another example is the pulse oximetry test, conducted on every newborn within the first two days of life, designed for the early detection of congenital heart defects. Similarly, a universal neonatal hearing screening programme has been in place since 2003. From 1 January 2025, familial hypercholesterolaemia screening will be introduced for all six-year-olds.

The second flagship key initiative is the mandatory and recommended immunisation programme. Thanks to publicly funded mandatory and recommended vaccinations, Poland has one of the highest paediatric vaccination rates in Europe. The introduction of hepatitis B (HBV) vaccination 30 years ago has successfully eliminated HBV-related public health concerns. From 1 September 2024, HPV vaccinations will be made available under a nationwide programme for all children aged 9 to 14, including within schools. Another major breakthrough is the introduction of free pertussis vaccinations for pregnant women, available from 15 October 2024. In the realm of preventive vaccination, prevention and digitisation must go hand in hand. Children in Poland receive vaccinations both within the public and private healthcare systems. Given that an E-card for Recommended Vaccinations already exists, introducing an E-card for mandatory vaccinations would enable comprehensive monitoring of vaccination coverage among children across the country.

The third achievement is the introduction of health education in schools from 1 September 2025. I am delighted that from this date, health education will be formally included in the school curriculum, as improving the long-term well-being of Poles is impossible without high-quality health education from an early age. However, I am concerned about the direction this education will take. Regrettably, paediatricians were not invited to contribute to the curriculum's development. As President of the Polish Pediatric Society, I do not know what the curriculum will entail. This will be a challenging subject to teach, requiring educators with authority and the ability to adapt content to children's and adolescents' needs.

## Edyta Sutkowska MD PhD

Committee on Clinical Sciences of the Polish Academy of Sciences, University Centre for Physiotherapy and Rehabilitation, Department of Clinical Physiotherapy and Rehabilitation, Wrocław Medical University

In the context of the Polish Presidency "export-worthy products", the nationwide educational programme *Keep Yourself Fit!* should be promoted. This initiative is co-organised by the Chief Sanitary Inspectorate, the Polish Federation of Food Producers, the Employers' Union, and the Provincial Sanitary and Epidemiological Stations as part of the implementation of the WHO strategy on diet, physical activity, and health. The aim of the Keep Fit! programme is to educate school children and their families on the sustainable development of healthy habits by promoting an active lifestyle and a balanced diet, with a focus on individual responsibility and informed choice. Every school that commits to participating in the programme and registers its students receives a free package of educational materials. Within the framework of the programme, schools can organise extracurricular activities that go beyond the core curriculum to support students'

overall development. These activities aim to cultivate students' interests, particularly in the areas of proper nutrition and the importance of daily physical activity. School-led projects should promote physical activity and encourage young people to adopt a balanced, varied diet.<sup>193</sup>

**The second "export product" is the sugar tax.** As a diabetologist, I see an increasing prevalence of overweight, obesity, and type 2 diabetes. Thanks to the annual revenue generated by the sugar tax for the National Health Fund, we have the opportunity to raise health awareness among Poles. Without this awareness, individuals are unlikely to seek out reliable information on healthy diets or active lifestyles. However, building health awareness takes time, and it is most effective when instilled from early childhood – within the family, in nurseries, and in schools. Many people obtain health-related information from the media, including television, radio, and newspapers. This, however, presents a challenge, as advertising in mainstream media frequently promotes unhealthy foods and alcohol. A recent study on physical activity, conducted by my centre among both working adults and senior citizens, found that in both groups, a lack of time was the primary obstacle to engaging in regular physical exercise.

## Prof. Halina Sienkiewicz-Jarosz MD PhD

President-Elect of the Polish Neurological Society, Chair of the National Council for Neurology, Head of the 1st Neurological Clinic at the Institute of Psychiatry and Neurology in Warsaw

Neurological diseases, particularly brain disorders, have become a key health priority in most highly developed countries. The World Health Organization, neurological associations in Europe and North America, as well as numerous governments, recognise the significance of brain diseases and have introduced action plans to promote brain health. Many neurological conditions are closely linked to ageing, which is a major, non-modifiable risk factor. Given current demographic trends, the prevalence of such diseases is expected to rise significantly unless effective prevention programmes are implemented. One of the key challenges ahead is educating society about neurological disorders and the available primary and secondary prevention strategies, which could help reduce the incidence of these conditions while mitigating their personal, social, and economic consequences. Poland has made notable progress in prevention from a neurological perspective.

The first major achievement, or an "export product" of the Polish Presidency, is the Neonatal Spinal Muscular Atrophy (SMA) Screening Programme, which has been implemented nationwide. Since its introduction three years ago, spinal muscular atrophy has been diagnosed in 100 newborns, approximately 70% of whom have received treatment. This includes access to therapies available within the national drug programme, such as gene therapy made possible through early screening.

The second key initiative is the National Programme for Counteracting Dementia Diseases, which is expected to be adopted and published in the first quarter of 2025, coinciding with the Polish Presidency of the EU Council. The programme aims to consolidate efforts in this field, requiring coordination not only within the healthcare sector but also across other government ministries. Plans include the development of specialised training materials for emergency services, such as the fire brigade, national and municipal police, as these professionals frequently encounter individuals displaying disoriented or irrational behaviour, as well as cases of missing persons with dementia. The programme will focus on five key pillars: education, early diagnosis, therapy, caregiver support, and long-term care. Special attention will be given to the needs of caregivers, ensuring they receive the necessary training and guidance to manage their responsibilities effectively. In addition, the programme will support research and innovation aimed at advancing the understanding and treatment of dementia. Raising public awareness is also a priority, with information campaigns designed to educate society on the nature and impact of dementia-related diseases.

<sup>193</sup> Ogólnopolski Program Edukacyjny "Trzymaj Formę!" [*Keep Yourself Fit!* National Educational Programme], https://www. trzymajforme.pl/rusza-xvi-edycja-ogolnopolskiego-programu-edukacyjnego-trzymaj-forme-101.



## Prof. Jacek Jassem MD PhD

Head of the Department of Oncology and Radiation Therapy, Medical University of Gdańsk

Regrettably, we have little to showcase in the field of cancer prevention. **One in three cancers is caused by smoking**. In 1995, when Poland introduced its anti-tobacco law, it was regarded as a model for the whole of Europe. Although we were not yet a member of the European Union, we received widespread praise for the measures introduced by this legislation. The next major step came in 2010, when a ban on smoking in public places was implemented. However, in terms of other primary cancer prevention initiatives, we have little to be proud of. Poles have poor dietary habits, engage in insufficient physical activity, and face alarmingly high levels of air pollution. If we wish to present a significant achievement during the Polish Presidency, we must take a bold, transformative step.

A key initiative that Poland should propose and champion in the Council of the European Union is the concept of a "Tobacco-Free Generation". Europe's Beating Cancer Plan sets an ambitious target: by 2040, less than 5% of the population should be using tobacco.<sup>194</sup> No EU member state has yet adopted a comprehensive legislative approach to achieve this – though the United Kingdom has already done so. If I recall correctly, the UK has introduced a measure whereby all individuals born after 2009 will never be legally permitted to purchase tobacco. If Poland were to put forward a similar initiative within the European Union, it would represent a modest yet highly significant and impactful contribution to cancer prevention.

Furthermore, I would like to highlight the European Code Against Cancer, a well-established framework that outlines practical steps for maintaining and improving health. This set of guidelines provides clear, evidence-based recommendations for reducing the risk of malignant tumours through simple, everyday actions. The European Code Against Cancer comprises 12 recommendations for cancer prevention, addressing both primary prevention – reducing exposure to risk factors (carcinogens) – and secondary prevention, which focuses on early detection of disease.<sup>195</sup> Poland was once close to achieving a 60% participation rate among women in mammography screening programmes. Today, this figure has plummeted to just 30%. In 2017, we discontinued the practice of sending invitations for mammograms. No country successfully implements screening programmes without actively inviting eligible participants, as invitation-based outreach remains a cornerstone of effective secondary prevention.

## **Janusz Meder MD PhD**

President of the Executive Board of the Polish Oncology Union, Head of the Conservative Department of the Lymphatic System Cancer Clinic at the Maria Skłodowska-Curie National Institute of Oncology – National Research Institute

It is crucial that the principles of coordinated, comprehensive, and interdisciplinary care, which we often discuss, are applied consistently across all decision-making levels. These levels must also function in a **coordinated**, **integrated**, **and comprehensive** manner, ensuring that all relevant decision-makers and stakeholders are actively engaged. Too often, we see initiatives being launched, seemingly heading in the right direction, only for a new actor to arrive and propose an entirely different approach. **Without a long-term**, **expert-driven continuum of action**, **extending over at least a decade**, **we will not achieve success**. If we fail to develop a ten-year comprehensive strategy for oncology, cardiology, psychiatry, neurology, and rare diseases – underpinned by legislation and dedicated funding – we will not succeed.

<sup>194</sup> European Commission, Commission proposes to extend coverage of smoke-free environments, https://commission.europa.eu/news/commission-proposes-extend-coverage-smoke-free-environments-2024-09-17\_en.

<sup>195</sup> European Code Against Cancer, https://pacjent.gov.pl/aktualnosc/europejski-kodeks-walki-z-rakiem.

A key achievement that we can showcase during the Polish Presidency is the preventive healthcare programmes implemented by the Polish Union of Oncology: the secondary school programme Mam haka na raka (Cancer: I've Got the Upper Hand)<sup>196</sup> and the nationwide initiative Zdrowa gmina (A Healthy Municipality)<sup>197</sup>. Our experience and the data collected from these large-scale public campaigns demonstrate the profound impact of educating young people while leveraging the capacity of local governments. There is no more effective means of educating society. The *Cancer: I've Got the Upper Hand* programme was implemented under the auspices of the European Union.

The second "export-worthy product" for the Polish Presidency may be the activity of Medical Raison d'État think tank. Established in 2016 at the initiative of the Institute of Political Studies of the Polish Academy of Sciences, the Polish Union of Oncology, the College of Family Physicians in Poland, and Green Communication, this think tank brings together influential figures, institutions, and communities to address the challenges affecting public health in Poland. Its goal is to build political consensus for essential reforms in the healthcare system. Recognising health as both a fundamental personal value and a key component of national security, the think tank has published over 50 reports documenting roundtable debates held at the Polish Academy of Sciences, alongside recommendations and conclusions. In 2018, we published *Theses for Health*, outlining the necessary directions for systemic change in healthcare.<sup>198</sup>

## Maciej Głogowski MD PhD

Head of the Surgical Department at the Lung and Thoracic Cancer Clinic, Maria Skłodowska-Curie National Institute of Oncology – national Research Institute

From the perspective of nicotine-related cancers, primary prevention measures – particularly reducing exposure to carcinogens – are essential. These are widely recommended by the oncology community as a means of lowering the incidence of malignant tumours.

A key "export product" of the Polish Presidency should be the development of a comprehensive public health strategy for tobacco control. There is consensus that smoking has a profound impact on disease prevention. Sweden has successfully addressed the issue of smoking through a combination of educational, fiscal, and legislative measures. Education campaigns have been implemented over many years. I am pleased that, from September 2025, health education will become part of the primary school curriculum. There is no doubt that it will be taught by professionals with expertise in the subject. If we are to discuss education, it must focus on the youngest generations, as our goal should be to cultivate a smoke-free population. This could be achieved by following the model introduced in New Zealand, where the legal age for purchasing cigarettes is raised annually. However, immediate regulatory action is required to control the distribution and sale of tobacco products. New products are continuously emerging on the Polish market, many of which are entirely unregulated. Some are even marketed as nicotine-free, meaning they do not fall under anti-tobacco legislation, yet they contain other psychoactive substances. Without proper oversight, we risk allowing increasingly harmful substances to enter the market. Additionally, as outlined in the EU directive, all flavoured additives should be immediately banned in tobacco products. Another crucial step is the complete elimination of tobacco advertising. When we enter shops, we can see that these products are widely available, reinforcing their accessibility.

<sup>196</sup> Mam Haka na Raka [Cancer: I've Got the Upper Hand] (a youth education programme), https://www.zwrotnikraka.pl/mam-haka-na-raka-program-edukacyjny-dla-mlodziezy/.

<sup>197</sup> Zdrowa Gmina [A Health Municiapality], https://www.puo.pl/pokonajmy-raka/zdrowa-gmina.

<sup>198</sup> Medyczna Racja Stanu [Medical Raison d'État], https://medycznaracjastanu.pl/.



## Prof. Bartosz Wielgomas MD PhD

President of the Polish Toxicological Society, Head of the Department and Department of Toxicology, University of Gdańsk

I represent the Polish Toxicological Society, and toxicology is closely linked to public health. Our role as toxicologists begins at the earliest stages of prevention, focusing on identifying environmental hazards that contribute to disease risk. Certain areas require particular attention, and we can draw valuable insights from programmes implemented in Western Europe. As a member of multiple scientific consortia in toxicology, biological monitoring, and environmental surveillance, Poland actively participates in these initiatives. However, at the national level, we lack harmonised programmes for monitoring population-wide exposure to toxic substances and other environmental hazards.

**One key priority for the Polish Presidency, or its "export product", should be mitigating the risks associated with nicotine use and emerging nicotine-related technologies.** These new developments present challenges for which we are currently unprepared. I closely follow legislative progress aimed at regulating these issues. As toxicologists, we are keen to support policymakers in shaping effective prevention strategies. In Poland, we have the capacity to analyse the composition of nicotine products and other substances available to the public, all of which are sold legally. However, under current regulations, the responsibility for ensuring the safety of these products rests entirely with manufacturers and distributors. At present, Poland has only one institution – the Office for Chemical Substances – that verifies whether these products comply with regulations restricting the use of the most hazardous substances, such as carcinogens, mutagens, and toxic chemicals.<sup>199</sup> However, this oversight is highly limited, and a more comprehensive regulatory framework is urgently needed. Recently, there has been increasing media attention on tobaccofree oral nicotine sachets, which are particularly popular in Scandinavia. In Poland, these products remain unregulated, are not systematically tested by any authority, and may still be accessible to minors.

Another key area of focus should be health education. As an academic teaching at the Faculty of Pharmacy, I have observed a decline in students' health awareness over the past two decades. Strengthening health education is therefore essential to reversing this trend and fostering a more informed society.

## Małgorzata Gałązka-Sobotka PhD (Economics)

Dean of the Centre of Postgraduate Medical Education and Director of the Institute of Healthcare Management at Łazarski University

I hope that Poland's EU Presidency will not merely serve as a platform for self-congratulation – especially when there may not be much to boast about – but rather as an opportunity for meaningful dialogue on the challenges we could collectively address at the European level. We should focus on developing instruments and tools that will strengthen our region. The reality is that Poland remains one of the countries with the least developed preventive healthcare within its health system. A fundamental flaw in our approach is that when evaluating the impact of public policies on the economy, we overlook the fact that any regulatory impact assessment should first consider its effects on public health. My personal aspiration is for **Health Impact Assessment (HIA) to become a standard practice in EU policymaking, embedding preventive healthcare and public health** Organization (WHO), HIA is a systematic approach to evaluating the potential health effects of a policy, strategy, plan, programme, or project – particularly concerning vulnerable or disadvantaged groups.<sup>200</sup> Without comprehensive health data systems, we will

<sup>199</sup> Office for Chemical Substances, https://www.gov.pl/web/chemikalia/biuro-do-spraw-substancji-chemicznych.

<sup>200</sup> WHO, Health Impact Assessment, https://www.who.int/health-topics/health-impact-assessment#tab=tab\_1.

struggle to make any significant improvements in the prevention of both communicable and noncommunicable diseases. If Europe fails to effectively address obesity, the long-term consequence will be a regression in the socio-economic and public health advancement of our communities. Rather than focusing on immediate outcomes, what could truly set us apart is not yet the results of our actions, but rather the vision and strategy for how we can work together at the European level to achieve them. Obesity is a major public health challenge across the entire continent – affecting both middle-income countries still on the path to dynamic development and the so-called "old Europe" alike. This shared challenge should unite us in action.

A key initiative that Poland can present to the European Union is the cross-sectoral dialogue titled Stop the Obesity Epidemic in Poland, along with the framework for a national strategic plan to combat obesity. In response to this challenge, the Łazarski University Institute of Health Management, in collaboration with the Polish Society for Obesity Treatment, has launched the Partnership for Obesity Prevention and Treatment and prepared a report entitled Obesity: The Scale of the Problem and Its Consequences – Framework for a Strategic Plan to Reduce Obesity in Poland. The report aims to provide a comprehensive analysis of the current obesity situation in Poland and to propose a framework for a national strategic plan that will enable an effective response to this pressing public health issue. The Partnership's approach is built on the principle of engaging a broad spectrum of stakeholders – including policymakers, scientists, civil society, and the business sector – in meaningful dialogue and joint action to curb the obesity epidemic in Poland. We firmly believe that, under strong central leadership, this report can serve as a foundation for widespread grassroots mobilisation. Only through coordinated, multi-sectoral commitment and determination can we bring about tangible improvements in public health and mitigate the growing risks associated with obesity in Poland. As part of the proposed national strategic plan, we advocate a series of initiatives and interventions, including: health education, promotion of a healthy lifestyle, access to nutritious food, enhanced infrastructure for physical activity, media campaigns promoting active living, and effective treatment and support for individuals already affected by overweight and obesity. Particular emphasis is placed on local governments, schools, and non-governmental organisations, which can play a pivotal role in implementing public health initiatives at the community level. The scale and scope of these proposed interventions are unprecedented globally, as confirmed by an analysis of international best practices. As Poland prepares to assume the Presidency of the Council of the European Union, this initiative has the potential to reshape the European policy agenda, reinforcing public health priorities, obesity prevention, and community-wide efforts to combat overweight and obesity.<sup>201</sup>

Two key implemented measures in obesity prevention in Poland are the sugar tax and the Comprehensive Medical Care Programme for Patients with Morbid Obesity Undergoing Surgical Treatment (KOS-BAR). The sugar tax, an excise duty imposed on the sale of sugar-sweetened products and beverages, was introduced in 2021 and contributes approximately PLN 1.5 billion annually to the budget of the National Health Fund. The KOS-BAR programme, launched in 2022, provides comprehensive healthcare for patients undergoing bariatric surgery for morbid obesity. The programme applies to patients aged 18 and over, diagnosed with ICD-10: E66, with a body mass index (BMI) of  $\geq 40 \text{ kg/m}^2$ , as well as patients with a BMI of 35–40 kg/m<sup>2</sup>, where surgically induced weight loss has the potential to improve obesity-related conditions. Under KOS-BAR, patients receive holistic, structured care at all stages of treatment, including: pre-surgical preparation, preoperative care, qualification for bariatric surgery, the surgical procedure itself, post-operative follow-up, and an individual rehabilitation plan. Currently, KOS-BAR operates in 19 centres across Poland, with the pilot phase covering approximately 11,000 patients with morbid obesity. The programme is fully financed through revenue from the sugar tax.<sup>202</sup>

<sup>201</sup> Otyłość. Skala zjawiska i konsekwencje. Założenia do stworzenia planu strategicznego redukcji otyłości w Polsce, Institute of Management in Health Care at Lazarski University. Partnership for Prevention and Treatment of Obesity, 2024, https://izwoz.lazarski.pl/fileadmin/user\_upload/Otylosc.\_Skala\_zjawiska\_i\_konsekwencje.pdf.

<sup>202</sup> Polish Ministry of Health, Program kompleksowej opieki medycznej dla chorych na otyłość olbrzymią leczoną chirurgicznie [Comprehensive Medical Care Programme for Patients with Morbid Obesity Undergoing Surgical Treatment], https://www. gov.pl/web/zdrowie/program-kompleksowej-opieki-medycznej-dla-chorych-na-otylosc-olbrzymia-leczona-chirurgicznie.



## Stanisław Maćkowiak

President of the Federation of Polish Patients and President of ORPHAN, the National Forum for Rare Disease Therapies

The patient should always be at the heart of the healthcare system, including preventive healthcare and public health, ensuring that their voice is heard and considered. From the patient's perspective, **Poland can take pride in maintaining a well-established and ongoing dialogue between key stakeholders: the decision-maker (the Ministry of Health), the payer (the National Health Fund), and patient organisations at the European level. Patient Councils have been established under both the Minister of Health and the Commissioner for Patient's Rights and patients are actively involved in various key bodies, such as the Council for Rare Diseases and the National Cancer Council. Additionally, patient organisations are invited to participate in meetings of the Transparency Council at the Agency for Health Technology Assessment and Tariff System.** 

A key "export product" of Poland's EU Presidency should be the preparation and adoption of a European Action Plan for Rare Diseases. Rare diseases pose a significant societal challenge. In Poland, around 3 million people are affected by rare diseases, while across Europe, this figure exceeds 36 million. Timely diagnosis is critical, as it marks the starting point of a patient's journey through the healthcare system. However, diagnosing rare diseases often takes several years, a challenge faced throughout Europe. Currently, only 3–5% of patients with rare diseases have access to pharmacological treatment, highlighting the urgent need for systemic solutions at the European level. As of 1 January 2025, Poland will assume the six-month presidency of the Council of the European Union. During this time, Poland should actively promote and support the optimisation of rare disease care. It is worth noting that previous presidencies of France, the Czechia, Sweden, Spain, Belgium, and Hungary included rare diseases among their health priorities. Therefore, Poland's presidency must also prioritise this issue. There should be a structured exchange of experiences regarding national plans and strategies for rare diseases, culminating in the implementation of a European Action Plan for Rare Diseases.

The second key priority for the Polish EU Presidency should be the expansion of Neonatal Screening Programmes, as newborn screening remains the most effective tool in the prevention of rare diseases. The Polish neonatal screening programme currently covers 30 disease entities. According to the latest 2024 publication, A Landscape Assessment of Newborn Screening (NBS) in Europe, a ranking of 32 countries was presented based on the number of diseases included in NBS panels.<sup>203</sup> Among EU-27 countries, Italy leads the ranking with 49 diseases detected through national-level screening, followed by Austria (31), Portugal (30), Poland (29), and Hungary (27). The publication further indicates that neonatal screening has the potential to detect up to 69 diseases, highlighting the urgent need to maximise the use of this tool, as patients with rare diseases - and their families - have the right to a timely diagnosis. In the context of expanding Poland's Neonatal Screening Programme, on 31 October 2024, the President of the Agency for Health Technology Assessment and Tariff System (AOTMiT) issued Opinion No. 78/2024 regarding the draft health policy programme Neonatal Screening Programme in the Republic of Poland for 2019–2026.<sup>204</sup> The AOTMiT President recommended the inclusion of six additional diseases in the current screening scheme. Similarly, the KFO 2024 Audit (July 2024) put forward a patient-led appeal advocating for the programme's further expansion to include 10 additional diseases.<sup>205</sup> Reinforcing this momentum, on 19 February 2024, representatives of rare disease patient organisations unanimously signed the Declaration for Neonatal Screening

<sup>203</sup> Charles River Associates (CRA), A Landscape Assessment of Newborn Screening (NBS) in Europe, 2024, https://media.crai. com/wp-content/uploads/2021/11/28135510/CRA-Insights-NBS-Policy-Updated-28-February-2024-vSTCCR.pdf.

<sup>204</sup> Opinion of the President of the Agency for Health Technology Assessment and Tariff System No. 78/2024 of October 31, 2024 regarding the draft health policy programme Neonatal Screening Programme in the Republic of Poland for 2019–2026, AHTAPol 2024, https://bip.aotm.gov.pl/assets/files/zlecenia\_mz/2024/180/OPZ/OP–0078–2024.pdf.

<sup>205</sup> Gierczyński J., Maćkowiak S., Audyt krajowego forum Orphan 2024. Potrzeby pacjentów z chorobami rzadkimi w zakresie dostępu do technologii medycznych i optymalizacji opieki w Polsce, National Forum for Rare Disease Therapy ORPHAN, Warszawa, August 2024, http://rzadkiechoroby.org/audyt/.



of Lysosomal Diseases in Warsaw. The declaration, initiated by the Polish National Forum for Rare Disease Therapy ORPHAN<sup>206</sup>, outlines recommendations for introducing screening for six lysosomal storage diseases.

## Michał Lipiński

Director of the Polish Promotional Emblem Teraz Polska (Poland Now) competition

On behalf of Krzysztof Przybył, the President of the Polish Promotional Emblem Foundation Teraz Polska, as well as myself and our entire team, I would like to express our sincere gratitude for the invitation and for the opportunity to be a partner of this prestigious conference. A conference that gives a new and meaningful perspective to the *Poland Now* slogan – this time as an "export product in the field of health" in the context of Poland's Presidency of the Council of the European Union. I believe this could introduce a new dimension to our long-standing promotional slogan, which for over 30 years has been showcasing the very best of what Poland has to offer.

Ladies and Gentlemen, we strongly support the promotion of good healthcare practices – something we have been actively engaged in for years. Even without a dedicated category for healthcare services and medical products, our commitment to this field remains evident. A prime example is the recognition of the Coalition for Healthy Ageing, which was awarded the *Poland Now* emblem as part of an honorary distinction. Another example is the Polish Federation of Food Producers, in collaboration with the Chief Sanitary Inspectorate, which runs a programme dedicated to promoting healthy practices.

We have always strived to promote and raise awareness of the quality of Polish food and the Polish economy, and now we have the opportunity to extend this support to the Polish medical sector. Applications for the 35th edition of the Poland Now competition are open until the end of January 2025. I truly hope that on 2 June 2025, at the awards gala, we will have the privilege of celebrating the winners of the 35th Poland Now competition in the category of healthcare services and best practices.

## Karolina Wasielewska

#### **Institute for Social Policy Development**

I have had the honour and pleasure of leading two previous discussions on key priorities, including **the digitisation of healthcare and child and adolescent psychiatry**. Prevention is inherently linked to both. Without **effective digitisation of the Polish healthcare system** – such as ensuring interoperability between hospital IT systems – hospitals will remain vulnerable to cyberattacks. In fact, hospitals are already among the most frequently targeted institutions in Poland, particularly in the context of the ongoing hybrid warfare against our country.

Regarding prevention in child and adolescent psychiatry, significant efforts are being made to improve psychiatric care. However, there is little discussion about the fact that not every issue requires medicalisation. Many young people simply lack someone to talk to and are left to face their problems alone. In many cases, enhancing communication – between peers, teachers, and parents – could play a crucial role in supporting young people struggling with mental health crises.

As a journalist, I work with communication daily, and I see many **opportunities to improve health-related messaging**. Take, for instance, obesity prevention – Dr. Andrzej Ryś, a well-known physician, senior European Commission official, and former Polish Deputy Minister of Health, recently told me during an interview for the White Paper (a summary of our efforts in preparation for the Polish EU Presidency) that a key issue is **food labelling**. The question

<sup>206</sup> Deklaracja na rzecz badań przesiewowych noworodków w kierunku chorób lizosomalnych [Declaration for Neonatal Screening of Lysosomal Diseases], 2024, http://rzadkiechoroby.org/wp-content/uploads/2024/02/29\_01\_2024\_deklaracja\_NBS.pdf.



remains: Do people actually understand these labels? Even when consumers read what is written on a product, do they truly grasp what they are buying? It is all too easy to shift the responsibility for prevention onto individuals without considering their educational background or social capital. We tell people to exercise more and prepare fresh meals instead of eating processed foods, yet we fail to acknowledge that five million Poles work in industry and 700,000 in warehouses and logistics centres. These are often the only employment options in certain communities. Many of these workers commute up to 150 km daily. I personally have a family member who spends five hours a day on a train commuting to work, followed by ten-hour shifts in an industrial facility. Under these circumstances, when are they expected to prepare balanced meals and engage in physical activity? Decision-makers should examine work culture in Poland, as the **current work culture does not support individual responsibility for health prevention**.

**Those in power should also lead by example when it comes to healthy living.** We know that the Prime Minister runs, and the President skis. Michelle Obama, for example, led a nationwide campaign promoting healthy food for children. So why, at Polish political rallies, do we always see roast pigs and sausages in the background? Perhaps it is time to showcase healthier alternatives. The influence of leaders and public figures in shaping pro-health behaviours cannot be overstated.

## Jakub Gierczyński MD PhD, MBA

#### **European Health Network**

Disease prevention encompasses measures aimed at preventing the onset of illness, minimizing its impact and associated disability, or, when prevention is not possible, delaying its progression. Primary, or phase one, prevention, consists of measures directed at healthy individuals and their living environment to reduce the likelihood of diseases or health disorders. This includes protective vaccinations, health education, and the promotion of a healthy lifestyle. Secondary (phase two) prevention focuses on the early detection of diseases and rapid corrective actions to halt their progression by identifying and eliminating risk factors. It targets individuals at risk and encompasses screening tests such as mammography for breast cancer or cytology for cervical cancer, periodic medical examinations, risk factor monitoring, and counselling. Tertiary (phase three) prevention involves therapeutic and rehabilitation measures undertaken when a disease has already fully developed, aiming to mitigate its consequences and reduce the risk of recurrence. Examples include medical rehabilitation and cholesterol-lowering treatment following a heart attack. Prevention strategies can be designed based on the target group, either at the level of an individual – referred to as a high-risk strategy – or at the population level, known as the population strategy. It can also be approached through the epidemiological triad, which includes neutralizing the source of infection, interrupting transmission pathways, and immunizing the population. Additionally, prevention can be classified by risk level as universal, selective, or indicated, depending on the specific needs of the population.<sup>207</sup>

According to the September 2024 report entitled *The Value of Prevention for Economic Growth and the Sustainability of Healthcare, Social Care, and Welfare Systems*, preventive healthcare plays a crucial role in fostering economic growth and ensuring the sustainable development of healthcare and social care systems in response to the challenges currently facing the European Union. These challenges include slow economic growth, demographic and epidemiological transitions, and a shift in the healthcare model from a reactive approach (focused on disease treatment) to a proactive one (emphasizing health promotion), with increased investments in

<sup>207</sup> Narodowy Instytut Zdrowia Publicznego PZH – Państwowy Instytut Badawczy (NIZP PZH – PIB), Profilaktyka chorób – definicja, ProfiBaza, https://profibaza.pzh.gov.pl/publikacje/swiadczenia–zdrowia–publicznego/05–profilaktyka–chor proc. C3 proc.B3b–definicja.

preventive healthcare.<sup>208</sup> Studies confirm that investing in preventive healthcare yields tangible, long-term benefits, **with every euro spent generating a return of 14 euros.** Despite this, only a small percentage of national health budgets are currently allocated to preventive healthcare, with even less funding directed towards vaccination programmes. **Given the economic, demographic, epidemiological, and political challenges confronting the European Union, investment in prevention has become an urgent necessity.** An ageing population across Europe is driving increased healthcare expenditures, while a shrinking working-age population leads to declining tax revenues. Forecasts indicate that by 2050, as much as 19.9% of the EU population will be over 80 years old, and one in three people (29%) will be aged 65 or older. The financial burden on EU Member States is further exacerbated by slow economic growth or declining GDP in some countries. Additionally, both infectious and non-communicable diseases – including cancer, cardiovascular diseases, neurological disorders, and rare diseases – are placing an increasing strain on national healthcare systems. Reactive measures are no longer sufficient; only substantial investment in preventive healthcare will enable Europe to effectively address these multifaceted challenges.

According to Eurostat data, in 2021, European Union Member States allocated EUR 95.3 billion to preventive healthcare, representing 0.65% of GDP. However, there were significant disparities in prevention investment levels across the EU. Austria recorded the highest expenditure on preventive healthcare among Member States, allocating 1.25% of GDP, followed by the Netherlands (0.96%) and Denmark (0.95%). Finland, Germany, and the Czech Republic also allocated more than 0.75% of GDP to health prevention. At the opposite end of the spectrum, Slovakia (0.12%), Malta (0.13%), and Poland (0.14%) recorded the lowest levels of spending, making them the only EU countries that allocated less than 0.20% of GDP to preventive healthcare in 2021.

When assessed on a per capita basis, 14 EU countries spent over  $\notin 100$  per person annually on preventive healthcare in 2021. Austria ( $\notin 566.4$ ) and Denmark ( $\notin 555.1$ ) had the highest per capita expenditures, while the Netherlands ( $\notin 476.9$ ) and Luxembourg ( $\notin 421$ ) also exceeded  $\notin 400$  per capita. In contrast, the lowest per capita expenditures were recorded in Malta ( $\notin 37.4$ ), Romania ( $\notin 30.5$ ), Bulgaria ( $\notin 28.7$ ), Slovakia ( $\notin 23$ ), and Poland ( $\notin 21.6$ ). The difference between the highest and lowest preventive healthcare per capita expenditure – comparing Austria and Poland – was striking, with a ratio of 27:1.

**Public (budgetary) funding was the primary source of financing for health prevention in 2021 in 24 EU Member States, with an average share of 63.7%.** The share of public funding varied significantly, ranging from 98.9% in Spain, 98.5% in Poland, and 99.5% in Denmark to 55.3% in Slovenia. Preventive healthcare financed through compulsory health insurance (also public) accounted for 81.6% of spending in Croatia, 76.4% in the Czech Republic, and 74.2% in France. Employer contributions covered 5.9% of total health prevention spending across the EU in 2021, with this share exceeding 10% in seven Member States. The highest proportions were recorded in Portugal (25.2%) and Poland (27%). Out-of-pocket expenses played a minimal role in financing health prevention, Averaging just 1.1% across the EU, indicating that private payments were not a significant source of funding in this area.<sup>209</sup>

<sup>208</sup> The European House – Ambrosetti, supported by IFPMA and Vaccines Europe, The value of prevention for economic growth and the sustainability of healthcare, social care and welfare systems, 2024, https://www.vaccineseurope.eu/media–hub/publications/the-value-of-prevention-for-economic-growth-and-the-sustainability-of-healthcare-social-care-and-welfare-systems/.

<sup>209</sup> Eurostat, Preventive health care expenditure statistics, 2024, https://ec.europa.eu/eurostat/statisticsexplained/index. php?title=Preventive health care expenditure statistics.



## **Part IV.** Recommendations of Experts, Professional and Industry Associations, and Other Healthcare Stakeholders

Key Areas of High-Impact, Clinical Medicine Overlooked in Health Policy Discussions

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**Committee on Clinical Sciences, Polish Academy of Sciences** 

#### Introduction

The definition of health policy priorities should be guided by a systematic approach. The foundation for prioritising actions in this highly significant area should be based on analyses that quantify the societal burden of specific health issues across multiple dimensions. This means considering not only commonly used indicators that measure the direct impact on affected individuals but also the broader consequences for society. The Committee on Clinical Sciences highlights that several health problems fail to receive due attention in public discourse relative to their actual population burden. Examples include brain diseases (as comprehensively addressed in the Brain Health Strategy of the European Academy of Neurology)<sup>218</sup>, chronic kidney disease, peripheral vascular diseases, and chronic obstructive pulmonary disease (COPD). From an organisational and interdisciplinary care perspective, the Committee particularly emphasises the need for better coordination of preventive measures and the management of patients with multiple chronic conditions, ensuring continuity of care between paediatric and adult medicine.

#### Chronic kidney disease

Chronic kidney disease (CKD) is diagnosed when, for at least three months and regardless of the cause, the calculated glomerular filtration rate (eGFR) is below 60 mL/min/1.73m<sup>2</sup> and/or there are clinically significant indicators of kidney damage, such as albuminuria/proteinuria, abnormal

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218 European Academy of Neurology, Brain Health Strategy.

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microscopic examination of urine sediment, or abnormal imaging results (e.g. ultrasound). According to this definition, CKD affects an average of 10% of the global population (over 850 million people), with considerable variation across different continents. In Poland, CKD is estimated to affect up to 12% of the population, posing a major challenge to the entire healthcare system. A large population study (PolSenior) also showed that CKD is significantly more common among people over 65 years of age in Poland, affecting over 29% of respondents. Unfortunately, awareness of CKD among these individuals was negligible, with only 3.2% of those diagnosed previously aware of their condition. Early detection of CKD is crucial not only for effectively preventing the disease from progressing to end-stage renal disease (ESRD), which necessitates costly treatments such as dialysis or kidney transplantation, but also because CKD significantly increases the risk of hospitalisation and mortality due to cardiovascular complications. Family doctors can detect early stages of CKD as part of so-called coordinated nephrological care by performing simple tests, such as measuring serum creatinine (and calculating eGFR) and determining albumin excretion in urine (albuminuria). These tests should be prioritised for individuals at increased risk of CKD, including patients with diabetes, hypertension, heart failure, generalised atherosclerosis, as well as those who are obese or elderly. A CKD diagnosis enables the introduction of nephroprotective treatment and appropriate dietary interventions (depending on the disease stage), which can significantly slow disease progression and reduce the risk of cardiovascular complications. It should also be emphasised that in recent years many new nephroprotective drugs have been introduced, making treatment highly effective today provided that CKD is diagnosed in time. Despite the available knowledge and treatment options, awareness of the high prevalence of CKD and its associated risks remains alarmingly low. In our opinion, the following actions are necessary: a) establishing CKD registries in Poland (including early-stage cases not yet requiring dialysis or transplantation); b) assessing the extent to which family doctors utilise early CKD detection methods and collaborate with nephrology specialists as part of coordinated nephrological care; c) evaluating the level of uptake of nephroprotective treatments among already diagnosed CKD patients; d) demonstrating the benefits of early CKD detection for the healthcare system (NFZ, Ministry of Health), including lower expenditure on dialysis, kidney transplantation, and cardiovascular complication management.

#### Peripheral vascular diseases

**Peripheral vascular diseases** (PVDs) are a significant health and social issue, encompassing disorders of the arteries, veins, lymphatic system, and microcirculation. The most common conditions include peripheral arterial disease, chronic venous insufficiency, lymphedema, diabetic foot, deep vein thrombosis, post-thrombotic syndrome, and vascular malformations. Despite their prevalence, public awareness of these diseases remains significantly lower compared to heart disease.

Lower limb amputations are among the most severe consequences of advanced PVDs. In Poland, the situation is alarming – it is the only country in the European Union where the number of amputations continues to rise. Approximately 30,000 amputations are performed annually, with a significant proportion involving patients with atherosclerosis and diabetic foot. For comparison, the amputation rate in Denmark is 2 per 100,000 inhabitants, while in Poland, it stands at 7 per 100,000. The impact of amputation extends beyond medical concerns. Many patients become unable to work, leading to an increase in disability pensions and a decline in quality of life. It is estimated that around 40% of amputees die within the first six months following surgery. The underfunding of endovascular procedures, compared to the relatively higher reimbursement for amputation, exacerbates this situation. Additionally, the lack of access to comprehensive rehabilitation, including walking training, which is not reimbursed, further worsens patient outcomes.

**Post-thrombotic syndrome** is a complication of deep vein thrombosis, affecting approximately 50% of patients within two years of a thrombotic episode. Without proper prevention and treatment, it can lead to severe complications, including chronic limb swelling, ulcers, and even amputation.



In Poland, **lymphedema** affects an estimated 500,000 people, with approximately 100,000 requiring specialist treatment. The majority of these patients are oncology patients. Insufficient public awareness and lack of access to appropriate diagnostics and therapy lead to treatment delays, increasing the risk of complications such as infections, including sepsis, and musculoskeletal damage, which may result in disability. Access to comprehensive anti-edema therapy in Poland remains limited, with reimbursement covering only selected procedures, thereby hindering effective treatment.

Inequalities in access to the diagnosis and treatment of PVDs also affect women. Studies indicate that women are less frequently referred for specialist examinations and procedures.

To counteract these adverse trends, it is essential to raise public awareness of PVDs, implement effective prevention programmes, and ensure equal access to diagnosis and treatment for all patients, regardless of gender. Only through coordinated action at the national and EU levels can we improve the situation of patients with peripheral vascular diseases, which are among the leading causes of mortality and disability in the EU. In Poland, an estimated 500,000 people are at risk of amputation due to vascular conditions. These are often patients over the age of 65 who lack adequate care and face difficulties in accessing specialist doctors – angiologists and vascular surgeons.

#### Chronic obstructive pulmonary disease

Chronic obstructive pulmonary disease (COPD), alongside asthma, is one of the most prevalent respiratory diseases. It is currently classified as the third leading cause of death worldwide, surpassed only by cardiovascular diseases and cancer. Epidemiological data indicate that COPD affects one in ten people over the age of 40. In Poland, its prevalence remains significantly underestimated, with estimates suggesting that over two million people are affected. The primary cause of the disease is tobacco smoking in various forms.

COPD is characterised by chronic respiratory symptoms such as coughing with or without expectoration of secretions and persistent, progressively worsening shortness of breath. Symptoms gradually intensify over months and years. The disease leads to a continuous, slow progression of symptoms, ultimately triggering and solidifying chronic respiratory failure. Diagnosis is relatively straightforward and requires spirometry, which confirms the presence of persistent airway obstruction. Chronic neutrophilic inflammation and oxidative stress, induced primarily by smoking, play a key role in both the development and persistence of the disease, causing damage not only to the lungs but also to the cardiovascular system. The progression of COPD is further accelerated by disease exacerbations, which lead to symptom aggravation, decline in lung function, onset or worsening of respiratory failure, reduced quality of life, increased treatment costs, and a heightened risk of depression and anxiety disorders.

An important yet often overlooked consequence of exacerbations is the development of complications affecting other organs, particularly the circulatory system. This relationship is referred to as cardiopulmonary risk, a term encompassing the likelihood of severe respiratory and/or cardiovascular events in patients with COPD. These events include, but are not limited to, COPD exacerbations, myocardial infarction, stroke, decompensated heart failure, arrhythmias (such as atrial fibrillation), and death resulting from any of these conditions. According to the Health Needs Map report, 10% of patients die within the first three months following a COPD exacerbation. During an exacerbation, COPD patients are approximately ten times more likely to experience severe cardiovascular events within the first seven days following a moderate or severe episode.

For this reason, early and accurate diagnosis of COPD, along with the implementation of appropriate treatment, is crucial to slowing disease progression and preventing exacerbations. Raising public awareness of the disease and its systemic consequences is equally important. This can be achieved at both the national and EU levels through effective tobacco control, multidisciplinary coordinated care, and widespread access to spirometry.



#### **Prevention of Cardiovascular Diseases in Children and Adolescents**

One of the key priorities of modern medicine is the prevention of cardiovascular diseases, the leading cause of adult mortality in Poland. Most preventive measures target adults, yet prevention is most effective when implemented in early childhood. Atherosclerotic plaques begin forming in blood vessels as early as a few years of age – a process that remains reversible if appropriate interventions are introduced. In adults, atherosclerosis is already irreversible, and medical efforts focus on preventing complications such as heart attacks and strokes. Primary prevention of cardiovascular diseases should be based on identifying children at high risk of developing atherosclerosis, implementing appropriate interventions within this group, and promoting a healthy lifestyle for children and their families. This aligns with ongoing initiatives, including health education programs in schools and efforts by the Ministry of Health to introduce screening tests for genetically determined lipid disorders. A proper diet, maintaining a healthy body weight, regular physical activity, monitoring blood pressure, cholesterol levels, and blood glucose, avoiding smoking, ensuring 7–9 hours of sleep per night, and maintaining oral hygiene are all crucial elements in cardiovascular disease prevention. Addressing modifiable risk factors for atherosclerosis in children and adolescents can significantly reduce the incidence and mortality rates associated with cardiovascular diseases.

# Organisation of Healthcare in the Transition Period Between Paediatric and Adult Care

**Organisation of healthcare in the transition period between paediatric and adult care** is a major challenge worldwide, including in highly developed countries. This issue primarily concerns **patients with chronic conditions** (e.g., congenital malformations, organ transplants, post-oncology treatment, diabetes, inflammatory bowel disease) and **rare diseases**. Increasing survival rates and longer life expectancy result from early diagnosis (highlighting the importance of screening), improvements in paediatric medical care (specialist training and collaboration within European Reference Networks [ERNs] for rare diseases), complication prevention (coordinated multidisciplinary care), and the availability of early and effective therapeutic interventions (drug programmes). Data on adult healthcare indicate that over 9% of adults with rare diseases were diagnosed in childhood. The number of such patients reaching adulthood is expected to grow. Transitioning to adult care requires a multi-year, staged process that prepares minors to make independent health decisions. Unfortunately, global data confirm that fewer than 20% of these patients receive appropriate transitional care that adequately prepares them for adulthood. This gap may lead to a significant decline in the quality of medical care and undermine previous diagnostic and therapeutic progress.

Patients with congenital heart defects represent one of the most challenging groups for the organisation of comprehensive care. Managing young adults with such conditions requires in-depth knowledge of their often complex cardiac anatomy, a thorough understanding of frequently multistage interventional and cardiac surgical treatments, and the ability to rapidly detect emerging complications such as arrhythmias, thrombotic events, or heart failure. Paediatric cardiologists primarily oversee the care of these patients, while specialised cardiac surgeons from paediatric centres perform complex surgical procedures. However, when reoperation becomes necessary in adulthood, uncertainty arises as to which cardiology-cardiac surgery team should undertake the procedure.

Poland, like other European countries, faces the challenge of developing systemic solutions for individuals with chronic and rare diseases diagnosed in childhood. Drawing on the experience of other healthcare systems, it is worth considering the identification of disease groups requiring coordinated care during the transition period, the establishment of a standardised patient transfer model from paediatric to adult care, and the involvement of the social sector in coordinating these efforts. Given the decreasing paediatric population and the growing number of elderly individuals (due to declining birth rates and increasing life expectancy), the often-limited readiness of young patients with chronic or rare diseases to transition to adult care, and paediatric specialists' expertise



being centred on developmental age issues, extending care within paediatric centres and prolonging the transition phase in cooperation with the receiving specialist or centre may be a viable approach. The advancement of telemedicine is set to enhance interdisciplinary collaboration, streamline the transfer of medical records, and support the development of so-called "chronic disease passports".

# Mental Health of Children and Adolescents – the Direction of Further Actions

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According to the World Health Organisation, health encompasses a person's total physical, mental, and social well-being – not merely the absence of disease or disability. It serves as a fundamental condition for a good quality of daily life, as well as for effective functioning and development across all life stages. Health should be perceived as both an individual resource and a social resource that shapes a healthy, threat-free environment, whether at the level of the immediate community, the nation, or the global stage, forming a collective health potential.

Experts unanimously agree that the early years of life significantly influence mental health, as well as cognitive, emotional, and social functioning. Good mental health during childhood is essential for optimal development, effective learning, forming fulfilling relationships, maintaining physical health, and independently navigating adult life. Safeguarding the mental health of young individuals is thus an investment in the future. The mental health of children and adolescents depends to a large extent on the influence of their immediate social environment. This multidimensional understanding of health is also reflected in the biopsychosocial model of health, which provides the theoretical foundation for numerous studies in the social sciences. This model takes into account a variety of factors relevant to an individual's health, highlighting the interconnectedness of biology, psychology, and social context in human functioning. Considering the developmental context, it is important to note that children and adolescents are particularly vulnerable to mental health challenges. Factors such as genetics, family environment, upbringing, education (school), peer relationships, and exposure to new technologies all significantly influence the psychological development of young individuals. Adolescents, in particular, face developmental tasks related to their stage of life, often grappling with peer pressure and, in some cases, challenging family circumstances. Adolescence is a period marked by profound biological changes that can have farreaching effects on psychological and social development.

In recent years, an alarming increase in mental disorders among children and adolescents has been observed. The pandemic, armed conflict, and economic crises have undoubtedly deepened this already unfavourable situation. The most comprehensive epidemiological data on the mental health of children and adolescents in Poland come from the EZOP II study, though it must be noted that this study was conducted before the COVID-19 pandemic. The results of this research were presented at the Conference Summarising the EZOP II Project, held at the Institute of Psychiatry and Neurology in Warsaw on November 15-16, 2021. The project, conducted between 2017 and 2020 (spanning 42 months), encompassed all age groups: children aged 0-6 years (with their parents), children and adolescents aged 7-17 years, and adults aged 18 years and older.

#### Children aged 0-6

Emotional-affective disorders, identified in over 6% of children, along with adaptive disorders, social communication disorders, and interactional disorders with others, affecting over 4% of children, are among the most common issues in this age group. Overall, the disorders described in the study were found in approximately 16% of children under the age of six. This translates to more than 420,000 children in this age group living with developmental disorders.



#### Children aged 7-17

The analysis revealed that over half a million children and adolescents in Poland suffer from mental disorders. This includes more than 200,000 children aged 7-11 and over 350,000 adolescents aged 12-17. Internalisation disorders, which are primarily anxiety disorders, affect over 300,000 children and adolescents, accounting for approximately 8% of children and 7% of adolescents. Mood disorders, including depressive disorders and manic episodes, were confirmed in significantly fewer cases – about 70,000 children and adolescents – with the vast majority being teenagers. Considering the similar prevalence of depressive and manic episodes, it is estimated that tens of thousands of children/adolescents may have suffered from bipolar disorder. Similarly, externalisation disorders affected approximately 300,000 children and adolescents. Among them, over 100,000 experienced disorders related to substance abuse.

Not only is the prevalence of mental disorders among children and adolescents increasing, but the number of young patients requiring and receiving professional assistance is also rising each year. An analysis of public sector health services conducted by the National Consultant in child and adolescent psychiatry revealed that the number of children and adolescents accessing psychiatric care has more than doubled over the last three years. In 2023, the Police Headquarters recorded 2,139 suicide attempts among individuals aged 7–18. In the 7–12 age range, there were 78 non-fatal attempts. In the 13–18 age range, there were 1,916 such attempts. Out of these 2,139 cases, 145 resulted in death. Suicidal behaviour data should not be analysed in isolation. The observation of trends and dynamics over longer periods of time is of crucial importance. Such extended annual periods must be considered. The first significant increase in suicide attempts among adolescents was observed in 2021, with a 70% rise compared to 2020. A further sharp increase of 40% was noted in 2022, as compared to 2021.

Another alarming indicator relates to the increased use of digital technologies by young people. According to the Teens 3.0 report, the time teenagers spend online on weekdays rose again, From 4 hours 50 minutes (2020) to 5 hours 36 minutes. During school holidays, teenagers spend an average of 6 hours 16 minutes in cyberspace. Over half (54.9%) of the surveyed teenagers often or very often perform other tasks while using the Internet or smartphones. More than four in ten teenagers (44.5%) have low self-esteem. Nearly half (44.6%) encounter online situations where their peers are attacked or insulted. More than half (53.9%) feel a high (10.6%) or above-average (43.3%) level of loneliness in social media. Three in ten (31.1%) teenagers admitted to having taken part in challenges in the past year that could jeopardise the physical or mental health of themselves or others, and 16.2% cannot go more than an hour without social media. For a significant group of 46.2%, physical appearance and attractiveness in the context of social media are particularly important.

The most important conclusions from a report prepared by NASK, *Teenagers vs. Digital Pornography*, include the following observations: one in five teenagers indicated that their peer watches pornography on the Internet several times a day (20.6%) or several times a week (20.9%). One-third of the youngest respondents could not determine whether the sexual reality depicted in pornographic films aligns with real life. Almost one in five respondents was less than ten years old when they first encountered pornographic films or photos, and more than one in five younger respondents admitted to the same practice. Almost one-third of 16-year-olds and just under one in five respondents aged 12-14 reported witnessing forced sexual acts online.

In response to the need for urgent changes in the mental healthcare of children and adolescents in our country, the Ministry of Health is implementing a new model of psychiatric care for this group. Its goal is to create a nationwide, comprehensive system that provides support to underage patients experiencing mental disorders and their families. Addressing the aforementioned issues and considering EU directives and strategic documents in Poland, the main assumptions of the model are as follows:

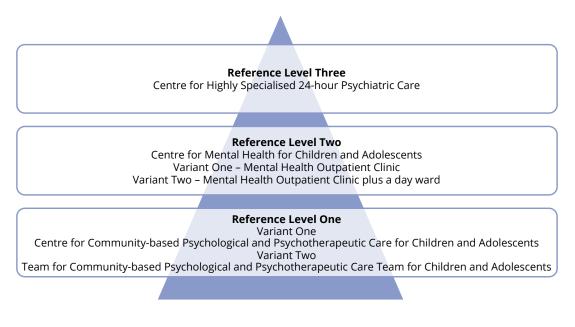
- deinstitutionalisation of psychiatric care for children and adolescents in Poland, in line with global trends, EU directives, and Polish strategic documents, meaning the gradual organisational



and financial shift from hospital-based treatment (primarily medical consultations) to outpatient and community-based care (mainly psychological and therapeutic consultations);

- implementation of a patient pathway in the mental healthcare system according to treatment standards and optimisation of the use of medical staff in the public service system, for instance, psychiatric consultations should be reserved for those children and adolescents who truly require medical diagnosis or pharmacotherapy;
- ensuring rapid intervention by non-psychiatrist specialists in the mental healthcare system, i.e., psychologists, psychotherapists for children and adolescents, and community therapists for children and adolescents;
- increasing the availability of outpatient and community-based services at the district level;
- development of community-based services, i.e., introducing an obligation to cooperate with the family and school environment outside the medical entity;
- creating a nationwide, comprehensive system providing support to underage patients experiencing mental disorders and their families levelling regional disparities;
- and developing medical staff tailored to the new organisational system of child and adolescent psychiatric services.

The implementation of the new model of the mental healthcare system for children and adolescents was preceded by pilot projects, including initiatives financed by the European Social Fund. Between 2018 and 2022, more than 10 community mental health centres for children and adolescents were established, and their performance and organisational solutions influenced systemic solutions. The new model consists of three reference levels:



Elaboration by the Department of Public Health of the Ministry of Health.

#### REFERENCE LEVEL ONE

Centers or teams of community-based psychological and psychotherapeutic care for children and adolescents are facilities accessible without a medical referral. They employ psychologists, psychotherapists, and community therapists who help children not requiring psychiatric diagnosis or pharmacotherapy. Their purpose is to provide an early response to emerging problems to prevent deterioration in the patient's health and hospitalisation. Ultimately, Reference Level One centres aim to operate in each district or group of districts, ensuring assistance close to the children's place of residence and enabling cooperation with the local environment, especially educational institutions. The first Level One centres became operational in 2020. As of 7 August 2024, 489 such centres (or units) of community-based psychological and psychotherapeutic care were operating in Poland.



#### **REFERENCE LEVEL TWO**

At the second reference level, psychiatrists work in mental health centres for children and adolescents. Patients requiring more intensive care in selected facilities can also access day care services. One Reference Level Two centre is to serve several neighbouring districts. As of 7 August 2024, there were 172 such centres, including 83 offering mental health clinic services and 89 with both mental health clinics and day wards.

#### **REFERENCE LEVEL THREE**

At the highest reference level are centres providing highly specialised, round-the-clock psychiatric care for patients with the most serious disorders, particularly in life- and health-threatening conditions, admitted on an emergency or scheduled basis. At least one Reference Level Three centre exists in each province. As of 7 August 2024, 34 centres of this type were operating in Poland.

A programme to support child and adolescent psychiatry has also been implemented, aimed at improving the system of mental healthcare for children and adolescents, particularly by improving infrastructure, modernising facilities, and co-financing a programme for preventing digital addictions. Furthermore, valuations of psychiatric services for children and adolescents were increased. This specialty is included on the list of priority fields, financially incentivising education in this area and providing additional residency positions. A key aspect of the new model is the development of the cadre of other specialists focussing on the mental healthcare of children and young people. Legislation has been implemented to introduce new professions:

- The "psychotherapy of children and adolescents" medical specialty was introduced via the Regulation of the Minister of Health of 31 January 2019 (Journal of Laws 2019, item 226). The curriculum for the specialty was announced in June 2019, and the first examinations took place in September 2020.
- The market qualification "Conducting community therapy for children and adolescents" was incorporated into the Integrated Qualifications System by the official notice of the Minister of Health of 19 December 2018 (Journal of Laws 2018, item 1279).
- A new specialty curriculum in clinical psychology focusing on children and adolescents was developed in April 2018.
- Changes were made to the specialty curriculum for child and adolescent psychiatry, incorporating the implemented model focused on interactions in the minor's natural environment based on intra- and inter-sectoral cooperation. Considering staff shortages, a new module for paediatric specialists, with a training period of three years, was introduced.

Understanding the factors influencing the mental health of children and adolescents is crucial for identifying their needs and challenges and, consequently, for determining solutions that can improve their situation. Identifying threats to mental well-being is essential for developing effective programmes and policies that promote and protect children and adolescents' mental health. It is worth noting that a given factor may act as a protective element or a risk factor depending on the context. For instance, a safe, non-violent peer environment at school serves as a protective factor, whereas the opposite constitutes a risk factor. Therefore, it is vital to outline the ecosystem children and adolescents depend on during their psychophysical development, considering each child's unique circumstances.

The objectives of Poland's Presidency in the area of children and adolescents' mental health should revolve around three key issues. These objectives support the main goals of policies [1]<sup>219,[220221</sup>2]

<sup>219</sup> https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union/comprehensive-approach-mental-health\_en.

<sup>220</sup> European Commission, Directorate-General for Education, Youth, Sport and Culture, *Wellbeing and mental health at school – Guidelines for school leaders, teachers and educators*, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2766/760136.

<sup>221</sup> https://ec.europa.eu/commission/presscorner/detail/en/FS\_23\_3051.



[3] recommended by the European Commission and the development of good practices<sup>222</sup> <sup>2232245],[6]</sup> in mental health. These are as follows:

- 1. Developing the competences and skills of specialists working in child and adolescent mental health and evidence-based therapies using a community-based mental health services approach.<sup>225</sup> The European Commission has recommended<sup>226</sup> that community-based services in local communities significantly enhance access to services for children, adolescents, and their families affected by mental health problems, while reducing loneliness among young people<sup>227</sup>. However, there are barriers, including a lack of competency among medical, educational, or social staff in local community collaboration And a limited number of programmes oriented towards community work and multi-disciplinary cooperation.
- 2. Promoting and developing conditions for more intensive cross-sectoral cooperation implementation in Member States. Poland's experience in implementing community-based mental health centres for children and adolescents highlights the challenges of cross-sectoral collaboration, particularly with regard to legal regulations on data security, funding, and organisational solutions such as the sharing of information between systems and registers maintained in different public sectors. Cross-sectoral approaches must be a horizontal criterion in developing directives for mental health protection for children and adolescents. Without proper legal frameworks and solutions for processing sensitive data<sup>228</sup>, collaboration between specialists from different sectors at the local community level will remain hindered, which affects, for example, such initiatives as the Multi-Sectoral MHPSS Assessment Toolkit<sup>229</sup>. The European Commission's project, Technical Member State support for cross-sectoral mental health services, is one of the few Commission and Member State initiatives testing solutions for intersectoral cooperation.
- 3. Strengthening the role of education providers<sup>230</sup> in preventing mental health crises and implementing solutions to reduce mental health crises in the workplace. A more robust implementation of the European Commission's recommendations in school and work environments may reduce suicidal behaviours among children and adolescents. In addition, the development of methods to improve parent-child bonding and strengthen parental skills should remain at the centre of prevention measures. Last but not least, the advancement of methods for improving parent-child bonds and strengthening parental competencies should remain a key component in this area.

225 https://eu-promens.eu/eu-promens.

- 228 https://www.consilium.europa.eu/en/press/press-releases/2024/03/15/european-health-data-space-counciland-parliament-strike-provisional-deal/.
- 229 https://www.mhpssmsp.org/sites/default/files/2024-07/Multi-sectoral proc.20MHPSS proc.20assessment proc.20toolkit proc.20field proc.20testing proc.202024.pdf.
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Second report based on data from the National Police Headquarters and its support service www.zwjr.pl, Warszawa 2023.

<sup>222</sup> https://ja-implemental.eu/.

 $<sup>223\</sup> https://webgate.ec.europa.eu/dyna/bp-portal/mental-health.$ 

<sup>224</sup> https://health.ec.europa.eu/publications/good-practices-mental-health-and-well-being-mental-health-services-community\_en.

<sup>226</sup> https://health.ec.europa.eu/publications/towards-community-based-and-socially-inclusive-mental-health-care\_en.

<sup>227</sup> The European Union Youth Strategy 2019–2027 (OJ C 456, 18.12.2018).

*Nastolatki 3.0.* [Teens 3.0] A report on the nationwide study of students and parents by the National Research Institute.



## **Issues and Priorities in Adult Psychiatry**

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"There is no health without mental health." Mental health is the foundation of a healthy society. Mental disorders represent one of the greatest challenges in healthcare. An epidemiological study conducted in Poland (EZOP II) found that more than a quarter of Polish adults – over eight million people – experience mental disorders at some point in their lives. However, only a small percentage of those affected receive psychiatric or psychological care. This is due not only to the limited availability of specialists but also to widespread societal prejudices and persistent stigma surrounding mental illness.

The ongoing reform of adult psychiatry – including the establishment of Mental Health Centres (MHCs) with more favourable flat-rate financing, and territorial responsibility for population-wide mental health – has significantly improved care, particularly for severely affected patients with schizophrenia and other psychoses. However, many areas still require improvement.

#### Fighting Stigma: Still a Key Priority

Mental illnesses have long been subject to social stigma. Despite major advances in psychiatry, they continue to be negatively portrayed in media, art, and everyday life. Numerous harmful myths persist, leading to discrimination in family settings (e.g., limiting patients' autonomy under the guise of concern), workplaces, public spaces, and even healthcare interactions. This stigma often stems from a lack of knowledge and fear of the unknown. In addition to public stigma, many individuals experience self-stigmatization - negative beliefs about themselves that impact quality of life, social interactions, and willingness to seek help. Last year, the Nie Widać Po Mnie ("You Can't Tell by Looking at Me") Foundation, in collaboration with the EPI-Bohater ("Epilepsy-Hero") Foundation, launched the educational campaign Straighten Your Gaze. This initiative aimed to raise awareness about: depression, schizophrenia, and epilepsy. As part of the project, two studies were conducted to assess public perceptions of mental disorders among adults in the general population, and attitudes among healthcare professionals. The research aimed to understand the level of knowledge and current myths and stereotypes about depression and schizophrenia and showed that the problem exists and is significant. Combating the stigma surrounding mental illness is a key objective of the Polish Psychiatric Association (PTP). To achieve this, efforts must focus on: education and public awareness, expanding community-based psychiatric care, integrating psychiatric wards into general hospitals, ensuring access to modern, evidence-based treatments, and enhancing the social inclusion of patients - for example, through supported employment programs, and Community-based social initiatives.

#### Access to Reliable and Professional Psychotherapy

Psychotherapy is a clinically proven treatment method. It can serve as a primary form of therapy (e.g., for personality disorders) or as a complementary approach alongside pharmacotherapy. For psychotherapy to be effective, it must be conducted under specific conditions by highly qualified professionals who adhere to ethical codes. Professional qualifications include completion of certified training programs and courses, passing professional examinations, and obtaining certification from recognised scientific societies or specialisation credentials (e.g., child and adolescent psychotherapy specialist) through a CMKP (Centre for Postgraduate Medical Education). To protect patient safety, the provision of psychotherapy by unqualified individuals must be strictly regulated – hence the need for statutory oversight.



#### **Optimising Care for Aging Patients**

The ageing population and rising life expectancy present significant challenges for psychiatry. Psychogeriatric patients are typically affected by multiple comorbidities, undergoing polypharmacy, and often facing social and financial difficulties (e.g., loneliness and economic hardship). The greatest challenges include depression – which occurs twice as often in older adults as dementia, and neurodegenerative diseases. To provide effective care, patients require comprehensive and reliable diagnostics (e.g., neuropsychological testing, neuroimaging), multidisciplinary medical support, and assistance from relevant institutions (e.g., Municipal Social Welfare Centres). Investing in preventive programmes for seniors is essential. These could include Senior Activity Centres, Universities of the Third Age, and development of telemedicine and ICT-based solutions.

#### **Specialist Programmes and Level Three Psychiatric Care**

Mental Health Centres (MHCs) currently provide the first level of psychiatric care. However, for a comprehensive reform of psychiatry to be effective, it is essential to develop and adequately fund specialized programmes. Level Two of psychiatric care refers to planned psychiatric treatment, provided through specialized inpatient, day-care, or outpatient services delivered by dedicated psychiatric wards and clinics. It is recommended that standardised diagnostic, treatment, and rehabilitation programs be developed for individuals with specific mental disorders, particularly for:

- treatment-resistant affective disorders and drug-resistant schizophrenia,
- first-episode psychosis,
- eating disorders,
- severe personality disorders,
- anxiety and psychosomatic disorders (e.g., neuroses requiring intensive psychotherapy),
- mental disorders in old age,
- mental disorders with comorbid somatic illnesses (including neurological disorders), and
- dual diagnoses (e.g., schizophrenia co-occurring with substance use disorders).

For psychiatric reform to be successful, it is imperative to develop a structured, multi-tiered system that ensures accessible community-based care (Level One), targeted, specialised treatment programmes (Level Two), and advanced psychiatric centres for the most complex cases (Level Three).

#### Addictions

Addiction is a major public health challenge. The example of the United States demonstrates that even a highly developed country with world-leading medical advancements has failed to control the opioid crisis, which contributed to the deaths of approximately 645,000 Americans between 1999 and 2021. In 2021 alone, around 80,000 people died due to opioid overdoses a tenfold increase compared to 1999. There can be no illusion that this epidemic will bypass Europe or Poland. Beyond opioids, the misuse of other psychoactive substances, particularly alcohol, remains a significant problem. According to the World Health Organization (WHO), alcohol is the third leading risk factor affecting public health and is associated with over 200 diseases and injuries. Every year, thousands of people in Poland die from alcohol-related causes, both directly and indirectly. A concerning trend has emerged in recent years: in 2021, the number of alcohol poisoning deaths increased by over 40% compared to the previous year, Deaths from alcohol-related liver disease rose by 5%. Nicotine addiction must not be underestimated, as it is highly prevalent among individuals with mental health disorders and significantly shortens life expectancy compared to the general population. New challenges in addiction prevention require effective interministerial collaboration, involving the Ministry of Health, the Ministry of National Education, the Ministry of Finance, the Ministry of Agriculture, and the Office of Competition and Consumer Protection. Regulatory measures in this area should be coordinated by a Government Plenipotentiary for Public Health, whose appointment should be treated as a priority.



One example of an initiative requiring strong interministerial collaboration is the National Strategy for the Control of Tobacco Smoking and the Use of Nicotine Products, developed by the Polish Psychiatric Association and submitted to the Chancellery of the Prime Minister. Effective implementation of this programme could significantly improve public health, and reduce the enormous financial burden of treating nicotine-related diseases, which cost the healthcare system billions.

#### Summary

To achieve these critical objectives, it is imperative to increase funding for psychiatry to reach the EU average of approximately 6% of public healthcare expenditure.

## Prevention – A Holistic Approach to the Patient and Cooperation Across Healthcare Sectors

## **Prof. Maciej Banach MD PhD**

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Prophylaxis, or prevention, forms the cornerstone of any healthcare system – at least in principle. A well-functioning system is essential to tackle the challenges posed by an aging population, multimorbidity, and demographic decline. In Poland, the annual number of births is currently 140,000 lower than the number of deaths, posing a major challenge for the healthcare system. Projections indicate that in the next 20–30 years individuals over 65 will make up 35–40% of the population, and those over 80 will account for more than 20%.<sup>1</sup> This presents not only a challenge in providing healthcare services for the elderly – many of whom have multiple risk factors and chronic conditions – but also in ensuring sufficient medical personnel. The generational gap and shortage of specialists exacerbate this issue. Moreover, there are insufficient outpatient specialist services and a lack of hospital facilities, including geriatric and palliative care beds, and long-term care services.

The key to addressing these challenges lies in well-designed preventive programs, which should be built on comprehensive health education. At every stage of the healthcare system, patients should be educated about a healthy lifestyle, self-examinations, warning signs of diseases, the benefits of vaccinations, and proper medication use, including why adherence is crucial – often for life. In a well-structured, coordinated model of primary prevention, education should account for up to 85% of all preventive measures. Its successful implementation requires the involvement of not only doctors and nurses but also physician assistants, dietitians, psychologists, and pharmacists. Only such a comprehensive educational model can lead to a situation where:

- 1. Patients are aware of alarming symptoms of various diseases and will report them early enough to enable timely diagnosis.
- 2. Patients seek medical attention only when symptoms justify it, which would help reduce the long waiting times for specialist consultations currently observed in Poland (e.g., 526 days for a paediatric genetic clinic, 491 days for an osteoporosis endocrine clinic, and nearly 190 days for a vascular surgery clinic).<sup>2</sup>
- 3. Patients avoid unnecessary appointment cancellations and will notify healthcare providers as early as possible in cases of cancellations. It is estimated that 1.4 million medical appointments per year are missed without cancellation, significantly contributing to extended waiting lists. The highest number of missed appointments occur in the following specialities: orthopaedics over 420,000 missed visits, cardiology 280,000 missed visits, physiotherapy over 180,000 missed visits, endocrinology approximately 120,000 missed visits, and oncology as many as 100,000 missed visits.<sup>3</sup>



- 4. Patients commit to lifestyle changes, including a well-personalised diet tailored to comorbidities and risk factors, regular, individually adjusted physical activity (currently, only 8% of Poles engage in daily physical exercise), avoiding harmful substances, and prioritising healthy sleep and stress management.
- 5. Patients follow medical recommendations, taking prescribed medications regularly without discontinuation or dose reduction. Data indicate that non-adherence is an independent risk factor for cardiovascular disease. For instance, strict adherence to statin therapy alone can reduce the risk of death by 45%.<sup>4</sup> The introduction of the PLIP (Personalised Lipid Intervention Plan) algorithm by the International Panel of Lipid Experts has significantly reduced non-adherence and discontinuation of statin therapy, solely through well-structured patient education.<sup>5</sup>
- 6. Well-educated patients are better equipped to navigate misleading health-related misinformation (fake news). They also feel more confident in consulting their doctors about any doubts regarding information they encounter related to health, symptoms, diseases, or treatments.
- 7. Educated patients serve as health ambassadors within their families, workplaces, and communities. They actively promote vaccination, regular screenings, medication adherence, and a healthy lifestyle. In Poland, less than 10% of adults receive an annual influenza vaccination – a figure that could improve through better awareness and education.

Health education should begin as early as possible, ideally during early school years, so that well-educated children can pass this knowledge on to their siblings, parents, and grandparents. A pioneering model for early health education was proposed years ago by Prof. Valentin Fuster from New York City (originally from Spain), who launched the Comprehensive Health Program, known as SI!. This programme continues to be implemented in Spain. A study conducted by the SHE Foundation aims to promote cardiovascular health from kindergarten to high school through interventions in four key areas: nutrition, awareness and knowledge of one's body and heart, physical activity, and emotional management.<sup>6</sup> The results of the SI! programme have clearly demonstrated that long-term health education for children and adolescents helps build a healthier society. As a result, people instinctively adopt healthy behaviours without requiring strict regulations or prohibitions. This includes choosing the right diet for themselves and their families, understanding the importance of personalised physical activity, avoiding excessive alcohol consumption and smoking, recognising the need for vaccination and preventive health screenings, regularly consulting doctors and adhering to prescribed medications. In 2019, Prof. Fuster announced the results of the FAMILIA study, which strongly confirmed that very early education – as little as two hours per week over four months in preschool – significantly improves knowledge about a healthy lifestyle among both children and their families.<sup>7</sup>

For the past 10–15 years, many experts in Poland have been advocating for the introduction of a health education curriculum similar to the Knowledge about Health concept. As a result, in September 2025, the subject *Health Education* – though unfortunately only as an optional course – will become part of the Polish school curriculum. Health Education will replace the subject Education for Family Life and will be offered to students in Grades Four to Eight of primary schools, and Grades One-Three of secondary schools, including general secondary schools, technical secondary schools, and first-degree vocational schools.<sup>8</sup> According to the curriculum framework, primary school students will acquire the following skills:

- engaging in activities that support the maintenance, improvement, and protection of health,
- recognising and responding to life-threatening and health-threatening situations,
- developing a positive self-image and fostering healthy interpersonal relationships,
- promoting healthy lifestyle habits within their communities,
- monitoring their own health across all dimensions,
- seeking, verifying, and analysing information about their own health and the factors influencing it.<sup>9</sup>



If effectively implemented, this subject could lead to significantly lower disease prevalence and better overall health indicators over the next 20–30 years. This has already been demonstrated by the *SI*! programme, and the Coordinated Primary Prevention Care Model implemented in Slovenia since the 1990s.

Do preventive programs exist in Poland? Definitely yes – starting from children's health check-ups (though participation rates are declining – only 75% of six-year-olds undergo routine check-ups) to compulsory vaccination programmes. It is also worth noting the expected introduction of lipid profile testing as part of the six-year-old health check-up, aimed at universal screening for familial hypercholesterolemia. This measure was approved by the Agency for Health Technology Assessment and Tariff System (AOTMiT) in 2024 and is estimated to help identify nearly 30,000 children with suspected familial hypercholesterolemia.<sup>10</sup> Unfortunately, in an era of science denialism – with trust in science in Poland among the lowest in Europe, especially post-pandemic – there has been a sharp increase in vaccine refusals for compulsory childhood immunisations. Between 2014 and 2023, the number of vaccination refusals increased nearly sevenfold, from 12,700 to almost 90,000 cases.<sup>11</sup> This has led to alarming increases in preventable infectious diseases: pertussis (whooping cough) incidence surged 35-fold in 2024, reaching 32,400 cases.<sup>12</sup> Measles cases also rose dramatically -246 cases recorded between January and 31 July 2024, which is >10 times higher than in the same period in 2023, and nearly 7 times higher than the entire year of 2023, when only 36 confirmed cases were reported in Poland.<sup>13</sup> Poland's primary healthcare system also includes prevention programmes targeting smoking cessation, and cardiovascular diseases (CVD) – available for individuals aged 35–65. Under the latter programme, every five years, eligible patients can receive a referral for blood pressure monitoring, and biochemical tests to assess cardiovascular risk. Based on these results, physicians can recommend health education and follow-up screenings in five years, ongoing Primary Care management outside the programme, or referral to a specialist for further treatment.<sup>14</sup> Despite the availability of these programs, participation remains low. In 2022, just over 220,000 patients participated<sup>14</sup> – a small fraction of those eligible.

It is important to highlight Poland's first health programme focused on the prevention of cardiovascular and lifestyle diseases – the 40 Plus Prevention programme, introduced in July 2021. This initiative offers free diagnostic packages for men and women, with the specific tests determined by a mandatory pre-screening survey. Since the programme's launch, nearly 5 million surveys have been completed by January 2025, while just over 4 million individuals have undergone testing.<sup>15, 16</sup> The programme is available to up to 20 million people aged 40 and over. While the programme's objectives are well-founded, and the scope of offered tests remains open for discussion, the main criticisms include the lack of targeted education for eligible participants, preventing many from fully understanding and utilising the programme, and no structured follow-up care for patients with abnormal results. Many individuals receive their test results without guidance on next steps. Ideally, patients at risk should be automatically referred to the Cardiovascular Disease (CVD) Programme (if results indicate cardiovascular risk), or coordinated primary care services for further monitoring and treatment.

Similar progressive initiatives in cardiovascular prevention were proposed under the National Programme for Cardiovascular Diseases (Narodowy Program Chorób Układu Krążenia, NPCHUK), which was adopted by the Polish Government in December 2022. The program, with a budget of PLN 2.7 billion for the years 2022–2032, focuses on five key areas: investment in medical personnel, education and prevention, patient-focused care, scientific research and innovation, and enhancement of the cardiac care system. NPCHUK sets highly ambitious goals, directly addressing the major cardiovascular health challenges in Poland, including:

- Reducing morbidity and mortality from cardiovascular diseases, with a particular focus on lowering excess mortality among men of working age, and Aligning Poland's health indicators (life expectancy, mortality rates, and disease prevalence) with EU–27 averages.
- Minimising regional disparities in disease incidence and mortality, by improving access to healthcare services.



- Lowering the prevalence of traditional cardiovascular risk factors, while addressing socioeconomic health inequalities.
- Enhancing the organisation of cardiovascular research, including: Strengthening Poland's research and innovation capacity, Improving risk assessment and identification of high-risk populations, and Developing innovative diagnostic and therapeutic solutions.<sup>17</sup>

As part of its investment in education, prevention, and lifestyle, the NPCHUK program aims to achieve: (1) a reduction in the percentage of girls and boys aged 11–15, and Women and men with excessive body weight; (2) an increase in the percentage of girls and boys aged 15, and women and men who declare themselves non-smokers; and (3) a decrease in alcohol consumption and a reduction in the prevalence of undiagnosed hypertension, alongside a decrease in average blood pressure across the Polish population.<sup>17</sup> Despite its broad scope, the program fails to address one of the most prevalent cardiovascular risk factors – lipid disorders. Lipid disorders affect up to 70% of the Polish population, yet their awareness remains critically low, with only 1 in 7 Poles recognising the condition, and Treatment effectiveness remains poor, with a success rate of only 20–25%.<sup>18</sup> Additionally, NPCHUK does not clearly define the expected reductions in key health indicators by 2032 – a fundamental aspect for ensuring proper implementation and accountability. Most importantly, many of the program's planned interventions have not yet been put into action. Despite its current shortcomings, NPCHUK holds promise for effective health education and primary prevention, particularly if it is monitored at mid-term intervals and continuously optimised to align with expectations and measurable health outcomes.

When discussing the treatment of lipid disorders, it is crucial to highlight the significant inefficiency and lack of physician support in diagnosing rare diseases related to cholesterol synthesis and metabolism – despite efforts dating back to 2009. The homozygous form of familial hypercholesterolemia (HoFH) has been diagnosed in only seven patients, out of an estimated 150 cases in Poland. Familial chylomicronemia syndrome (FCS) – there is no available data on the number of diagnosed and treated patients. The situation is not much better for heterozygous familial hypercholesterolemia (HeFH). While it does not meet the criteria for a rare disease (prevalence 1:250–1:300), it substantially increases cardiovascular risk. Only 7,000 patients have been diagnosed in Poland – just 5% of the estimated total affected population.<sup>19</sup> This underscores the urgent need for the implementation of the National Plan for Rare Diseases, which has already been approved twice in recent years and holds the potential to significantly improve patient outcomes.<sup>20</sup>

In summary, although the Polish healthcare system has various preventive programmes, they remain highly fragmented, lacking coordination, and poorly implemented or not fully operational. Instead of developing new initiatives from scratch, Poland could adapt proven models, such as Slovenia's coordinated primary prevention program (introduced in 1998), which reduced myocardial infarction risk by over 50%, and lowered premature mortality risk by nearly 20% within a decade.<sup>21</sup> If properly implemented, such an approach could help Poland move out of the high cardiovascular risk group, where 80,000 heart attacks and 80,000 strokes occur annually, and over 160,000 deaths per year are attributed to cardiovascular diseases. It is also worth noting that two million patients in Poland live with diagnosed cancer, and just over one million people survive a heart attack – yet 26% die within three years post-infarction.<sup>22</sup> To reverse these alarming trends, prevention must become a priority – as it remains the most effective tool for reducing disease burden. Perhaps Poland's Presidency of the European Union presents an opportunity to make prevention a central health policy initiative.

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## **Vaccination Throughout Life**

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Vaccination is one of the most crucial pillars of public health and the most effective tool for combating infectious diseases in both children and adults. It plays a key role in preventing 26 infectious diseases, their complications, and related deaths. WHO experts estimate that approximately 122 million people owe their lives to vaccines, without which they would not have survived childhood. This is due to the fact that over the past few decades, millions of children have been vaccinated against childhood diseases such as measles, tuberculosis, poliomyelitis, diphtheria, pertussis, and pneumococcal pneumonia. According to WHO data, nearly one billion vaccine doses are administered globally each year, saving the lives of approximately 2.5 million people, including children, adolescents, but also adults. Adult vaccination is just as important as childhood immunisation, as unvaccinated adults are more vulnerable to infectious diseases such as pneumococcal pneumonia and influenza. This is due to immunosenescence (the ageing of the immune system), a progressive decline in immune cell activity with age, as well as the burden of chronic diseases, particularly among older adults. The mortality risk from vaccinepreventable diseases in adults is estimated to be around one hundred times higher than in children. People over the age of 65 are particularly vulnerable to severe infectious diseases and therefore require protection through vaccination. According to WHO's current strategy, vaccination is now considered a fundamental component of a healthy lifestyle, alongside non-smoking, proper nutrition, adequate sleep, and age-appropriate physical activity. Vaccines are intended for people of all ages and are important at every stage of life, as WHO highlights: "Vaccines protect health for all generations". This aligns with observed demographic changes, disease epidemiology, and global healthcare system challenges. Vaccination provides both individual and population-level protection. Maintaining herd immunity requires a high vaccination coverage rate, which should be at least 90%. In Poland, universal vaccination of children and adolescents has been implemented since the 1960s as part of the National Immunisation Programme (NIP), which includes the schedule of mandatory and recommended vaccinations. Mandatory vaccinations are free of charge for individuals aged 0–19, whereas recommended vaccines are partially or fully financed by patients. The systematic and uninterrupted implementation of immunisation over the past 60 years has led to a significant reduction or elimination of diseases such as diphtheria, poliomyelitis, pertussis, measles, hepatitis B, and invasive bacterial infections. The nationwide vaccination requirement has increased the number of immunised individuals, thereby reducing the risk of epidemics. In recent years, the NIP has introduced free vaccinations against pneumococcal infections (since 2017) and rotaviruses (since 2021), along with expanded vaccination recommendations for at-risk children. A further milestone was the introduction of free, recommended vaccinations against human papillomavirus (HPV) for girls and boys.

In this context, the systematic expansion of the list of reimbursed vaccinations for seniors is crucial. Currently, pneumococcal vaccination is fully reimbursed for individuals aged 65+ in high-risk groups. Among bacterial pathogens, pneumococci are responsible for the highest mortality rates among children and older adults. Among seniors, pneumonia ranks as the fourth leading cause of death. Globally, 1.5 million people die each year from pneumococcal infections, including approximately 1 million due to pneumonia. Another example of fully reimbursed vaccines for seniors aged 65+ includes influenza and COVID-19 vaccinations. Each year, 5–10% of the adult population and 20–30% of children worldwide contract the influenza virus. Influenza and influenza-like viruses cause between 250,000 and 500,000 deaths worldwide annually. In Europe, influenza claims 38,500 lives each year. Epidemiological studies indicate that between 25 and 100 million people in the European Union contract influenza annually. Influenza and COVID-19 infections



affect people regardless of age and geographic location, with significant seasonal fluctuations in infection rates. The populations most vulnerable to severe disease and hospitalisation include young children and older adults. Another partially reimbursed vaccine for seniors (50% refund) is the herpes zoster (shingles) vaccine. Shingles affects up to 30% of adults over 50, and in many cases, has a complicated course, particularly in ocular and auricular shingles, with a prolonged recovery period and persistent pain lasting up to a year.

From the perspective of maintaining herd immunity, which prevents epidemics and outbreaks of infectious diseases, an important element – beyond the implementation of mandatory and recommended vaccinations within universal programmes – is booster vaccinations, i.e., single vaccine doses administered at intervals of several years. These single-dose booster shots are administered at regular intervals, as determined by observational epidemiological studies. In Poland, beyond annual seasonal vaccinations, it is recommended to administer a booster dose of the diphtheria-tetanus-pertussis (DTP) vaccine every 10 years to maintain immunity against these diseases.

Another important aspect of vaccination strategy implementation concerns vaccinations recommended for pregnant women. This is a special population group for whom vaccinations serve a dual role: protecting the mother from illness, and ensuring the newborn's health and immunity for several months before the first scheduled vaccinations in the National Immunisation Programme. Currently, pregnant women can receive vaccinations against diphtheria, tetanus, pertussis, influenza, COVID-19, and respiratory syncytial virus (RSV) to safeguard both maternal and neonatal health.

In conclusion, as Poland's socio-economic and geopolitical landscape evolves, new challenges emerge in optimising the vaccination system to meet current needs. The COVID-19 pandemic highlighted several opportunities, including the electronic vaccination registration system, accessible via the Individual Patient Account (IKP), digital records of administered vaccinations, and authorising pharmacists to conduct pre-vaccination assessments and administer vaccines. These measures have already proven to be effective and widely applicable across the country, yet further expansion and accessibility are needed. Improving access to vaccination by streamlining the patient pathway is another key challenge, particularly for vulnerable groups, such as older adults, chronically ill patients, persons with disabilities, and residents of long-term care homes and care institutions. Enhancing vaccine access also requires the implementation of a reimbursement mechanism, enabling economically disadvantaged individuals to afford recommended vaccines or multiple immunisations.

A vaccination schedule based on age, physiological condition, and chronic disease status is now a necessity. This approach will increase public awareness, facilitate healthcare professionals in delivering education and vaccination services, and most importantly, improve public health and overall quality of life.

## **Oral Health Priorities in Poland**

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Oral health is more than aesthetics – it is a fundamental pillar of overall health.<sup>12</sup> The oral cavity is where the digestive tract begins, facilitating the initial breakdown and absorption of food, while also serving as a primary sensory interface with the environment, including exposure to substances such as tobacco smoke and alcohol. The mouth also plays a vital role in saliva production and the warming of inhaled air before it enters the respiratory system. Conversely, the oral cavity is a mirror of the body's health. Many systemic diseases manifest early signs in the oral cavity, often



long before symptoms appear elsewhere in the body. These symptoms can be observed much earlier and properly monitored. This makes it crucial to understand and monitor oral diseases and conditions, such as tooth decay (caries), periodontal (gum) disease, tooth loss, oral cancer, oral trauma, congenital anomalies (e.g., cleft lip and palate), malocclusion, and many other conditions, the majority of which are preventable. It is estimated that oral diseases affect nearly 3.5 billion people worldwide. Collectively, these conditions have an estimated global prevalence of 45%, making them more common than any other non-communicable diseases (NCDs).

According to the World Dental Federation (FDI), untreated tooth decay is among the most serious oral health issues globally, with far-reaching consequences beyond the oral cavity. Between 1990 and 2019, the number of oral disease cases increased by over 1 billion (a 50% rise). This means that more people developed tooth decay than were born during this period.<sup>231</sup> Tooth decay affects approximately 514 million children worldwide.

In Poland, according to Ministry of Health estimates, tooth decay affects nearly every adult and 82% of six-year-olds.<sup>232</sup> Other statistics indicate that only 6.8% of 19-year-olds are cariesfree. Furthermore, data from the latest who Global Oral Health Report show that in Poland 46% of caries cases among children under nine remain untreated, and the prevalence of tooth loss in individuals aged 20+ is nearly 12%.<sup>233</sup> As a result, the percentage of edentulous adults (toothlessness) is steadily increasing, particularly among individuals aged 35-44 and 65-74. During these stages of life, the average number of retained natural teeth declines sharply, and periodontal disease becomes widespread. In 2013, only approx. 5% of the surveyed individuals did not have periodontal disease. Additionally, 39% of older adults experience reduced saliva production and dry mouth (xerostomia), conditions that increase with age.<sup>3</sup> Over the years, lifestyle changes have exacerbated oral health challenges. Increasingly busy schedules, irregular eating habits, and frequent consumption of highly processed foods have contributed to greater exposure to acids from dental plaque, heightening the risk of tooth decay. As a result, we are much more likely to expose our teeth to acids from plaque.<sup>234</sup> As a key pillar of oral health prevention, dental professionals advocate for early education on good oral hygiene habits, ensuring that children integrate proper dental care into their daily routines from an early age and maintain these habits throughout life. Thanks to this, we keep a better standard of hygiene. Oral hygiene is not just a matter of aesthetics - it is a fundamental aspect of public health that cannot be ignored.<sup>12</sup>

Poor oral hygiene significantly contributes to the development of tooth decay (caries) and periodontal disease, ultimately leading to tooth loss. This, in turn, can result in dietary changes that cause or exacerbate digestive system disorders. Tooth loss leads to loss of occlusal support, which can contribute to temporomandibular joint (TMJ) disorders. Additionally, certain bacteria present in dental plaque, particularly in individuals with periodontal disease and poor oral hygiene, produce acetaldehyde – a compound that, when spread through saliva, may have genotoxic effects.

Another crucial aspect is the correlation between dental caries and obesity, which manifests not only as an increase in BMI but also as fat accumulation in various organs (visceral obesity). The global burden of both conditions is close to 2 billion cases. Tooth decay is not solely a result of inadequate oral hygiene; dietary habits play a significant role. Excessive consumption of sugar from snacks, processed foods, and sugar-sweetened beverages (SSBs) is one of the leading factors driving the global rise in oral diseases, cardiovascular diseases, cancer, obesity, and diabetes.

<sup>231</sup> WHO, Who Global Oral Health Report, 2022, 10.

<sup>232</sup> Ministry of Health, Monitorowanie Stanu Zdrowia Jamy Ustnej Populacji Polskiej w latach 2016–2020 [Monitoring the Oral Health Status of the Polish Population 2016-2020], Assessment of the Oral Health Status and its Conditions in the Polish Population at the Ages of 6, 10 and 15 in 2018, 57.

<sup>233</sup> WHO, WHO Global Oral Health Report, Country Profile – Poland.

<sup>234</sup> A sticky, colourless biofilm containing bacteria that naturally accumulates on the surface of teeth within four to 12 hours after brushing. Substances in food and beverages interact with plaque bacteria, leading to the release of acids.



According to the latest data from the Ministry of Sport and Tourism, more than 52% of Poles struggle with overweight and obesity, with 13% having a BMI exceeding 30. Unfortunately, the number of obesity cases continues to rise annually, and the most concerning trend is its increasing prevalence among children and adolescents. 19% of 11-year-old girls and 41% of 11-year-old boys are overweight or obese. Paediatricians attribute this to poor dietary habits and lack of physical activity, while dentists emphasise the role of frequent consumption of sugary drinks and snacks, such as sweet pastries, chocolate bars, and gummy sweets. While obesity is frequently discussed in the context of preventing premature deaths caused by heart attacks, strokes, or diabetes complications, less attention is given to its relationship with periodontal disease and tooth decay, both of which can ultimately lead to tooth loss.<sup>10</sup>

The increased risk of periodontitis has been proven to correlate with excessive body weight, waist circumference, subcutaneous fat percentage, and serum lipid levels. This is due to the influence of specific proteins called cytokines and fat-derived hormones. Some cytokines protect the body against inflammation, while others promote inflammatory processes, making them a key factor in the development of periodontitis. Additionally, oxidative stress – an imbalance between free radicals and the body's antioxidant defences – can also contribute to the destruction of periodontal tissues. Thus, tooth decay (caries) is an early indicator of poor diet, while periodontal disease is a consequence of obesity and overweight, alongside other metabolic diseases. <sup>10</sup> A link between periodontal disease and Alzheimer's disease has also been identified. Recent research refers to Alzheimer's as "brain diabetes", a form of diabetes affecting the brain.<sup>11</sup>) This may be associated with bacterial biofilm dysbiosis, caused by early colonisation of the oral cavity by Streptococcus mutans, which results from excessive sugar exposure in early childhood (1.5–3 years of age). This alters the bacterial composition of the oral microbiome, encouraging acid-producing bacteria, leading to: a decrease in calcium, phosphorus, and fluoride levels, and a shift in taste preferences, which influences long-term dietary habits.

Sugar is also recognised as a primary oncogenic factor contributing to cancer development. According to the 2024 Global Cancer Observatory, oral and lip cancer ranks 16th globally in incidence and 15th in mortality. Each year, over 600,000 cases of oral cancer are diagnosed worldwide. It is the most common malignant tumour of the head and neck region, and the sixth most prevalent cancer globally. In Poland, oral cancer accounts for approximately 2.5% of all malignant tumours. The most common sites of occurrence include: the floor of the mouth, the underside of the tongue, the retromolar triangle, and the cheek. Oncology statistics are unforgiving. Despite advancements in diagnostics and treatment, most patients seek medical attention at advanced stages (Stage III and IV). Early detection of malignant lesions significantly improves treatment outcomes. For oral cancer, the five-year survival rate reaches 80% when diagnosed at an early stage. However, over 50% of patients die within five years of diagnosis. Oral cancer often develops silently, with no noticeable symptoms in its early stages. As a result, many patients delay seeking medical care until the disease is already advanced. The effectiveness of cancer treatment depends on: early diagnosis, and prompt initiation of appropriate therapy. Often, the first subtle clinical signs of the disease indicate that the neoplastic process is already significantly advanced. People over the age of 50 are at particularly high risk. A significant percentage of these individuals no longer have natural teeth, making them less likely to attend regular dental check-ups - which is a critical mistake.<sup>235</sup>

Nutrients 2021 Jun 21;13(6):2122.

<sup>235</sup> Perks A. et al., Profilaktyka nowotworów jamy ustnej, Ero FDI, 2021.

<sup>&</sup>lt;sup>6</sup>Rutkowska M., Hnitecka S., Nahajowski M., Dominiak M., Gerber H., "Oral cancer: The first symptoms and reasonsfor delaying correct diagnosis and appropriate treatment", Adv Clin Exp Med. 2020;29(6):735–743.

<sup>&</sup>lt;sup>7</sup>https://pl.dental-tribune.com/news/wiekszosc-dzieci-i-nastolatkow-w-polsce-ma-wady-zgryzu/.

<sup>&</sup>lt;sup>8</sup> Leszczyszyn A., Hnitecka S., Dominiak M., "Could Vitamin D3 Deficiency Influence Malocclusion Development?",

<sup>&</sup>lt;sup>9</sup> Krawiec M., Dominiak M., "The role of vitamin D in the human body with a special emphasis on dental issues: Literature review", Dent end Med Probl 2018 Oct-Dec; 55(4):419-424.

<sup>&</sup>lt;sup>10</sup> https://gazetalekarska.pl/od-otylosci-do-prochnicy/.

<sup>&</sup>lt;sup>11</sup> https://diagnosis.pl/cukrzyca–a–alzheimer.

<sup>12</sup> https://wroclaw-medical-university.shorthandstories.com/uczmy-si-szczotkowa/.



Although one of the greatest achievements of modern medicine is the introduction of screening programmes, which in some high-income countries are now mandatory for oral cancers, studies have unfortunately shown that patients remain largely unaware of the role of dentists in cancer screening. One study found that only 14% of participants knew that their dentist routinely performed oral cancer screenings. A 2020 study by Rutkowska et al.<sup>236</sup> revealed that only 47.5% of patients sought medical attention due to noticing an initial symptom. Nearly half of patients delayed seeking medical care for 3-6 months after symptom onset, usually visiting a General Practitioner (GP) first (35.7%), followed by a dentist (31.8%). These findings highlight the urgent need to improve oncological awareness in society, particularly among healthcare professionals, including GPs and dentists. Mandatory educational programmes for doctors - including medical students - that focus on detailed patient history-taking and clinical examination could help reduce diagnostic delays and shorten the time to treatment. Additionally, it is crucial to educate patients about maxillofacial oncology, particularly: raising awareness of early symptoms, encouraging self-examinations, and prioritising regular dental check-ups, particularly for high-risk individuals. These efforts should be implemented both in dental practices and through public awareness campaigns. Early cancer detection significantly increases the chances of treatment at an early stage, leading to less invasive surgical procedures, faster and less demanding recovery, and improved post-treatment quality of life.

Malocclusion and dental defects are among the most prevalent oral health problems, alongside tooth decay (caries) and periodontal disease. More than 60% of Polish children and adolescents aged 11-18 experience bite-related issues. It is crucial to emphasise that malocclusion is not merely an aesthetic concern; it can also lead to serious health complications, including issues related to: breathing, digestion, speech articulation, and overall quality of life. These changes often result from improper tooth loading, which is strongly linked to bone loss in the alveolar processes of the mandible and maxilla (recession), and dysfunction of the temporomandibular joint (TMJ). Early intervention is key, and parents play a crucial role in recognising and addressing these issues promptly. Many parents of children and adolescents are unaware of the specific consequences of malocclusion. While nearly 75% of parents acknowledge that untreated malocclusion can lead to serious health problems, only half can name any of these consequences. This low awareness may stem from a lack of communication from specialists. Studies indicate that only just over 30% of parents were informed about the effects of malocclusion by a dentist or orthodontist. In most cases, doctors simply diagnose the issue and propose treatment without explaining the broader health implications. Thus, raising awareness among healthcare professionals - including dentists and orthodontists - about the need to educate patients on the potential health impacts of malocclusion is essential. An improper bite alignment can contribute to more than just tooth decay and periodontal disease. It can have a significant impact on overall health, affecting multiple bodily functions. Patients with malocclusion may suffer from gastrointestinal problems. Due to improper chewing, individuals tend to swallow larger food particles, which can lead to digestive issues, including: abdominal pain, acid reflux, and stomach ulcers. Incorrect bite alignment can significantly impact speech clarity, causing issues such as lisping. Severe malocclusion can obstruct airflow through the upper airways, increasing the risk of obstructive sleep apnoea (OSA).<sup>7</sup> Symptoms of OSA include breathing pauses, wheezing, and snoring. Malocclusion can contribute to chronic jaw misalignment, leading to persistent headaches, and postural disorders affecting the spine and musculoskeletal system.

It is important to highlight the relationship between malocclusion and vitamin D deficiency. Vitamin D plays a critical role in the immune, muscular, nervous, and cardiovascular systems. It is also essential in dentistry and carbohydrate metabolism. Currently, vitamin D deficiency is prevalent both in Poland and globally. This deficiency is influenced by multiple factors, including geographical latitude, underlying diseases, and lifestyle choices. Data indicate that over 90% of people of colour (including Black, Hispanic, and Asian populations) and nearly 75% of White individuals in the United States suffer from low levels of 25-hydroxycholecalciferol (25(OH) vitamin D). In Poland, studies show that 70% of the population has vitamin D concentrations



below 20 ng/ml (50 nmol/ml). Preliminary research suggests that vitamin D plays a crucial role in maintaining normal bone metabolism and has antibacterial and anti-inflammatory properties, which may help modulate periodontal disease. Maintaining optimal vitamin D levels is also essential in the treatment of periodontitis.<sup>9</sup> In cases of vitamin D deficiency, there is a significantly higher occurrence of malocclusion, particularly associated with maxillary narrowing, crossbite, retrognathic bite (Class II malocclusion), and deep bite.<sup>8</sup>

The multifaceted nature of oral health, though not fully explored due to space limitations, clearly highlights its connection to overall health. This underscores the need for systemic action to integrate oral health into primary healthcare in Poland. A greater emphasis on health awareness is required to enhance understanding of the role and significance of oral health within the broader context of general health.

## Challenges, Problems, and Solutions in the Field of HIV in the Context of the Polish Presidency of the Council of the European Union

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Introduction: The Epidemiological Situation in the EU and Poland

Human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS) remain significant public health challenges both in Poland and across the European Union. In 2023, an estimated 39.9 million people worldwide were living with HIV/AIDS. In the same year, 1.3 million people were diagnosed with HIV, and 680,000 died from AIDS-related illnesses.<sup>241</sup> A recent report from the European Centre for Disease Prevention and Control (ECDC) presents 2023 HIV/AIDS surveillance data, highlighting substantial variations in epidemic trends across the WHO European Region. In 2023, 112,883 new HIV diagnoses were reported in 47 of the 53 countries in the region, including 24,731 cases from EU/EEA countries, Corresponding to an incidence rate of 12.7 per 100,000 inhabitants, representing a 2.4% increase from 2022 (12.4 per 100,000 inhabitants).<sup>242</sup> However, significant geographical disparities remain, with Eastern European countries reporting higher incidence rates than Western and Central Europe (32-6 vs. 6-2 vs. 4-2 cases per 100,000 inhabitants, respectively), with Eastern European countries reporting higher incidence rates than Western European countries reporting higher incidence rates than Western European countries reporting higher incidence rates than Western and Central Europe (32-6 vs. 6-2 vs. 4-2 cases per 100,000 inhabitants, respectively), with Eastern European countries reporting higher incidence rates than Western European countries reporting higher incidence rates than Western European countries reporting higher incidence rates than Western and Central Europe (32-6 vs. 6-2 vs. 4-2 cases per 100,000 inhabitants, respectively), with Eastern European countries reporting higher incidence rates than Western and Central Europe (32-6 vs. 6-2 vs. 4-2 cases per 100,000 inhabitants, respectively). Notably, Ukraine is estimated to have 260,000 people living with HIV.

In Poland, the first cases of HIV infection were reported in 1985. Poland reported its first HIV cases in 1985, involving six individuals with haemophilia, four men who have sex with men (MSM), and a female sex worker. The first case of AIDS was recorded in 1986. In response to the emerging epidemic, the Ministry of Health established the first specialised HIV treatment unit in Warsaw

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<sup>241</sup> https://www.unaids.org/sites/default/files/media\_asset/UNAIDS\_FactSheet\_en.pdf.

<sup>242</sup> https://www.ecdc.europa.eu/en/publications-data/hiv-aids-surveillance-europe-2024-2023-data#:~:text=For proc.20the proc.20EU proc.2FEEA proc.20countries, 3.8 proc.20per proc.20100 proc.20population.



that same year.<sup>243</sup> Since then, HIV treatment and care have been provided through a network of specialized centres coordinated by the National AIDS Centre. Antiretroviral therapy (ART) is fully accessible to all individuals living with HIV in Poland.

Despite over 40 years of the global HIV pandemic, the infection remains a serious health challenge in Poland. In the last three years, the country has observed a significant increase in new HIV infections. By the end of 2023, a total of 32,935 HIV infections, 4,194 AIDS cases, and 1,496 AIDS-related deaths had been registered.<sup>244</sup> However, HIV-related mortality is likely underestimated due to frequent omissions of HIV testing in differential diagnoses.

In 2024, 2,291 new HIV cases were recorded, with a significant number diagnosed at an advanced stage, including 183 AIDS cases.<sup>245</sup> As of 30 September 2024, approximately 20,281 patients, including 181 children, were receiving ART.<sup>246</sup> Reports from the National Health Fund (NFZ) and the National Institute of Public Health based on 2010–2021 data indicate that 19% of AIDS-related deaths occurred in individuals diagnosed within six months of their HIV diagnosis<sup>247</sup>, highlighting a persistent issue of late HIV diagnosis and a high percentage of late presenters diagnosed in Poland.<sup>248</sup> It is estimated that 20-30% of people living with HIV in Poland remain unaware of their status.

Migration also significantly impacts Poland's HIV epidemiology. Late HIV diagnosis rates among migrants and refugees are alarmingly high, exceeding 70% among Ukrainian nationals.<sup>249</sup> If these negative epidemiological trends are not addressed promptly, serious public health and economic consequences are likely in the coming years.

#### **UNAIDS Goals for Ending the HIV/AIDS Epidemic**

One of WHO's Sustainable Development Goals (SDGs) is to eliminate AIDS as a public health threat by 2030. To track progress towards this overarching goal, specific objectives related to prevention, care, life expectancy, and social issues have been established. These specific targets foresee that in 2025, 50% of people at high risk of acquiring HIV and 5% of those at moderate risk will have access to HIV pre-exposure prophylaxis (PrEP). HIV incidence and AIDS-related deaths will be reduced by 75% compared to the 2010 baseline. Additionally, 95% of people living with HIV should be aware of their HIV status, 95% of those diagnosed should be receiving antiretroviral therapy (ART), and 95% of those receiving ART should have achieved viral suppression (known as the 95-95-95 targets). Social targets aim to reduce inequalities by committing to lowering stigma and discrimination against people living with HIV, gender-based inequalities and violence, and the percentage of countries enforcing repressive laws and policies – such as the criminalization of sex work, same-sex sexual behaviour, and HIV transmission – to below 10%. Currently, most of the 95-95-95 targets remain unmet in Europe.

#### HIV Prevention, Including Aspects of Combination Prevention

Combination prevention is an HIV prevention strategy that tailors interventions to local epidemiological and cultural conditions<sup>250</sup>, combining different intervention methods tailored to the specific needs of a given population and epidemiological context. It integrates biomedical, structural, and behavioural approaches. An example of a biomedical approach is pre-exposure prophylaxis (PrEP) – the use of antiretroviral drugs by HIV-negative individuals to reduce the risk of infection. In Poland, access to PrEP remains limited, as consultation, testing, and medication

<sup>243 &</sup>quot;Ponad 40 lat z HIV. Rozmowa z prof. Andrzejem Gładyszem" [Over 40 years with HIV. Interview with Prof. Andrzej Gładysz], Practical Medicine.

<sup>244</sup> https://aids.gov.pl/hiv\_aids/450-2-2/.

<sup>245</sup> https://wwwold.pzh.gov.pl/oldpage/epimeld/2024/INF\_24\_12B.pdf.

<sup>246</sup> https://aids.gov.pl/hiv aids/450-2-2/.

<sup>247</sup> 

 $<sup>248\</sup> https://ezdrowie.gov.pl/portal/home/badania-i-data/healthe-data/reports/nfz-o-health-hiv-aids.$ 

<sup>249</sup> Parczewski M., Witak-Jędra et al., "Zasady opieki nad osobami żyjącymi z HIV. Zalecenia", PTN AIDS 2024, 49, 318.

<sup>250</sup> https://www.unaids.org/sites/default/files/media\_asset/progress-towards-95-95\_en.pdf.

costs are borne by the patient. Given the rising number of HIV diagnoses, Poland should follow the example of other European countries by expanding access to this proven prevention method, alongside educational initiatives and screening for other sexually transmitted infections (STIs). Post-exposure prophylaxis (PEP) – a short-term regimen of antiretroviral medication taken after potential exposure to HIV – is available free of charge for occupational exposure cases in Poland. However, PEP following sexual exposure (e.g., condom failure) is only available on a self-pay basis, creating barriers to access.

Behavioural prevention includes education, promoting safer sex practices such as consistent condom use, reducing the number of sexual partners, and routine HIV testing. However, in recent years, Poland has seen a decline in educational campaigns and youth-targeted interventions. According to a study by the National Centre for AIDS, 87% of Poles believe that HIV does not concern them<sup>251</sup> – which highlights the urgent need for public awareness initiatives.

In Poland, there is still a lack of modern combination prevention strategies and educational and preventive programs targeted at key populations. HIV testing is mainly conducted in 29 consultation and diagnostic centres Located in major cities, financed by the National Centre for AIDS under the Ministry of Health. Free and anonymous HIV, HCV, and syphilis testing is offered along with pre- and post-test counselling. However, HIV self-tests are only available for purchase or through limited NGO-funded initiatives. There is no systematic access to HIV testing in primary healthcare, although discussions are ongoing at the Ministry of Health. Medical professionals' awareness of the importance of HIV testing is still insufficient, leading to late diagnoses, even in cases where patients have visited multiple specialists.

In summary, available tools in the fight against the HIV pandemic include testing, rapid access to antiretroviral therapy, and pre- and post-exposure prevention. The rise in new HIV diagnoses in Poland in recent years highlights the urgent need to strengthen prevention efforts, including the implementation of a nationwide HIV pre-exposure prevention program with access to medical and educational interventions, as well as the promotion of regular HIV testing. The implementation of combination prevention is crucial to halting the HIV epidemic in Poland.

#### Epidemiological and Clinical Benefits of Antiretroviral Therapy

The introduction of combination antiretroviral therapy (ART) in 1995 – which is based on drugs targeting two stages of HIV replication – marked a breakthrough in HIV treatment. Once considered fatal, HIV is now a manageable chronic condition, and people living with HIV who receive ART now have a life expectancy comparable to the general population.<sup>252253</sup>

The use of modern antiretroviral drugs in recent years, characterised not only by high efficacy but also by safety, enables complete suppression of HIV replication, as reflected in undetectable HIV viral loads in blood serum (<50 copies/ml). As a result, antiretroviral therapy helps prevent immune system deterioration and the associated severe infectious complications, cancers, and central nervous system disorders. It also reduces the risk of chronic inflammation-related diseases, such as cardiovascular and metabolic conditions. We are increasingly setting bold and ambitious priorities in the care of people living with HIV. In 2017, the HIV Medicine Association (HIVMA) officially announced the U=U (Undetectable equals Untransmittable) consensus, stating that **a person living with HIV with an undetectable viral load does not transmit the virus through sexual contact.** This consensus was based on data from studies conducted between 2008 and 2016, which analysed over 100,000 unprotected sexual encounters and found zero risk of transmission

<sup>251</sup> Walendzik-Ostrowska A., Majka R., Dec-Pietrowska J., Brodzikowska M., Ankiersztejn-Bartczak M., "Psychosocial contexts of the HIV epidemic in Poland", Przegl Epidemiol. 2023;77(3):302-316. doi: 10.32394/ pe.77.28. PMID: 38329029.

<sup>252</sup> Günthard H.F., Saag M.S., Benson C.A., et al., "Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults", JAMA 2016;316(2):191-210.

<sup>253</sup> Parczewski M., Witak-Jędra et al., Zasady opieki nad osobami żyjącymi z HIV. Zalecenia, PTN AIDS 2024.



when the HIV-positive individual maintained an undetectable viral load over an extended period.<sup>254</sup> As a result, antiretroviral therapy is not only a treatment but also the most effective method of HIV prevention (Treatment as Prevention – TasP).

Guidelines for starting ART have evolved significantly. For many years, the decision to initiate therapy depended on the presence of severe HIV-related comorbidities, including AIDS-defining illnesses, CD4 lymphocyte count, and HIV viral load. However, a better understanding of the disease's pathomechanisms, including the role of immune system activation in the development of HIV-related complications, along with the introduction of increasingly advanced combination therapies – often in the form of a single daily tablet with high efficacy and a favourable safety profile – has led to the initiation of ART for all individuals diagnosed with HIV, regardless of CD4 count or viral load.

Despite these advances, research continues on developing drugs that could eliminate HIV from the body entirely. Until a cure is found, ensuring universal access to treatment and prevention remains critical.

#### Situation of people living with HIV in Poland

In the Polish healthcare system, individuals diagnosed with HIV must proactively seek out treatment at specialized HIV treatment clinics. According to the European Centre for Disease Prevention and Control (ECDC), 84% of those diagnosed start teatment<sup>255</sup>, but 16% do not engage in care, increasing their risk of AIDS-related complications and potential HIV transmission. Barriers to treatment include fear of HIV disclosure to healthcare providers and other patients, stigma and self-stigmatisation due to misconceptions about living with HIV, lack of trust in the healthcare system among non-heteronormative individuals, who may also fear disclosing their sexual orientation, and language and cultural barriers for immigrants. In the case of non-heteronormative people, an additional barrier is the fear of revealing sexual orientation to medical staff, and in the case of immigrants – a language or cultural barrier. Currently, there is no systemic mechanism in Poland to actively retain people in care or support those who have discontinued treatment.

In major Polish cities, non-governmental organizations (NGOs) provide psychosocial support for people living with HIV, typically through individual counselling, support groups, and peer networks. Some organizations follow a patient-centred model of assistance that does not fully consider individual agency and is instead based on predefined, imposed solutions. In recent years, peer-led support initiatives – where people living with HIV assist others based on their own experiences – have gained traction. These initiatives, help fill gaps in the mental health care system for members of this community. However, NGOs struggle with chronic underfunding. Most support services operate on a voluntary basis, which often limits their reach and effectiveness. Expanding financial support for these organizations is crucial to ensuring long-term access to care and mental health services.

Stigmatisation of HIV infection remains a major challenge for most people living with HIV. The topic of HIV is still largely overlooked and virtually absent from public debate, only receiving attention on December 1 – World AIDS Day. As a result, fewer than 10 people in Poland have publicly disclosed their HIV status. The social campaign I Live with HIV, featuring individuals openly speaking about their diagnosis, was only launched in 2024, thanks to the efforts of a non-governmental organisation.

A particularly concerning form of stigma exists within the medical community. Many people living with HIV do not disclose their status when seeking medical care outside HIV treatment clinics, fearing discrimination or denial of services. Knowledge about HIV among healthcare professionals

<sup>254</sup> Rodger A.J., Cambiano V., Phillips A.N., et al., "Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study", Lancet 2019;393(10189):2428–38.

<sup>255</sup> https://www.ecdc.europa.eu/sites/default/files/documents/hiv-dublin-continuum-care-progress-report-2023. pdf.



is often outdated, leading to unnecessary fear, reluctance, and in extreme cases, outright refusal to provide treatment.

Legal stigma is also evident in Polish law. HIV infection is the only condition explicitly singled out in the Criminal Code, whereas other infectious and sexually transmitted diseases are grouped together. Under current legislation, exposing someone to HIV can result in up to five years of imprisonment. However, recent actions by the Ministry of Health offer hope for decriminalizing HIV exposure and reducing penalties.

Despite advances in treatment and prevention, barriers to healthcare access, low testing rates, and persistent stigma remain significant issues for people living with HIV in Poland. The Polish Presidency of the Council of the EU presents an opportunity to take meaningful action to eliminate these barriers and advance public health across Europe.

# Understanding Bladder Cancer: Prevention, Public Awareness, and the Diagnostic-Therapeutic Pathway

### **Prof. Piotr Rutkowski MD PhD**

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Bladder cancer is an example of a malignancy in which treatment has seen remarkable advancements in recent years. Once considered a "forgotten" disease, it now holds new promise thanks to groundbreaking medical discoveries – including novel diagnostic methods, treatment regimens, and innovative pharmaceutical and non-pharmaceutical technologies. These advances offer patients the possibility of living well for many years despite their condition. However, it is crucial to implement a range of organisational and systemic measures that align perfectly with the priorities of the Polish Presidency of the European Union, particularly initiatives focused on prevention and raising public awareness.

#### The Epidemiological Situation of Bladder Cancer in Poland

According to the National Cancer Registry, in 2022, bladder cancer was the fourth most frequently diagnosed malignancy among Polish men (5.7%). At the same time, it ranked fourth among cancers with the highest mortality rate in men (6%).<sup>256</sup> Current data published by the European Commission and the Organisation for Economic Co-operation and Development (OECD) indicate that cancer incidence trends in Poland align with those observed in other European Union countries, including for bladder cancer.<sup>257</sup>

<sup>256</sup> Wojciechowska U., Didkowska J., Barańska K., Miklewska M., Michałek I., Olasek P., Jawołowska A., *Nowotwory złośliwe w Polsce w 2022 roku*, 2025.

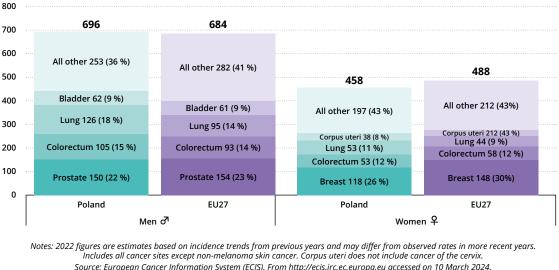
<sup>257</sup> Poland. Country Cancer Profile, https://cancer-inequalities.jrc.ec.europa.eu/sites/default/files/docs/ccp2025/ec-oecd-pl-2024-1680-en.pdf [accessed February 2025].



#### Figure 1.

*The most common cancers in Poland align with trends observed across European Union countries* – data from the European Cancer Inequalities Registry, Poland – Country Cancer Profile.

## The most common cancers among Polish men and women follow the same patterns as those across the EU



#### Age-standardised incidence rate per 100 000 population, estimates, 2022

© European Union, 2024. The incidence percentage breakdown was re-computed based on age-standardised incidence rates and as such differs from the percentage breakdown of absolute numbers shown on the ECIS website.

In the European context, according to data from the World Health Organization (WHO), the incidence rate of bladder cancer in Poland in 2022 was 12.9<sup>258</sup>, placing it within the average range for European countries. Unfortunately, the mortality figures were significantly less favourable. That same year, Poland recorded the highest bladder cancer mortality rate in Europe, at 5, the worst outcome among the countries analysed.<sup>259</sup>

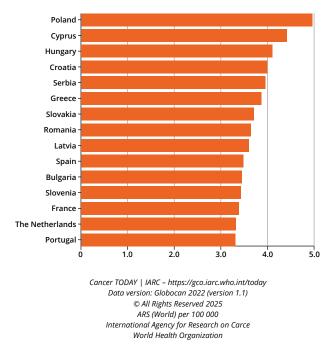
<sup>258</sup> ASR - estimated age-standardised incidence rate.

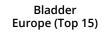
<sup>259</sup> WHO, IARC (International Agency for Research on Cancer), 2022, https://gco.iarc.fr/today/en/dataviz/1 [accessed February 2025].



*Figure 2. Bladder Cancer Mortality in Poland in 2022, according to Globocan 2022* 

#### Age-Standardized Rate (World) per 100 00, Mortality, Both sexes, in 2022





The population affected by bladder cancer is diverse. Men and individuals from high-risk groups – such as smokers and those working in certain manufacturing sectors, including the refinery, rubber, and tanning industries<sup>260</sup> – are at a higher risk of developing the disease. Advanced age is also an independent risk factor.

Bladder cancer is characterized by non-specific symptoms, including haematuria, painful urination, and pain in the lower abdomen or lumbar region. These symptoms can resemble a urinary tract infection, increasing the risk of misdiagnosis or inappropriate treatment, such as prolonged antiinflammatory therapy or unnecessary antibiotic use.<sup>261</sup> As a result, patients often seek specialist care too late and are diagnosed at an advanced stage of the disease, which negatively impacts prognosis and limits treatment options.<sup>262</sup>

Despite the high prevalence of bladder cancer and the significant societal burden associated with its rising mortality rate in Poland, there is currently no comprehensive care programme for patients with this type of cancer. Additionally, coordinating bladder cancer treatment is challenging because the disease falls within the scope of multiple medical specialities – urologists, oncologists, and clinical oncologists. This, combined with its non-specific symptoms, further prolongs the diagnostic process. The situation is further complicated by the lack of multidisciplinary teams that could ensure a coordinated approach to diagnosis and treatment. Effective collaboration between specialists is essential for making optimal therapeutic decisions. Early diagnosis also depends on recognising the critical role of Primary Care doctors and ensuring they have access to appropriate clinical guidelines for managing patients with suspected bladder cancer. Without an integrated approach and seamless information exchange between specialists, achieving successful treatment outcomes becomes significantly more difficult.

<sup>260</sup> Długosz J., Dziurda D., Kucharz J., Jakubiak K., Jakubiak L. Tupikowski K., *Rak pęcherza moczowego. Ścieżka pacjenta i algorytm postępowania terapeutycznego*, 2024.

<sup>261</sup> Gladiator Association, Poradnik Pacjenta z rakiem pęcherza moczowego Stowarzyszenia [Bladder Cancer Patientis Guide], http://gladiator-prostata.pl/poradnik-pacjenta-pecherz/ [accessed February 2025].

<sup>262</sup> Długosz J., Dziurda D., Kucharz J., Jakubiak K., Jakubiak L. Tupikowski K., Rak pęcherza moczowego. Ścieżka pacjenta i algorytm postępowania terapeutycznego, 2024.



#### Bladder Cancer as a Public Health Challenge

The need to establish standards for coordinated care of bladder cancer patients was recognised several years ago by both the medical community and public institutions and has been incorporated, among others, into the following documents:

- 1. Opinion of the Transparency Council No. 223/2020 of 7 September 2020 on the development of appropriate organisational solutions for comprehensive oncological care in organ-specific cancers: urological cancers malignant bladder cancer. At that time, the Transparency Council already indicated that: "The development of a model for the comprehensive organisation of oncological care, implemented through medical entities such as comprehensive urological cancer treatment centres, along with diagnostic and treatment evaluation measures, responds to the need to enhance the quality and effectiveness of diagnosis and treatment. It also aims to improve oncological treatment outcomes, ultimately leading to the expected enhancement of patients' quality of life at every stage of the disease".<sup>263</sup>
- 2. The parliamentary report of 18 July 2018, prepared on the initiative of the Parliamentary Team for Patients' Rights in cooperation with the Polish Urological Association, the National Consultant in Urology, and the Experts for Health Foundation<sup>264</sup>, highlighted "the need to ensure high-quality comprehensive oncological treatment by reorganising the healthcare system".
- 3. Documents published by the Ministry of Health, including the Regulation of the Minister of Health of 27 February 2018 (Journal of Laws of 2018, item 469, as amended) and the Announcement of the Minister of Health of 6 September 2024 on key recommendations in the field of oncological care regarding the organisation and clinical management of bladder cancer (Journal of Laws of 2024, item 70).

Bladder cancer has also been incorporated into the implementation of the National Cancer Strategy (NSO). As part of the work carried out by the National Monitoring Centre (KOM), guidelines for diagnostic and therapeutic procedures are being developed. In 2024, these efforts in oncology encompassed three key documents:

- 1. Guidelines for the diagnostic and therapeutic management of patients with bladder cancer;
- 2. Summary of guidelines for the diagnostic and therapeutic management of bladder cancer;
- 3. Key recommendations for bladder cancer Announcement of the Minister of Health of 6 September 2024.

KOM oversees the development and updating of guidelines by relevant scientific societies and research teams, including through the adaptation of both national and international studies. The guidelines developed within the NSO provide a set of evidence-based recommendations for oncology practice, ensuring the highest standard of patient care.<sup>265</sup>

It is also important to highlight grassroots initiatives led by patient associations and experts, including the 2024 report *Bladder Cancer: Patient Pathway and Therapeutic Management Algorithm.* This report is the final outcome of a project undertaken by a coalition of patients, clinicians, healthcare system experts, and stakeholders from the medical sector. The authors of the document put forward a series of recommendations, which, in their view, should contribute to improved treatment outcomes for bladder cancer patients in Poland.

<sup>263</sup> AHTAPol, Opinia Rady Przejrzystości nr 223/2020 z dnia 7 września 2020 roku w sprawie opracowania odpowiednich rozwiązań organizacyjnych w zakresie kompleksowej opieki onkologicznej w nowotworach narządowych: nowotwory urologiczne – nowotwór złośliwy pęcherza moczowego (ICD-10 C67) [Opinion of the Transparency Council No. 223/2020 of 7 September 2020 on the development of appropriate organisational solutions for comprehensive oncological care in organ-specific cancers: urological cancers – malignant bladder cancer (ICD-10 C67)], https://bipold.aotm.gov.pl/assets/files/zlecenia\_mz/2018/089/ORP/U\_36\_288\_07092020\_o\_223\_rak\_pecherza\_moczowego\_31s\_zacz.pdf [accessed November 2024].

<sup>264</sup> Polish Urological Association, National Consultant in Urology, Experts for Health Foundation, Nowotwór pęcherza moczowego – rekomendacje z zakresie kompleksowej opieki nad pacjentem, 2018, https://ekspercidlazdrowia.pl/wp-content/ uploads/2018/06/Raport\_nowotwor\_pecherza.pdf [accessed November 2024].

<sup>265</sup> NSO: Wytyczne [National Cancer Strategy: Guidelines], https://nio.gov.pl/instytut/nso/nso-wytyczne/ [dostęp: luty 2025 r.].



According to the authors of the report, in the context of prevention and education, it is essential to consider, among other things, raising public awareness of the link between smoking and bladder cancer, promoting recognition of early symptoms (including haematuria/microscopic haematuria), and highlighting the initial diagnostic steps (such as general urinalysis and ultrasound). It is also crucial to support primary care physicians, for example, by implementing educational programmes on haematuria diagnostics.<sup>266</sup> In addition, the report outlines specific recommendations for optimising the diagnostic and therapeutic pathway, including the use of the Diagnostics and Oncological Treatment (DiLO) card for rapid urological diagnosis and the necessity of multidisciplinary collaboration. Optimising subsequent stages of the patient pathway should include, among other measures, improving access to cystoscopy, ensuring faster access to the TURBT procedure and pathological assessment, and enhancing availability of therapeutic options recommended by international scientific societies – such as neoadjuvant chemotherapy, non-reimbursed immunotherapy drugs, and combination therapy.<sup>267</sup> Long-term monitoring of treatment outcomes within the National Cancer Care Network, based on qualitative indicators, is also of critical importance. The National Cancer Care Network Act introduces key changes in the organisation and management of oncological care, including for bladder cancer patients, facilitating cooperation and coordination of the patient pathway between centres with varying levels of specialisation.

#### **Next Steps**

Poland's assumption of the Presidency of the European Union and the inclusion of preventive healthcare among ministerial priorities present an ideal opportunity to raise public awareness about cancer, including bladder cancer. The only effective long-term strategies to address this public health challenge are reducing exposure to risk factors and providing appropriate health education to support early diagnosis and coordinated patient care.

In the short term, efforts should focus on further developing the coordination of diagnostics and patient care, highlighting the need to introduce the National Cancer Care Network and ensure access to all recommended therapeutic options. This includes further amendments to the drug programme dedicated to the treatment of urothelial cancer in Poland. Changes in the availability of therapeutic options should be guided by international and national clinical guidelines. At the same time, the effective implementation of diagnostic and therapeutic guidelines – starting from the level of Primary Care doctors – is crucial. This should lead to a more standardised approach and a unified patient pathway across the country.

### **European Cancer Organisation**

#### **Richard Price**

**Policy Director** 

## A competitive high-functioning EU that serves its citizens well is an EU that leads the world in cancer policy

"Europe's Beating Cancer Plan is a key pillar of a stronger European Health Union and a more secure, better-prepared and more resilient EU... By working as a team and combining efforts at national and EU level, we can overcome individual weaknesses, reduce fragmentation, and deliver a more effective and more equal response to cancer... Europe's Beating Cancer Plan places the interests and well-being of patients, their families and the wider population at its heart, every step of the way"

<sup>266</sup> Długosz J., Dziurda D., Kucharz J., Jakubiak K., Jakubiak L. Tupikowski K., Rak pęcherza moczowego. Ścieżka pacjenta i algorytm postępowania terapeutycznego, 2024.

<sup>267</sup> Ibid.



#### Introductory remarks to Europe's Beating Cancer Plan, 4 February 2021

Europe's Beating Cancer Plan will forever be a landmark in the history of the global fight against cancer. It has been an unprecedented effort to bring about united action by 27 countries against a common challenge and foe: the hundreds of diseases represented by the term 'cancer'.

Now four years into its being, notable achievements to date include:

**On cancer prevention:** World-leading cancer prevention legislation has been secured, including ambitious new limits on air pollution and new legal protections for citizens and workers against many other carcinogens.

**On HPV cancer elimination:** Europe is now a global front-runner in achieving the WHO's cervical cancer elimination goal because of the Beating Cancer Plan's HPV cancer elimination goal. Whereas at the point of publication of Europe's Beating Cancer Plan, only a minority of countries conducted Gender Neutral Vaccination, now all EU countries are politically committed to this policy.

**On cancer screening:** New forms of cancer screening are being piloted across Europe as part of EU-supported cross-border coordination. This includes pioneering efforts for lung, prostate and gastric cancer screening. A growing set of EU guidelines have now been developed to underpin the quality of screening that all EU citizens should expect to be adhered to in their country. Initiatives such as Cancer Image Europe are helping to secure cutting-edge research in the region on early detection and diagnosis.

**On quality of cancer care:** A new EU Network of Comprehensive Cancer Centres is building capacity, connecting centres across the EU & beyond and helping bring the best quality of care to patients. Where once the comprehensive cancer care model appeared a distant prospect in many countries, hope is being made reality as a result of the EU's cancer plan. More than 100 cancer centres in 25 countries are also participating in the ground-breaking EU inter-speciality cancer training programme. This comes online at the same time as multiple new EU supported digital training programmes for oncology professionals.

**For cancer survivors:** Europe's Beating Cancer Plan is providing a framework to help advance the concept and reality of a 'right to be forgotten' for cancer survivors. This refers to legal protections that prevent financial institutions, insurers, and other entities from discriminating against individuals based on their past cancer diagnosis after a certain period of remission. Only 2 countries in the EU provided such protections in 2019. Now 9 countries offer legal protections and 6 countries non-regulatory protection, with a growing understanding of the benefit of a more common European approach through mechanisms like the Mortgage Credit Directive.

This is but a flavour, with other developments such as new European networks of oncology expertise, an EU Cancer and Public Health Genomics Platform, a European Cancer Patient Digital Centre, a Cancer Survivor Smartcard, an EU Network of Youth Cancer Survivors, an expansive European Cancer Inequalities Registry and much more all flowering as a result of Europe's Beating Cancer Plan and the EU Research Mission on Cancer. But the Plan must be sustained if its full potential is to be reached. Which brings us to the current political moment.

## Europe's Beating Cancer Plan, the Von der Leyen Commission priorities and the next multiannual financial framework

Any election gives opportunity for at least an element of reset, even if continuity is on the ballot paper. So, it is the case with the 2024-29 European Commission. Continuity in some key personalities, including the Commission President Ursula von der Leyen, but new agendas and priorities being emphasised as well.

Contrasting President von der Leyen's political guidelines for her 2024-29 European Commission with tone of the 2019 version brings forward the difference in tone and spirit. In 2019, the "Great Recession" and its various fallouts, appeared to be retreating to the background. Confident hopes



for a "Green New Deal", digital strategies and cancer masterplans conveyed optimism in the coordinating role of the EU in meeting major societal challenge areas. By contrast, 2024's guidelines carry the heavy weight of the experience of the Covid-19 pandemic, the shock of Russia's war of aggression against Ukraine, and the ever-growing understanding of Europe's competitiveness challenge with the USA and China.

The mood music is being set ahead of critical debates in 2025 about the next EU multiannual financial framework 2028-2034 accordingly.

At no time in politics are priorities not in competition with each other to at least some degree. It can be anticipated that this iron law will be present in discussions on the next EU financial framework.

However, the extent to which health and cancer are really in competition with the policy needs being articulated by President von der Leyen currently – such as defence, democratic resilience and the boosting of EU economic dynamism – could be over-stated.

Indeed, the experience of Europe's Beating Cancer Plan and the EU Research Mission on Cancer, may already case study alignment of priorities.

Necessarily, EU cancer policy must always have the improvement of patient outcomes as the overriding objective. Yet this should not obscure the interplay of robust EU cancer policy with other major objectives of the EU:

**On digitisation:** through the Cancer Plan and Cancer Mission, a series of objective-focused test cases in cross-border digital collaboration are being proven. This includes new data sharing platforms such as Cancer Image Europe and the European Cancer Patient Digital Centre, to prototype pan-EU patient 'smartcards' to support portable and secure transfer of patient data, to a series of common, and quality assured, digital skills programmes available to every healthcare professional in Europe.

**On the EU's place in the world:** The Cancer Plan and Cancer Mission are also actively supporting the EU's relations with its neighbourhood region, with countries such as Bosnia and Herzegovina, Ukraine, Moldova and Norway being active participants in implementation of the Cancer Plan projects, and other countries such as Canada and Israel being prominent partners in the delivery of the EU Research Mission on Cancer. To add to this, there is also untapped potential in the Cancer Plan and Cancer Mission to be an aid to the delivery of the growing Commission ambitions to boost EU competitiveness.

#### Economic competitiveness and strong EU health policy: Mutually reinforcing

The arguments of the Draghi Report on EU Competitiveness appear well made and presented. The statistics do not lie. European countries are on the whole lagging in economic growth rates compared to other regions and have been for some time. Structural deficiencies are leading to inadequate conversion of Europe's possession of world-leading research and education centres into areas of global economic leadership. Recommendations of the report, including the need to better consolidate and coordinate effectively large-scale research effort at EU level in significant sectoral areas, carry logic.

But the Draghi report and the EU competitiveness agenda now needs to move from discussions in the abstract and broad principles, to real world example and initiative.

Those close to, and observing regularly, the implementation of Europe's Beating Cancer Plan and the EU Research Mission on cancer will be familiar with some of the complaints raised within the Draghi report:

- Regulatory burden stifling innovation efforts;
- To much diffusion of research efforts;
- Discovery not translated soon enough into (clinical) reality.

For this reason and more, ECO will be working in 2025 with its Research Policy Network to bring forward some of the convergences of the Draghi agenda with long-held frustrations within the



European cancer research community. Unblocking "the economy" can be made less removed for the public when applying the approach to unblock cancer research.

#### EU cancer policy: an ally of current EU priorities

The new headline themes of the 2024-29 European Commission and the political urgencies being presented currently in the context of next Multiannual Financial Framework are not oppositional to maintaining strong EU cancer policy. They are complementary.

Implementation of Draghi principles and recommendations can help to unblock innovations in cancer prevention, detection, treatment and care, that are otherwise waiting to be discovered and brought to reality in Europe.

A maintained emphasis on an open and inclusive Cancer Plan and Mission can bind the EU and its neighbours further in common cause and collaboration, with the benefits of partnership approach across borders to shared challenge made manifest.

By keeping a policy focus on the issues closest to any voter's heart – the health of themselves, their family and loved ones – the democratic underpinnings of EU action are enhanced. A political unity exists, and can be expressed, for strong cooperation across national borders on cancer.

The challenge of the 2024-29 European Commission and the next Multiannual Financial Framework isn't about which 'favourites' to pick for attention. Rather, it is to ensure that all EU actions synergise and support each other well.

Europe's Beating Cancer Plan and Cancer Mission are vehicles for improving cancer care and outcomes. But the clear example-setting pathway that is being laid via its implementation can also prove that European Commission ambitions on topics such as digitisation, economic competitiveness and democratic resilience are more than words, but apply to real examples. Their pursuance is about more than moving economic statistics. They can result in actual daily benefits that every citizen can understand and appreciate.

As the Polish Presidency of the EU begins the process of coordinating national governments in long term budget debates, we recommend an un-siloed approach to priorities. Saving more lives from cancer and delivering other EU agendas can go together well.

# EFPIA – European Federation of Pharmaceuticals and Associations

### Sibilia Quilici

**Executive Director Vaccines Europe** Prevention as a Pillar of Health Security, Economic Stability, and Resilience in the EU

#### Context

The EU is facing an urgent and unprecedented 'permacrisis,' where economic challenges, demographic shifts, climate change, rising chronic diseases, relentless infectious threats, antimicrobial resistance (AMR) and a shrinking healthcare workforce are converging to push healthcare systems to the brink. [1]

Hospitals are overwhelmed, healthcare professionals are stretched thin, and the most vulnerable patients are increasingly at risk. In January 2025, in Belgium, flu patients waited over four hours in emergency rooms. [2] In France, 90 hospitals were forced to trigger an emergency measure known as « white plan » due to the ongoing flu outbreak. This plan allows hospitals to postpone certain surgeries and bring back staff from leave.

Non-communicable diseases (NCDs) represent a significant challenge in Europe, both in terms of their impact on health and on the economy. The economic burden on EU healthcare systems is particularly important because of its ageing population. NCDs account for the largest share



of EU countries' healthcare expenditures, costing EU economies over 700 billion euro per year. Furthermore, premature deaths due to four major NCDs (cardiovascular diseases, cancers, respiratory diseases and diabetes) cost EU economies 0.8% of GDP, with further losses incurred due to the lower productivity and employment rates of people living with chronic health problems.

Climate change is amplifying health risks through heatwaves, air pollution, and the spread of vector-borne diseases. Investing in prevention is critical – not only to safeguard public health but also to ensure the resilience of Europe's healthcare systems against these escalating threats. Without urgent action, healthcare as we know it will collapse under the mounting pressure.

Preventive health must be at the core of any political strategy to ensure health security, strengthen the EU's economic resilience, and build a sustainable, equitable society. Investing in prevention reduces healthcare costs, reduces hospital visits, ensuring resources are available for those who need them most, enhances workforce productivity, and safeguards public health against future crises – making it not just a health imperative, but a strategic necessity for Europe's future.

#### Prevention first: A key solution for a healthier future

In 2021, over 1 million premature deaths in the EU could have been prevented with better care and prevention [3]. Yet, gaps persist, leaving many at risk. Healthy lifestyles, screenings, and vaccinations save lives and reduce healthcare burdens. Vaccination is the most effective and cost-efficient tool for disease prevention. However, adult immunisation remains underutilized, with inconsistent coverage across Europe. To fully harness its potential, an environment that ensures high vaccination rates across all life stages is needed.

A comprehensive, digitalized vaccination infrastructure is crucial. The European Health Data Space (EHDS) and electronic health records can streamline tracking, improve Member States's communication and monitoring, and fight vaccine hesitancy. Strengthening supply chains will prevent shortages, while a harmonized EU packaging system can eliminate bottlenecks. The COVID pandemic showed us the enormous language diversity of vaccines' packaging and leaflets requirements across EU countries may significantly reduce supply chains' efficiency, slow down emergency response to shortages, and limit availability in small markets. One of the solutions to prevent vaccine shortages and ensure vaccine availability to patients/targeted populations as well, as vaccine movement between EU Members Sate is to introduce the EU common pack and electronic Patient Information Leaflet (ePIL) in the EU [4]. Digital tools are also vital to combat misinformation and build trust, boosting vaccine uptake. The EU Health Technology Assessment (EU HTA) must also ensure timely, equal access to new vaccines, based on their unique specificities, to accelerating their integration into national immunisation programs.

Expanding vaccination access is crucial. Allowing more healthcare professionals, including pharmacists and nurses, to administer vaccines has proven effective. In France, pharmacists vaccinated 1.3 million people in a week against influenza [5], showcasing the impact of broader access. This approach must extend to other adult vaccines to ensure convenience and wider coverage.

Life-course immunisation must be integrated into national immunisation plans with clear guidance and adequate funding. Infectious diseases not only cause direct illness but also exacerbate existing conditions in patients with non-communicable diseases, compounding their health challenges and increasing the overall burden on healthcare systems. There is evidence suggesting that vaccination against infections (such as influenza, pneumococcal, SARS-CoV-, and respiratory syncytial virus) is especially important for patients with increased cardiovascular risk or existing CVD particularly among the elderly. [6] Adult vaccination policies vary across Europe, leaving key populations, pregnant women, older adults, and those with chronic conditions, underserved. Aligning adult and childhood immunisation schedules and using digital registries for routine reminders can boost adherence.

Beyond access, **awareness and education** are vital. Many adults underestimate the risks of vaccinepreventable diseases like influenza, pneumococcal infections, and HPV-related cancers. National



and EU campaigns must inform the public and healthcare professionals, ensuring vaccines become a routine part of medical consultations, especially for at-risk groups.

**Investment in innovation and research** is crucial. Diversifying vaccine technologies will offer tailored solutions for different populations and enhance efficacy. Stronger collaboration between policymakers, healthcare professionals, and manufacturers will accelerate vaccine development and deployment.

By prioritizing prevention, expanding access, embracing digitalization, and promoting life-course immunisation, Europe can enhance vaccination coverage, protect the vulnerable, and strengthen healthcare resilience. Achieving this, however, **requires sustained investment** and policy commitment, recognizing vaccines as a high-value tool that saves lives, cuts costs, and boosts societal resilience.

#### Health investments: a pillar for economic growth and stability

Investing in prevention is a **strategic economic choice** that boosts productivity, lowers healthcare costs, and supports long-term sustainability. Vaccine-preventable diseases create significant socioeconomic burdens, including productivity losses and caregiver responsibilities. Adult vaccination alone can yield up to a 19-fold return on investment (ROI) by reducing hospitalisations and keeping the workforce active. [7] Despite these benefits, many EU Member States spend less than 5% of their health budgets on prevention, putting strain on healthcare systems.[1]

This underinvestment in prevention underscores the **urgent need for structural reforms and increased funding**, particularly through the **EU's fiscal and budgetary frameworks**. The recent reform of the EU economic governance rules, the **New Economic Governance Framework (NEGF), adopted in April 2024,** introduced additional flexibility within the **Stability and Growth Pact**, allowing Member States to develop long-term investment plans grounded in "credible and prudent assumptions" and prioritising "social and economic resilience." [8] However, these measures did not include the adoption of a "Golden Rule" for health investments, a mechanism that would classify key health expenditures as strategic investments, targeting initiatives with strong ROI potential. Such initiatives would **encompass preventive care, immunisation, and health infrastructure improvements.** 

Further guidance from the European Commission is critical. Member States need support to assess the returns of health investments and develop strategic investment plans that align with the new governance framework. Vaccination programs which offer one of the highest ROI should be recognised as core components of these strategies.

The upcoming discussions on the next Multiannual Financial Framework (MFF) for 2028-2034 provide a unique opportunity to position healthcare and prevention as a strategic "social security investments", aligned with the requirements of the NEGF. This approach aligns with the prioritisation seen in defence and green/digital transitions. The EU Health Coalition advocates for ring-fencing health budgets under the new fiscal rules to maximise the sector's medium and long-term economic benefits.[9] By securing dedicated and sustainable funding for prevention and immunisation, the MFF can act as a catalyst for socio-economic resilience across the EU. Strategic health investment reduces immediate healthcare costs while boosting productivity and population well-being, fostering a cycle of growth, stability, and prosperity.

The EU's evolving fiscal policies must fully leverage the unique opportunity to position prevention and immunisation, as a cornerstone of social security investment. Strengthening funding mechanisms, digital infrastructure, data collection, and life-course immunisation policies will unlock the full value of vaccination, securing both healthier populations and a sustainable European economy.

By embracing prevention as a strategic priority, Europe can safeguard its healthcare systems, enhance societal resilience, and secure a healthier, more sustainable future for all.



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# Employers' Union of Innovative Pharmaceutical Companies INFARMA

## **Michał Byliniak**

Director General of the Employers' Union of Innovative Pharmaceutical Companies INFARMA

The Polish Presidency comes at a pivotal moment. It is the first full presidency of the new European Parliament term and will play a significant role in shaping the programme for the new European Commission.

Although health policy remains a national competence, the European Union also plays a significant role in shaping it. The EU's actions complement national policies with the aim of improving public health, combating epidemics, providing health education, and issuing early warnings in the event of cross-border threats.

This presents a unique opportunity for a fresh discussion on EU health security, which aligns closely with the overarching theme of the Polish Presidency: "*Security, Europe!*" The experience of the COVID-19 pandemic has clearly demonstrated that security is not only about stable and uninterrupted European medicine supply chains but also about the overall health of societies, efficient healthcare systems, and the development and accessibility of innovation.

However, new challenges lie ahead in both the area of **health** and Europe's **competitiveness**, and both will have a direct impact on health security. Under Poland's leadership, Europe should develop new mechanisms to safeguard the health of its citizens. **Under Poland's leadership**, **Europe should develop new mechanisms to safeguard the health of its citizens**.



Even before the Polish Presidency began, INFARMA called on the government to set ambitious objectives to improve prevention, strengthen Europe's competitiveness in biomedical sciences, and accelerate the digital transformation of healthcare.

As priorities, INFARMA highlighted the importance of the following areas, which should be considered in the health-related work of the Presidency:<sup>1</sup>

- A HEALTH POLICY FOUNDED ON PREVENTION. All EU citizens have the right to equal access to high-quality medical services. The new health policy should be based on uniform recommendations for prevention, early diagnosis, and reducing the economic and social burden of chronic diseases.
- A COMPETITIVE AND INNOVATIVE EUROPE. The innovative pharmaceutical sector in Poland and Europe is one of the most strategically and socially significant branches of the economy. Europe must be at the forefront of innovation and medicine development to ensure the health and economic security of the Europeans.
- THE DIGITAL TRANSFORMATION OF HEALTH CARE. It is essential to support the development of technology and accelerate digital processes to enhance the efficiency, accessibility, and quality of healthcare services.

For this reason, as an industry, we support all **four priorities** adopted for implementation by the Ministry of Health during the Polish Presidency: prevention and health promotion, mental health of children and adolescents, the digital transformation of healthcare, and medicines security.

As societies age and other risk factors increase, the incidence of chronic and lifestyle diseases is rising. Cardiovascular diseases remain the leading cause of death in both Poland and Europe. According to the latest report by the Central Statistical Office, published in December 2024, in 2021 there were 166,600 new cases of malignant cancer in Poland – an increase of 17.2% compared to 2020<sup>2</sup>, the height of the pandemic. Similar trends are observed in other therapeutic areas. It is estimated that the economic cost of managing cardiovascular diseases alone amounts to approximately PLN 56 billion. This includes direct healthcare and social care costs as well as indirect costs related to informal care and lost productivity.<sup>3</sup> In this context, prevention and health promotion become even more critical. Studies show that investing in prevention yields significant benefits: Every euro spent on prevention generates a return of 14 euros.<sup>4</sup> Similarly, adult vaccination programmes can deliver up to a 19-fold return on investment. Given current health challenges, slow economic growth, and ongoing demographic and epidemiological shifts, a fundamental shift in healthcare models is needed – from a reactive (disease treatment) to a proactive (health promotion) approach, with strong investment in preventive healthcare.

Europe is also struggling with **declining competitiveness**, as highlighted in a report by Mario Draghi<sup>5</sup>, which outlines the necessary changes. The final shape of the EU pharmaceutical legislation reform, which will continue to be negotiated under the Polish Presidency, will be crucial in addressing these challenges, particularly as the Hungarian Presidency was unable to reach a compromise. This reform represents the foundation of the pharmaceutical market, affecting the entire process of research, registration, distribution, and patient access to new medicines. It will shape the industry's future for decades to come - either giving a strong impetus to research and development or stalling progress for years. These upcoming negotiations and the final compromise reached among Member States will determine this direction.

Unfortunately, the findings of the Draghi Report align with data from recent industry reports. Despite a 38% global increase in clinical trials over the past decade, Europe's share has halved over the same period. Economically, Europe is also falling behind: While the United States has steadily increased research and development spending over the past decade, Europe's R&D expenditure has grown by 4.4% annually, compared to 5.5% in the US and a staggering 20.7% in China.

The ambitious goals set in the Draghi Report should be commended, as they outline a roadmap for **restoring Europe as a prime destination for research and development investment** and enhancing its production capabilities. If pharmaceutical companies are to catch up and compete on



an equal footing, the report's recommendations must be implemented swiftly, alongside a coherent and comprehensive **life sciences strategy**, as proposed in the European Commission's agenda. It is therefore crucial that the final version of the pharmaceutical reform and the life sciences strategy include measures that **foster innovation and strengthen the competitiveness of the European industry**. At the EU level, it is essential to establish a regulatory and intellectual property (IP) framework that incentivises biopharmaceutical innovation, ensures predictability and stability, reduces bureaucracy, and demonstrates that the European Union is open to research and manufacturing investment.

As an industry, we are committed to making Europe once again a global hub for research, development, and the production of new diagnostic methods, therapies, and vaccines. This mission drives our ongoing efforts. Significant progress is already being made in the development of innovative medicines, contributing to more effective treatments that reduce the social, systemic, and economic burden of diseases while meeting patient needs and improving healthcare. Oncology remains the largest area of clinical research, accounting for nearly one-third (29%) of all trials. In addition, cell and gene therapies (CaGT) constitute a growing share, highlighting the sector's investment in cutting-edge approaches to cancer treatment.

The **digital transformation** of healthcare is also of paramount importance in improving patient outcomes, increasing system efficiency, and accelerating the development of innovative treatments. To achieve these goals, public-private cooperation is crucial in implementing modern solutions such as data analytics, artificial intelligence, electronic health records, telemedicine, and the interoperability of health data systems. A key component of healthcare digitalisation is the creation of the **European Health Data Space** (EHDS), a regulatory framework aimed at improving medical data interoperability, enhancing information security, and supporting research and innovation in health. Health data is a key driver of the **development of innovative medicines** and is essential for facilitating scientific research and improving patient care. The Draghi Report underscores the importance of making health data available for secondary use to improve healthcare, treatment outcomes, and innovation. However, certain challenges – such as intellectual property concerns, data governance, fragmentation risks, and compliance penalties – must be addressed. To ensure that healthcare digitalisation and EHDS implementation are feasible and future-proof, regular public-private collaboration and consultation with the pharmaceutical sector are essential.

INFARMA also supports efforts to strengthen Europe's pharmaceutical security. Ensuring patient access to cutting-edge therapies is fundamental to health security, and the innovative pharmaceutical sector plays a crucial role in this process. Poland has the potential to contribute significantly to medicines security through active participation in the discovery of new molecules. Access to state-of-the-art treatments that offer the best chance of recovery is a fundamental right for every patient. For treatment to be successful, uninterrupted access to medicines must also be ensured. However, continuous access to innovative therapies is essential to ensure a truly patient-centred definition of pharmaceutical security. The European pharmaceutical industry already plays a vital role in ensuring medicines security across the continent, generating benefits for both patients and EU economies. The European innovative pharmaceutical industry is already able to ensure an appropriate level of drug safety for citizens across Europe.

Enhancing access to innovation and preserving the European industry's competitive position are among the key challenges facing Poland and the European Union. To fully benefit from European pharmaceutical innovations, Poland must increase access to modern therapies. According to the Access GAP monitoring system, Poland's access to innovative treatments and diagnostics has improved by five points, reaching 58 on a 100-point KPI scale. However, the pace of change remains too slow. Greater availability of innovative medicines will enhance medicines security, but at the very least, Europe must maintain its current global standing. At the same time, generic medicines account for more than 55% of the Polish pharmaceutical market, giving Polish patients broader access to established treatments compared to citizens in other EU countries.



As INFARMA, we believe that the Polish Presidency, which we will support to strengthen Europe's security in every area, will be successful and will set the directions for the development of the European Union for the coming years.

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## Polish Association of Employers of the Pharmaceutical Industry – Medicines For Poland

## Grzegorz Rychwalski

Vice-President

#### Priorities of the EU Presidency in the Area of Medicines and Pharmaceutical Production

The Polish Presidency of the Council of the European Union coincides with the most significant reform of EU pharmaceutical law in 20 years. The changes proposed by the European Commission aim to ensure uninterrupted, faster, and broader access to medicines for Europeans while enhancing the Union's strategic pharmaceutical security. The outcomes of these changes will impact not only the condition of the pharmaceutical industry in Poland but also the availability of medicines and the development of our economy.

The COVID-19 pandemic has clearly shown that we need Community mechanisms to supply Europe with effective, safe and affordable medicines. Today, there is no doubt that the European Union must regain its pharmaceutical sovereignty. It needs regulatory changes that will increase its pharmaceutical production and accelerate the introduction of new medicines, including antibiotics, oncology therapies and rare diseases.

#### Work on the Revision of EU Pharmaceutical Law: the State of Play

On 26 April 2023, the European Commission adopted a package of amendments to European pharmaceutical law. Unfortunately, the proposal did not include provisions for introducing a legal and financial mechanism to restore Europe's pharmaceutical security. Instead, the document focused on extending the periods of market exclusivity for medicines.

The current EU provisions guaranteeing market monopolies for medicines include: a 20-year patent term, eight years of data exclusivity, followed by two years of market exclusivity, extendable by an additional year (commonly referred to as the "8+2+1" framework). This 11-year period represents the longest market exclusivity in the world. In comparison, the US system typically provides for five years of market exclusivity.



While the proposed amendments aimed to reduce data protection periods to six years, numerous exceptions were introduced. These would allow companies to extend protection periods to a maximum of 13 years, effectively increasing exclusivity by two years compared to current provisions.

Additionally, the changes proposed introducing a Transferable Exclusivity Voucher (TEV) for antimicrobials, primarily antibiotics, intended to incentivise their production. The TEV would grant an additional year of exclusivity, which companies could apply to another product or sell to a third party. This mechanism risks benefiting wealthier companies by enabling them to purchase vouchers to extend monopolies on their most profitable drugs.

On 10 April 2024, the European Parliament adopted its position on pharmaceutical law reform. Key provisions included a 7.5-year baseline for data exclusivity, extendable to 8.5 years, resulting in a maximum regulatory exclusivity of 11.5 years (a slight increase from the current 11 years).

The Parliament also supported the broad scope of the Bolar Exception, which allows the use of patent-protected pharmaceutical substances for preparatory work aimed at registering a competing product. This enables another manufacturer to begin all necessary preparations for market entry before the expiration of the monopolist's market exclusivity, allowing competition to commence almost immediately after the exclusivity period ends. The exception would also cover price-setting and reimbursement processes.

The trilogues (negotiations between the European Parliament, the Council, and the Commission) are expected to take place under the Polish Presidency between 1 January and 30 June 2025. These discussions aim to finalise a unified position.

As Medicines for Poland, we hope that Poland will influence the reform to benefit both patients and domestic drug manufacturers.

#### Priorities of the Polish Presidency in the Area of Medicines and Pharmaceutical Production:

# 1. Legislation to promote the production of active substances and medicinal products in the European Union should be tackled in order to repatriate their production to European countries, including Poland.

Having a robust industrial sector in Europe is pivotal for establishing the EU's strategic independence, directly enhancing both security and the global competitiveness of European companies. While the European Commission has expressed ambitions to return the production of medicines and their ingredients to Europe, it has yet to propose concrete regulations to achieve this. Therefore, the European Commission should be urged to urgently draft a legislative act implementing the provisions of the pharmaceutical strategy and other EU strategic documents. EU legislation should foster conditions that support development and incentivise investment across Member States. Without targeted support, the relocation of medicine and ingredient production to Europe is unlikely to succeed due to the inherently higher production costs in Europe compared to Asia.

Currently, three-quarters of active pharmaceutical ingredients (APIs) are manufactured in Asia. According to Nikkei Asia, China's share in the global export volume of key ingredients in 2020 was 86% for tetracycline and doxycycline and 63% for vitamin B1. Any disruption to the supply chain – whether due to a pandemic, factory breakdowns, transport issues, or political decisions by Asian leaders – could leave the world without essential medicines. And the supply chain could be interrupted by a pandemic, a breakdown in a Chinese factory, transport problems, as well as political decisions by Asian leaders.

Until the mid-1990s, Europe and the United States produced 90% of the APIs used globally. Today, this figure has dropped to just 20%. The primary drivers for the pharmaceutical industry's migration from Europe to Asia were the need to reduce production costs and meet payer expectations. Additionally, reconciling European environmental protection standards with the pollution levels generated by API production proved challenging, making Asia a more attractive manufacturing location.



Various bodies, including the European Parliament and the European Economic and Social Committee, have called on the European Commission to take immediate action to establish a fund supporting API and essential medicine production. These appeals also stress the importance of geographically distributing the proposed financial support across the EU.

## 2. Drug monopolies should not be prolonged and competition should be introduced as quickly as possible.

Extending the monopoly period delays the emergence of price competition in the pharmaceutical market, forcing European patients to wait longer for affordable treatment options. It also increases reimbursement costs for national payers, including Poland's National Health Fund (NFZ), and results in significant financial losses for healthcare budgets. Every day's delay in competition results in multimillion-euro losses for healthcare budgets. Furthermore, prolonged monopolies may stifle innovation, as they disincentivise the search for and introduction of new inventions until monopoly rights expire.

To foster the development of pharmaceutical production within the EU, it is essential to ensure predictability and legal certainty, enabling rapid access to competing medicines – including biologics and value-added products – immediately after intellectual property rights expire. EU pharmaceutical legislation must eliminate practices that artificially delay market competition.

Patent expirations and the end of market exclusivity drive competition, leading to price reductions. This not only helps balance healthcare budgets but also significantly increases access to pharmacotherapy for patients across the EU.

It is also critical to address advancements in artificial intelligence and big data, which have expedited drug development and reduced costs. Thanks to digitalisation, the process of bringing the drug to market has also been shortened. Despite these efficiencies, market exclusivity periods remain unchanged or are even proposed for extension.

The European Commission has argued that there is no link between extended drug monopolies and the introduction of new products. However, evidence demonstrates a correlation between prolonged monopolies and delayed access to therapies, as well as increased costs for national payers and patients.

Harmonised support for the Bolar amendment will also be vital to avoid delays in introducing competition within the EU pharmaceutical market.

Furthermore, implementing a ban on patent linkages is essential, as this mechanism significantly hinders competition.

## **3.** Drug shortages should be prevented by a reform of public procurement and drug pricing systems rather, not by imposition of overstocking obligations.

A major cause of shortages in essential medicines is the declining profitability of their production. In Poland, 2019 saw more medicines withdrawn from reimbursement than added. Between 2015 and 2021, of 51 reimbursed therapies that lost market exclusivity, competing medicines with the same substance were introduced in only 12 cases. To address this, it is crucial to reduce the downward pressure on generic drug prices and index them to inflation or an aggregated cost index for the pharmaceutical industry. Regulations must ensure the long-term stability of the sector.

Introducing a comprehensive shortage prevention strategy, leveraging successful examples like Poland's ZSMOPL (Integrated System for Monitoring Trade in Medicinal Products), could mitigate the risk of shortages.

The introduction of accelerated regulatory efficiency and digitalisation efforts would support the availability of medicines and ensure effective, data-based environmental risk assessments.

Imposing overstocking obligations or extending the shortage notification period for shortages to six months and will not address the current situation related to shortages of medicinal products. Instead, these measures may lead to the withdrawal of critical medicines. A two-month notification period, already in practice in most Member States, would harmonise procedures and avoid overwhelming regulatory bodies with false alarms.



The adoption of a harmonised definition of "critical shortage in a Member State" is crucial to improve coordination across Europe. EU solidarity mechanisms, as proposed by the European Commission, could also play a vital role. Recent shortages in the Union have shown that solutions can be found by redistributing medicines between countries rather than increasing local safety stocks.

## **Polish Pharmacy Chamber of Commerce**

### Irena Rej

#### **President of the Board**

Healthcare, a key area of the upcoming Polish Presidency, requires continuous adaptation to evolving conditions, challenges, and needs. During the six-month term of the Presidency, we must both define our own priorities – topics that the government believes should be added to the EU agenda – and address ongoing issues that stem from the European Union's existing work. We should continue the efforts initiated by previous presidencies, leveraging the knowledge and experience of other EU countries, as well as scientific advancements, digitalization, and artificial intelligence. This approach allows for more effective and comprehensive actions in various areas, ensuring that we build on past experiences while planning for the future.

Topics discussed during the Polish Presidency, as well as those beyond it, reflect broader societal challenges that remain relevant over time. This is particularly evident in the context of preventive healthcare, care for an aging population, and ensuring pharmaceutical security by striving to produce raw materials and finished medicines in Europe. Strengthening pharmaceutical capabilities lays the foundation for comprehensive pharmaceutical care, benefiting children, adolescents, and middle-aged and elderly individuals alike.

The Polish Presidency of the EU will focus on four thematic areas: health, security, law, and the future.

One of the key priorities of the Polish Presidency, which also aligns with ongoing EU initiatives, is the reform of EU pharmaceutical law. The goal of this reform is to enhance drug security and ensure real access to medicines for patients. Addressing this issue involves not only pharmaceutical legislation but also the development of mechanisms to support production capacity, solidarity measures, and research and development initiatives. It is crucial to guarantee equal access to safe, effective, and affordable medicines for all EU patients. Europe must invest in research, foster innovation, and strengthen cooperation among Member States. A pressing issue is the declining production of medicines within Europe, exacerbated by the drastic reduction of the EU's share in the global production of active pharmaceutical ingredients (APIs), which are now primarily supplied by China. A proposed solution is the establishment of an EU-wide Critical Medicines List, a set of tools designed to counteract the overall decline in European pharmaceutical production. The aim is to minimise the risks associated with access to medicines. The Critical Medicines Act would strengthen the EU's production capacity, secure access to essential APIs, and support the local manufacture of medicines, ensuring real pharmaceutical security for patients while minimizing risks associated with medicine availability.

A particularly significant priority of the Polish Presidency is the mental health of children and adolescents, especially in the face of new societal challenges such as excessive internet use, stress, and lack of physical activity. All EU Member States recognize the growing importance of this crisis. Poland will be the first to introduce this issue to the EU agenda and initiate discussions at the EU level. As part of this initiative, a report will be developed, containing initial recommendations and incorporating existing instruments to prevent and mitigate the mental health crisis.

Another priority of the Polish Presidency is the digitalisation of healthcare services. Efforts should be made to standardize IT systems across the EU, ensuring that doctors in any EU country have access to a patient's medical history from another Member State. Existing IT



infrastructure can already facilitate such a cross-border exchange of medical data, enabling continuous health monitoring while ensuring data security. The Polish Presidency also aims to present Poland's ZSMOPL system as a model that could be successfully implemented in other European countries.

Beyond the core priorities, the Polish Presidency will advocate for addressing several additional key topics, including Enhancing cooperation on rare diseases between EU Member States. Ideally, this should be done by establishing a centralized data hub for rare diseases would facilitate knowledge accumulation, Improve early diagnosis and treatment standards, and minimize risks related to medicine accessibility across the EU. The current fragmentation of rare disease data across individual Member States makes effective collaboration difficult.

Another noteworthy area is epidemiological monitoring. There is a need to improve the monitoring of epidemiological trends to ensure accurate data on lifestyle and infectious diseases across different regions of the EU.

Advancing Laboratory Diagnostics is also an important topic as the strengthening of laboratory diagnostics is essential for precise treatment strategies, particularly in oncology.

In summary, the rotating nature of the EU Presidency ensures that, over time, the European Union maintains a consistent focus on its most pressing issues that are universally relevant for all EU Member States. This approach allows each Member State to contribute its expertise while benefiting from the experiences of others.

## The Polish Chamber of Commerce of Medical Devices POLMED

## Arkadiusz Grądkowski

President of The Polish Chamber of Commerce of Medical Devices POLMED

#### Introduction

The Polish Chamber of Commerce of Medical Devices POLMED ("POLMED") is an organisation representing manufacturers, importers, and distributors of medical devices. We represent and support nearly 120 companies operating in the medical devices industry. POLMED includes both small Polish entrepreneurs and large international corporations, which enables us to offer a comprehensive perspective on the market, encompassing the challenges faced by both local businesses and multinational enterprises. Through its daily activities, the POLMED Chamber collaborates closely with companies directly involved in the distribution of various types of medical devices, providing us with in-depth insight into industry-specific issues and allowing us to share an informed perspective.

Medical devices are one of the key pillars of any healthcare system, alongside pharmaceuticals and a well-trained workforce. Without these devices, patient treatment would not be possible. Currently, nearly 2 million different medical devices and technologies are available worldwide. Our industry is the second most innovative in the European Union, surpassed only by the digital communications sector in terms of the number of patent applications. In 2023 alone, nearly 16,000 patent applications were filed with the European Union Intellectual Property Office.

The COVID-19 pandemic underscored the critical importance of the medical devices industry and the need for access to these essential products. Disruptions to supply chains revealed Europe's lack of self-sufficiency in medical device production, making it dependent on non-European countries that prioritized domestic needs. To address this, it is crucial to build a robust European industry and enhance Europe's attractiveness for medical device production, importation, and distribution.



Amidst Poland's Presidency of the Council of the European Union, we have a unique opportunity to shape EU policy in a manner that benefits both Poland and the entire Union. Leveraging the knowledge and experience of industry experts will enable us to better understand complex market dynamics and implement innovative solutions that will have a lasting impact on economic growth and healthcare advancement.

While current legal regulations were introduced to enhance patient safety, they have also led to unintended consequences such as reduced availability and a decline in the EU's attractiveness for medical device businesses.

In light of these challenges, POLMED presents the following key proposals for the medical devices industry. Their implementation will contribute to improving the situation for both Polish and European patients, as well as healthcare providers and businesses operating in the health sector.

#### Health and Product Security in the European Union

The first half of this decade was defined by responses to and recovery from the COVID-19 pandemic. The second half should focus on applying lessons learned from the pandemic to build more resilient healthcare systems and a strong, stable medical device industry. Current challenges and future crises should be addressed with the same ambition and commitment as post-pandemic recovery efforts, emphasizing prevention, retention of healthcare professionals, and rapid access to medical care.

In this context, POLMED believes that the European Union should prioritize the following actions:

- Enhancing healthcare worker retention by encouraging Member States to support them with tailored technologies, digital solutions, robotics, and automation.
- Strengthening European competitiveness and autonomy in securing critical materials and components essential to the continued delivery of key medical technologies during crises.
- Developing effective measures to protect suppliers of critical healthcare technologies from international trade disruptions and supply chain failures, while fostering a strong, sustainable medical device industry.

#### Postulates of POLMED in the Field of Medical Devices

#### Proposed Amendments to the MDR and the IVDR

As POLMED, we believe that ensuring adequate availability of medical devices in the European Union and Poland requires an appropriate legislative environment, necessitating urgent amendments to Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic devices (IVDR).

The MDR and IVDR have failed to achieve their objectives of creating a robust, transparent, predictable, and sustainable regulatory framework that ensures a high level of health and safety while promoting innovation in the medical device market. Representatives of the medical industry are in consensus and have adequate evidence that the current MDR and IVDR regulations lead to shortages of devices in medical entities and slow down the pace of innovation. Policies and procedures under MDR and IVDR are perceived as complex and unpredictable, making it difficult to develop and market novel products in Europe. The data show that there is a sharp decline in the number of medical technology and IVD companies that would first consider introducing new products in Europe. Many devices available under the previously applicable EU directives have been withdrawn from the market because obtaining the CE mark in the light of the new regulations is too complicated, time-consuming, and expensive. The Directives in their current form lead to shortages of medical devices, hinder innovation, and create unnecessary burdens for the medical device industry, particularly affecting many small and medium-sized enterprises (including Polish companies), which in turn impacts access to medical technologies for patients and healthcare



systems in Europe and Poland. Data collected by MedTech Europe and other organisations<sup>268</sup> indicate the following:

- Up to one in three medical devices and laboratory diagnostic devices have been withdrawn from the EU market due to MDR and IVDR.
- Half of all health professionals surveyed in 2022 said they had problems with the availability of medical devices. Among them, only one in three found that substitute products were as effective as the original ones.
- Approximately 30% of manufacturers do not consider the EU market as the primary location for launching new devices, meaning that patients in Europe may lose access to key innovations – or at best, face long delays in accessing state-of-the-art healthcare. Under the previous legislative framework, the percentage was significantly higher, and the EU market was regarded as an absolute priority.

We believe that these problems can only be solved through legislative changes in both regulations to make them more efficient (simpler, less burdensome), more innovation-friendly, and better implemented. However, legislative changes at the EU level require time, so immediate solutions are needed to accelerate improvements in the regulatory environment.

In the opinion of POLMED, it is necessary to introduce changes in MDR and IVDR – the most important of them are presented below:

#### **Reducing Deadlines and Costs of the Conformity Assessment Procedure**

The timeframes and costs of the conformity assessment procedure must be reduced. Taking immediate action in this area is crucial to preventing the impending threat of unavailability of medical devices and attracting investment in the introduction of innovations in Europe.

Manufacturers of medical devices already cite long approval timelines and unpredictable certification costs as the main reasons for not adapting their products to MDR and IVDR requirements. Due to these obstacles, one in three manufacturers introduces innovative solutions exclusively or primarily outside Europe.

The entire conformity assessment procedure carried out by notified bodies should be as transparent as possible for manufacturers – therefore, mandatory deadlines for the duration of conformity assessments should be introduced. Our proposal assumes the introduction of a six-month deadline for the certification of quality management systems and a three-month deadline for the certification of technical documentation.

Notified bodies also should be required to publish reports on the costs and timelines for certification of various types of medical devices to improve transparency regarding conformity assessment fees.

#### Accelerating the Evaluation of Changes in Medical Technologies

The assessment of modifications in medical devices must be expedited to ensure that patients have timely access to the latest medical technologies.

The number of changes requiring the involvement of notified bodies should be reduced, and the necessary conformity assessment procedures should be simplified as much as possible. Currently, even urgent changes from a patient's perspective experience certification delays lasting several months.

Reports by other organisations:

<sup>268</sup> MedTech Europe, Transition to the IVD Regulation – MedTech Europe Survey Results for October 2022 (a survey report), October 2022; MedTech Europe, Analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation (a survey report), April 2022; MedTech Europe, Analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation (a survey report), April 2022; MedTech Europe, Transition to the IVD Regulation – MedTech Europe Survey Results for October 2022 (a survey report), October 2022;

German Chamber of Commerce and Industry (DIHK), the MedicalMountains cluster initiative, and the German industry association SPECTARIS, *Current assessment of the German medical device manufacturers on the effects of the EU MDR* (a survey report), December 2023;

Biomedical Alliance in Europe, Clinicians concerned about limited availability of medical devices (a survey report), January 2023.



To speed up the process, assessments should be limited to essential cases only. The number of changes requiring the involvement of notified bodies should be reduced, and the necessary conformity assessment procedures should be simplified as much as possible.

#### **Creating A Fast-Track Pathway for Innovative Medical Technologies**

A simple and transparent regulatory pathway should be established to fast-track the approval of innovative technologies within a fixed 120-day deadline.

Currently, developers of modern medical devices lack clarity regarding what evidence must be provided before and after market entry. The complexity of European regulations discourages manufacturers of the latest technologies from entering the European market. For this reason, a dedicated framework for technological innovations is required, ensuring that entrepreneurs developing the most advanced medical device projects will prioritize Europe as their first market of choice.

A well-thought-out, holistic approach to supporting innovative solutions in the healthcare system will attract the most advanced medical technologies to Europe and meet the needs of patients who are currently awaiting diagnosis, treatment, and care.

#### Adapting Certification to the Life Cycle of Medical Devices

There is an urgent need to adapt the certification process to the life cycle of medical devices. In our opinion, removing the time limit on the validity of certificates would eliminate serious bureaucratic burdens and help prevent bottlenecks in certification during transitional periods.

Currently, the MDR and IVDR regulations require recertification every five years, which imposes unnecessary burdens on both manufacturers of medical devices and notified bodies while not bringing additional benefits. This is because, regardless of this requirement, the notified body is already obliged to conduct continuous assessment of devices and quality systems after their certification. Based on this system, notified bodies already have sufficient mechanisms allowing them, in justified cases, to suspend issued certificates. Given that this system is already in place, the mandatory five-year recertification requirement appears to be an excessive bureaucratic burden.

#### Establishment of a European Medical Devices Authority

The MDR and IVDR require a single, coherent body responsible for overseeing and managing the regulatory system for medical devices. This body's primary purpose should be to ensure that innovative solutions reach patients and healthcare systems in a timely manner. Additionally, it should also ensure consistency between regulations governing medical devices and other European legislative frameworks.

This role could be assumed by the European Medicines Agency (EMA). However, for this to happen, the Agency would need to adopt an operational and organisational model appropriate for medical devices, which differs from the approach currently used for medicinal products.

The following conditions should be maintained to ensure the effective application of this solution:

- Inclusion of the EMA as the regulatory body for medical devices must not introduce additional complexity or unnecessary administrative burdens;
- The medical device industry must remain within a certification-based system using notified bodies, maintaining a clear separation from the centralized authorization model applied to pharmaceuticals;
- Supervision of medical devices and in vitro diagnostic devices should be carried out by a dedicated and specialized management board, appointed in accordance with the specific needs of the medical devices sector;
- The EMA must employ experts with in-depth knowledge of medical devices and ensure proper training of personnel responsible for regulating medical devices and in vitro diagnostic devices. It is crucial to recognize that, despite their apparent similarities, the medical devices sector and the pharmaceutical sector face distinct challenges and regulatory requirements;



• Establishment of this new authority that would supervise and manage the regulatory system for medical devices (or the appropriate expansion of the EMA's mandate) should not result in unnecessary costs or bureaucratic inefficiencies.

#### Actions That Do Not Require Changes to the MDR and IVDR

In addition to legislative amendments, there are also ways to improve the European medical device regulatory system without introducing changes to existing laws. These improvements can be implemented by utilizing the competencies of existing institutions and issuing clarifications and guidelines on the application of current regulations

Key areas that require immediate attention from the European Commission or the Medical Device Coordination Group (MDCG) include:

- accelerating and fully implementing the 19-point action plan for facilitating the transition to the new regulatory framework, as outlined in MDCG 2022/14. In particular:
  - o introducing measures to ensure structured dialogue before and during conformity assessment,
  - providing clear guidelines on the use of existing evidence, ensuring that data does not have to be duplicated unnecessarily,
  - reducing the documentation burden associated with the preparation of technical files for medical devices;
- allowing for the full use of electronic instructions for use (eIFU) for all medical devices and in vitro diagnostic devices, thereby improving accessibility and sustainability.
- facilitating the European Union's accession to the Medical Device Single Audit Program (MDSAP) as a full-fledged member.

#### Postulates of POLMED regarding the general healthcare system

In recent years, the dynamic development of digital technologies and an ageing society have become key factors influencing the efficiency and accessibility of medical services. Appropriate solutions in the fields of digital transformation, health prevention, and the adaptation of the system to evolving demographic needs are of fundamental importance for improving public health and ensuring high-quality healthcare for all citizens.

In the face of these changes, the fundamental task is to create an effective ecosystem that will not only meet the healthcare needs of citizens but also foster innovation and enable the introduction of modern solutions in medical care.

Below, we present the most important priorities that should be addressed during the Polish Presidency.

#### **Digital Transformation of Healthcare**

One of the key priorities is the digital transformation of both the European and Polish healthcare systems. In an era of rapidly evolving digital technologies, it is crucial to create a favorable environment for further digitization in the healthcare sector. This will facilitate access to innovative diagnostic and therapeutic solutions, while also contributing to more efficient and personalized patient treatment.

In the opinion of POLMED, during the Polish Presidency of the Council of the European Union, decision-makers should focus on:

- Creating the best possible environment in Europe (including Poland) for medical technologies that utilize artificial intelligence, in order to support innovation and ensure rapid patient access to safe and effective AI-based medical devices.
- Investing in digital health competencies to enable citizens, patients, and healthcare professionals to effectively use digital healthcare solutions. Unfortunately, despite advancements in digital healthcare, both patients and healthcare workers often remain reluctant to use such solutions due to a lack of knowledge or experience.



• Developing a truly unified Digital Single Market for health and health data, ensuring a harmonized approach among EU member states regarding identification, authentication, cybersecurity, and interoperability of digital health technologies.

A crucial element in achieving these objectives is the legislative work currently in progress at the European level, particularly the Regulation on the European Health Data Space (EHDS). Additionally, it is essential to prepare guidelines for newly adopted legal acts that have yet to come into full force, such as the AI Act and the Data Act.

It is necessary to ensure that these legal acts are fully aligned with medical device regulations, namely Regulation (EU) 2017/746 (MDR) and Regulation (EU) 2017/745 (IVDR), ensuring consistency in conformity assessment requirements. We express our willingness to cooperate and share our expertise to support further legislative work in this area.

#### **Promotion of Preventive Healthcare**

Public health is becoming increasingly important, particularly in the context of an ageing population. Therefore, a key priority should be to support preventive and educational initiatives aimed at promoting a healthy lifestyle. Investments in disease prevention and early diagnosis are crucial to reducing future healthcare expenditures related to the treatment of chronic and age-related diseases.

#### Healthcare in the Context of Demographic Changes

Poland, like many other EU countries, faces demographic challenges that directly impact the healthcare system. The stability and availability of medical devices should be prioritised to ensure a high quality of life and proper healthcare services for all age groups. This is particularly critical for the elderly, who should not be perceived as a burden on society but rather as a group requiring adequate medical and social support.

#### **Other Regulatory Changes**

In addition to the key priorities outlined above, POLMED highlights the need to take a broader view of the healthcare system and introduce further changes to enhance its functionality. In our opinion, the Polish Presidency should focus in particular on:

- addressing delays in payments in commercial transactions;
- ensuring sustainability in the healthcare sector;
- strengthening the safety of medical products in the European Union.

A more detailed discussion of these postulates follows.

#### Addressing Delays in Payments in Commercial Transactions

One of the most significant challenges for the medical devices market in Poland (and in many EU countries) is the issue of late payments by hospitals, particularly public hospitals. According to industry assessments, broader amendments to the provisions on late payments in commercial transactions (currently governed by Directive (EU) 2011/7/EU on combating late payments in commercial transactions) are necessary, with a particular focus on delays in payments by institutions financed from the state budget. The failure to introduce appropriate changes and the continuation of the current situation lead to the exclusion of small and medium-sized enterprises from the market, as they lack the financial resources to finance medical entities' operations for extended periods.

The Late Payment Directive is currently under review, and POLMED supports the inclusion of appropriate regulatory safeguards in the revised legislation to take into account the impact of late payments on the medical devices sector, particularly for small and medium-sized enterprises (SMEs).

If this legislative amendment is adopted by the end of 2024, it is crucial that the Polish Presidency of the Council of the European Union cooperates with the European Commission to monitor



whether the adopted measures are fully and swiftly implemented at the national level. This will play a key role in supporting the competitiveness of the medical technology industry, especially in the SME sector.

#### Sustainability

The European Green Deal is the EU's new growth strategy aimed at transforming the Union into a fairer and more prosperous society, with a modern, resource-efficient, and competitive economy, striving for net-zero greenhouse gas emissions by mid-century. A holistic approach to sustainability in the healthcare sector means continuously improving efficiency while maintaining the highest health and safety standards to meet patients' needs.

According to POLMED, the European Union should focus on the following key aspects of sustainable development in the medical devices sector:

- Encouraging cooperation and partnerships between all healthcare stakeholders to drive systemic changes and the continuous improvement of social, ecological, and economic efficiency in healthcare systems;
- Leveraging legislative trends in ecology and digitalisation to enhance overall system efficiency and sustainability performance;
- Ensuring that future regulations align with sector-specific requirements, reinforcing the sustainability of medical technologies while considering the entire product life cycle;
- Developing realistic regulatory pathways that provide medical device manufacturers and their supply chains with sufficient time to comply with new requirements, ensuring uninterrupted access to critical medical technologies for patients and physicians;
- Achieving true regulatory harmonization to strengthen the European Single Market, which remains the EU's strongest economic asset, fostering both high environmental protection standards and a competitive medical technology sector.

#### **Summary**

The presented set of postulates reflects the shared aspirations and needs of our industry in response to the rapidly changing economic landscape and the numerous challenges we face each year. The Polish Presidency of the Council of the European Union represents a unique opportunity to address these challenges and secure the stable growth of our economy.

At a time of economic crises affecting both Poland and the European Union, we cannot afford to squander this opportunity. The Polish Presidency of the Council of the EU provides a strategic moment to influence the future of European economic policy, ensuring tangible benefits for entrepreneurs and citizens alike. The POLMED proposals for the Polish Presidency are based not only on strong substantive arguments but also on practical feasibility. This is why it is crucial to listen to industry experts who experience these challenges firsthand in their daily work.

POLMED calls for full commitment to implementing the presented postulates, which directly address current challenges and aim to ensure sustainable development and economic stability for our industry and the broader economy. We strongly believe that, through collaborative efforts, we can not only overcome present difficulties but also lay the foundation for future success.

### **Polish Supreme Chamber of Physicians and Dentists**

### Magda Wiśniewska MD PhD

Chair of the Council of Experts of the Polish Supreme Chamber of Physicians and Dentists

#### Effective Fight Against the Surge in Obesity and Type 2 Diabetes

Obesity is classified as a pandemic due to the number of people affected and the rapid pace of its spread. According to CBOS data, 21% of adult Poles suffer from obesity, and more than half of the Polish population has excessive body weight. Globally, over one billion people have been



diagnosed with obesity, and more than one-third of the world's population is now classified as overweight. In Europe, 59% of adults and nearly 30% of children are overweight or obese. Unfortunately, Poland ranks among the leading countries in childhood and adolescent obesity. The majority of young people do not outgrow obesity, with four in five obese teenagers continuing to struggle with excessive weight in adulthood. Obesity and overweight rates continue to rise across the EU, and no Member State is currently on track to meet the shared goal of halting the obesity epidemic.

What is particularly concerning is that obesity is one of the few diseases where complications are treated rather than the root cause. Obesity is a major contributor to over 200 other diseases and conditions, including its presence in nearly 90% of type 2 diabetes patients, 35% of those with ischemic heart disease, and 55% of hypertensive patients. It is also a significant risk factor for cancer development.

In the European Union, 1 in 13 deaths annually is attributed to excessive body weight. The direct costs of obesity-related healthcare have been estimated at over 7% of total health expenditures in Europe, a figure comparable to the cost of cancer treatment. This underscores the urgent need for enhanced prevention efforts, individualised treatment strategies, and the implementation of effective public health interventions. Such initiatives must be multidisciplinary, incorporating prevention strategies alongside modern treatments, including lifestyle modifications, psychological support, pharmacotherapy, and bariatric surgery.

Type 2 diabetes is widely recognized as the first non-communicable epidemic of the 21st century. In Poland alone, over 3 million people suffer from this disease. Within the WHO European Region, it is estimated that 74 million adults (11.9% of men and 10.9% of women) and around 300 children and adolescents are living with diabetes. Alarmingly, diabetes-related deaths are on the rise and are expected to double between 2005 and 2030.

Diabetes is a complex and multifactorial disease, closely associated with other health conditions and requiring intervention across all levels of care. If left undiagnosed or poorly controlled, serious vascular complications can arise, including cardiovascular diseases (heart attacks, ischemic strokes, heart failure), chronic kidney disease, diabetic retinopathy, diabetic neuropathy, diabetic foot syndrome.

In all EU Member States, diabetes accounts for approximately 9% of total healthcare expenditures(26), and up to 75% of these costs are linked to preventable complications. Prevention has been proven to be more effective than any treatment in reducing the incidence, prevalence, and complications of certain types of diabetes. Moreover, prevention remains the most cost-effective long-term strategy for diabetes control. The prevention, management, and treatment of diabetes serve as key indicators of a healthcare system's quality, efficiency, and resilience. Effective diabetes care also contributes to better outcomes for other non-communicable diseases.

There is an urgent need for comprehensive strategies focused on prevention and counteraction against type 2 diabetes, as well as on early diagnosis to prevent the development of complications. Additionally, it is essential to ensure equal access to safe, effective, and affordable therapies across the EU.

#### **Treatment of Mental Disorders**

The Eurobarometer survey has highlighted that mental health problems are becoming an increasing economic and social burden. According to the 2024 study, 46% of the EU population experienced mental disorders, primarily depressive moods or anxiety disorders, yet only one in two EU citizens sought help. Even before the COVID-19 pandemic, one in six EU residents struggled with mental health issues, generating costs related to treatment and sickness absence estimated at 4% of GDP. It is further estimated that the total cost of mental health problems in the 27 EU countries and the UK exceeds 4% of GDP, amounting to over EUR 600 billion. Almost every second young European reports that their mental health needs are not fully met, and in several EU countries, the percentage of young people experiencing depression symptoms has more than doubled since the pandemic.



This underscores the urgent need for further investment in mental health reforms, including better healthcare systems, increased support for mental health professionals, and measures to eliminate stigma and discrimination related to mental health conditions.

The National Programme for Mental Health Protection (NPOZP) for 2017–2022 outlined key systemic changes, including deinstitutionalisation of mental health services, optimising patient pathways within the mental healthcare system to enhance the efficient use of medical staff, expanding access to outpatient services, developing community-based mental health services, with a mandate to cooperate with families and schools, and offering comprehensive training for mental health professionals. In Poland, a three-tiered system of mental health support for children and adolescents has been introduced: The system's foundation is the Reference Level One comprising of community psychological and psychotherapeutic care centres for children and adolescents. Reference Level Two includes mental health centres for children and adolescents, including outpatient clinics and day wards. Reference Level Three is comprised of highly specialised psychiatric care centres providing 24-hour inpatient care. As of today, over 500 Level One centres have been established nationwide, marking a significant development in Poland's mental healthcare system. Recent reforms in Poland's mental healthcare system have led to the creation of new professions in child psychiatry, including community therapist for children and adolescents, and a new healthcare specialties - child and adolescent psychotherapy and clinical psychology of children and adolescents. Continued cross-sectoral cooperation and mental health prevention strategies must be prioritised to further enhance the effectiveness of mental healthcare.

#### **Prevention of Caries and Periodontal Disease**

Oral diseases are among the most prevalent health problems, with treatment costs in the EU accounting for 5-10% of public health expenditure, making oral diseases the fourth most expensive category to treat. Gum inflammation and tooth decay are fully preventable with appropriate measures. Key preventive measures should include:

- proper oral hygiene,
- topical application of fluoride compounds,
- dietary modifications, including reducing carbohydrate intake,
- tobacco control,
- reducing alcohol consumption,
- regular dental check-ups.

Implementing healthy lifestyle changes not only prevents oral diseases but also reduces the risk of obesity, diabetes, cardiovascular diseases, cancer, and strokes – conditions clinically linked to poor oral health.

Greater emphasis should be placed on comprehensive health education in oral hygiene and proper dietary habits, tailored to specific age groups to effectively address their needs.

## Measures to Adapt to the Changing Demographic Situation: Ageing of the Population in Poland and Europe

#### **Effective Fight Against Cancer**

Cancer is the second most common cause of death, following cardiovascular diseases. However, innovative treatments and improved access to healthcare have enabled many Europeans to live longer after a cancer diagnosis. In 2020, 1.2 million people in the EU died of cancer, and nearly 3 million new cases were diagnosed. Although Europe accounts for less than 10% of the world's population, it records 25% of all cancer cases globally. Cancer survival rates vary significantly across EU Member States, with differences exceeding 25%. Nearly 75% of all diagnosed cancers in the EU affect individuals aged 60 and older. One in three EU citizens is expected to experience cancer in their lifetime. Almost 40% of cancer cases in the EU could be prevented. Given these alarming figures, cancer prevention and treatment remain a top EU priority in healthcare policy. The Europe's Beating Cancer Plan is designed to support EU Member States in preventing cancer



and enhancing the quality of life for cancer patients, survivors, their families, and caregivers. This plan prioritises key areas where the EU can provide the most value.

These are as follows:

- prevention,
- early detection,
- diagnostics and treatment,
- quality of life of cancer patients and survivors.

## Reversing the Hierarchy of Healthcare Services by Shifting More Services to Lower Levels of Healthcare

Such measures are rational as they will improve healthcare accessibility and reduce costs. It is necessary to expand diagnostic and therapeutic capabilities within the Primary Care and Specialist Outpatient Care systems.

## Developing Non-Medical Competencies of Medical Personnel to Enhance the Quality and Efficiency of Services

#### Addressing Urinary Incontinence in an Ageing Society

Urinary incontinence is a significant public health issue affecting a large proportion of the European population. This condition has a profound impact not only on patients and their families but also on national healthcare systems, the economy, the environment, and society as a whole. The Policy Office of the European Association of Urology (EAU) has launched a new pan-European campaign titled An Urge to Act, aimed at achieving meaningful changes in EU policy on incontinence. Urinary incontinence is a widespread problem that affects individuals of all genders, regardless of age or socioeconomic background. It is often a result of other medical conditions or a side effect of treatment. It is a debilitating, chronic issue that can severely impact a patient's quality of life. The physical, psychosocial, and economic consequences for both patients and their caregivers are substantial. Despite the availability of preventive, management, and treatment options for urinary incontinence, these interventions are not being fully implemented. As a result, many patients experience unnecessary suffering. Moreover, the economic burden associated with incontinence – including healthcare costs, lost productivity, reduced quality of life, and environmental concerns due to the disposal of incontinence products – places a considerable strain on individuals, families, and society. Healthcare professionals and informal carers make significant efforts within the existing constraints of various European healthcare systems. Currently, health systems are not yet fully adapted to support the care of people with incontinence.

Policies and regulations across the EU and within individual Member States must prioritize urinary incontinence care, given its prevalence and the widespread availability of effective solutions. Without intervention, urinary incontinence will become one of Europe's major public health challenges. Now is the time for urgent action to address the growing burden of incontinence-related health issues.

A European study on the economic impact of urinary incontinence found that the cost of caring for patients with this condition in the EU in 2023 reached approximately EUR 69.1 billion. These costs include: the impact of incontinence on patients' health, expenses related to medical consultations and hygiene products, work absences due to the condition, admissions to long-term care facilities, environmental costs associated with incontinence product waste. If no measures are taken, the economic burden of urinary incontinence is projected to increase by 25% by 2030, reaching EUR 86.7 billion. This financial strain will be exacerbated when factoring in the disposal costs of non-biodegradable hygiene products used in incontinence management.

#### **Prehabilitation Before Elective Procedures**

Prehabilitation refers to a comprehensive preparation process before surgery or long-term treatment, such as oncological therapy. The goal of prehabilitation is to optimize the patient's health status



to ensure better tolerance of surgical procedures, minimize complications, and facilitate a faster recovery.

Prehabilitation consists of four key components:

• Eliminating harmful habits, particularly smoking. Smoking is not only a risk factor for numerous severe diseases but also significantly increases the likelihood of complications, such as pneumonia, postoperative wound infections, and even mortality.

Nutritional preparation, which is particularly crucial for malnourished and debilitated patients. Performing surgery on severely malnourished individuals drastically increases the risk of complications. This is especially relevant for oncology patients, Though proper nutritional preparation should extend to a broader group of surgical candidates.

- Tailored physical exercise programs to improve overall physical fitness. Even minimal physical activity can stimulate anabolic processes, aiding in weight restoration and wound healing. Exercise is especially beneficial for obese patients preparing for elective procedures such as joint replacement, hernia repair, reconstructive surgery, and bariatric surgery.
- Psychological support, particularly for oncology patients. Psychological intervention helps patients better understand their treatment and reduces fear and anxiety, which often accompany major surgeries and cancer therapies. This is a crucial element of patient-centred support as anxiety and stress negatively impact both a patient's well-being and treatment outcomes, including in oncology.

Implementing a robust Patient Blood Management strategy and remote patient monitoring for post-surgical high-risk cardiac patients will facilitate shorter hospital stays, reduce complications, and enhance patient recovery outcomes.

## **Polish Federation of Hospitals**

### Jarosław J. Fedorowski MD PhD, Professor of Medicine, University of Warmia and Mazury in Olsztyn

President of the Polish Federation of Hospitals, Governor and Member of the Presidium of the European Federation of HOPE Hospitals, Vice-President of the "Zdrowe Zdrowie" (Healthy Health) Corporation of Employers of the Republic of Poland

The vision of the Polish Federation of Hospitals is a sustainable healthcare system that transcends divisions. One of the main activities of the PFSz is the promotion of best practices in healthcare, particularly in management and organisation. As a widely recognised representative body, the PFSz integrates hospitals of all ownership models and security levels within the State Healthcare Services (PSZ) system, as well as hospitals operating outside of it – both those under contract with the National Health Fund (NFZ) and those without. The Federation also includes hospitals providing Specialist Outpatient Care (AOS) services, Primary Care Providers (POZ), Treatment and Care Facilities (ZOL), rehabilitation hospitals, and non-hospital medical entities such as public and private outpatient care centres. This broad mandate enables the PFSz to effectively advocate for key issues within the Polish healthcare system. Additionally, the Federation is a member of Employers of Poland, the largest employers' association in Poland, where it participates in discussions on the organisation of the entire service sector, including consumer expectations regarding healthcare.

The PFSz's mandate is further strengthened by its active membership in international hospital and healthcare organisations, which have long promoted the highest standards of medical care through the exchange of experiences among leading hospitals and healthcare organisations, both at the European and global levels. We are members of the Brussels-based European Hospital and Healthcare Federation (HOPE) and the Geneva-based International Hospital Federation (IHF), the only global hospital organisation. Through these platforms, including European and global



congresses (such as the HOPE AGORA Congresses and IHF World Hospital Congresses), we, as representatives of Polish hospitals, have the opportunity to exchange experiences, including in the areas of healthcare organisation and reforms in other countries. Lessons learned at the European and global levels should, of course, be applied locally. Lessons learned at the European and global levels should, of course, be applied locally.

The PFSz participates in the social dialogue on the healthcare system at the national, European Union, and global levels.

## **Reform of Hospitals and the Healthcare System in Poland: A Model for Other EU Countries** – **Proposals from the Polish Federation of Hospitals**

We believe that the primary goal of reforms should be to benefit patients, not only through a wellfunctioning hospital system but also via an efficient and integrated healthcare system as a whole. It is crucial to ensure seamless cooperation across healthcare sectors to deliver value throughout the entire treatment cycle and maintain public health. One well-established approach is the so-called "inversion of the service pyramid", shifting certain procedures from hospital settings to outpatient care where medical safety permits.

One of the key reform proposals from the PFSz involves rational consolidation of healthcare resources (both hospital and outpatient). The Federation advocates for the development of coordinated healthcare organisations that compete based on treatment outcomes rather than volume of services. The 2017 hospital reform in Poland did not yield the expected results, largely because security levels assigned to hospitals within the State Healthcare Services network were not subsequently translated into hospital reference levels. Moreover, there were no clear guidelines for cooperation between hospitals at different security levels, nor were mechanisms introduced to encourage such collaboration. To address these shortcomings, the PFSz proposes introducing hospital reference levels and, in the next step, establishing incentives for healthcare providers to enter into cooperation agreements, such as consortia, to ensure continuity of care and maximize patient outcomes through high-quality treatment and prevention.

Improving hospital safety criteria is particularly important for institutions with low patient volumes, which may struggle to maintain adequate procedural numbers, such as maternity services. The situation varies across regions, both demographically and geographically. Hospitals in districts surrounding large cities face specific challenges, as do those in border districts or those located far from larger urban centres.

Additionally, the Federation has been long advocating for the widespread implementation of "oneday surgery", ensuring that procedures are conducted in a manner appropriate to the patient's condition and the medical provider's resources.

Medical effectiveness should be the key criterion in restructuring plans, with financial performance assessments considered secondary and analyzed only in conjunction with healthcare outcomes. In healthcare economics, the concept of cost-effectiveness is crucial, with medical technologies being a key component. As a rule, analyses in this area begin with an assessment of medical technology. Therefore, restructuring plans should first target hospitals with insufficient treatment outcomes (so-called medical loss). In cases of financial analysis and restructuring (financial loss), a report and potential recovery plan for medical activities should be prepared first, while financial performance assessments should be considered secondary and analysed only in conjunction with healthcare outcomes. Any hospital with a net financial loss (or operating at a loss) should first be evaluated based on its treatment outcomes.

The proposal of the Polish Federation of Hospitals assumes the introduction of a four-tier hospital reference system, covering emergency and acute care While financially incentivizing Primary Care Providers to offer extended services beyond standard working hours. The second step would be the development of an incentive framework to foster collaboration between hospitals, Specialist Outpatient Care providers, Primary Care Providers, and Treatment and Care Facilities. Subsequently, we propose establishing a framework for the creation of Coordinated Healthcare



Organisations in the form of consortia comprising cooperating medical providers, including those outside the State Healthcare Services system. These organisations should be funded based on achieved health outcomes, fostering competition for quality rather than cost. Only such a model can introduce positive competition in the health care system – competition for value for the patient (so-called added value), instead of competition for the price of the service (so-called zero value). The approach to the value-based model for the patient should be a step-by-step approach. In the target model, legislative promotion of same-day surgery will not be necessary, as Coordinated Healthcare organisations, being remunerated based on treatment outcomes, will inherently be motivated to perform each procedure in the most appropriate manner.

The ultimate model should be value-based healthcare for the patient. On the other hand, the endgoal model of internal organisation of general hospitals should be a model based on departments (areas of therapy) defined according to the degree of intensity of medical and nursing care (therapy): intensive therapy, progressive therapy, acute therapy, subacute therapy (rehabilitation), chronic therapy (long-term care). Of course, this model cannot be used dogmatically and must take into account specific characteristics of a given medical field (e.g. obstetrics, emergency medicine or psychiatry).

Coordinated Healthcare organisations should be accredited as widely as possible by independent accreditation bodies, however, previously authorised to operate in Poland by the Ministry of Health or preferably, by a national council for the accreditation of medical entities, as proposed by the PFSz during consultations on the Quality and Patient Safety Act.

#### **European Proposals**

At the EU level, the PFSz advocates for strengthening healthcare cooperation among Member States, particularly in cybersecurity and health security. The Federation supports incorporating sustainability costs into healthcare service pricing, both at the national and EU levels, to account for hospital efforts in sustainable development. Promoting mental well-being initiatives, especially for medical professionals, is essential in combating burnout and improving workforce resilience.

We further suggest that one of the priorities should be the broadest possible inclusion of nongovernmental organisations in the health sector, particularly national hospital employers' organisations, in the social dialogue on healthcare. We propose that the voices of European nongovernmental organisations in the health sector, such as the European Hospital and Healthcare Federation (HOPE), be given greater weight in the Council of the European Union, the European Parliament, and the European Commission. The HOPE Exchange Programme, a unique initiative on a global scale, deserves support.

## **Employers of Private Medicine**

### Beata Plewka, Sylwia Rozbicka, Anna Bogucka, Dominika Pluskota-Bugajny, Agnieszka Skowrońska, Karolina Kryszkiewicz, Marta Warzocha-Szkupińska, Agnieszka Motyl

The Role of Pharmaceutical Care in Preventive Healthcare and Pharmacovigilance

The Organisation for Economic Co-operation and Development (OECD) and European Commission report, *Health at a Glance: Europe 2024 – State of Health in the EU Cycle*, highlights several factors requiring decisive action to adapt healthcare systems in European countries to growing health needs and societal demands. Two key priorities have been identified: promoting healthy longevity and addressing shortages of medical personnel. These priorities are based on conclusions related to an increase in the proportion of people aged 65 and over from 16% to 21%, with projections reaching 30% by 2050, a shortage of general practitioners, and a rising prevalence of chronic diseases, with 60% of people over 65 suffering from at least one chronic condition.



These trends align with WHO reports, which indicate that chronic diseases are among the leading causes of premature death. According to WHO projections, type 2 diabetes alone will affect more than 640 million people worldwide by 2030, with the rapid increase in cases leading to it being described as a 21st-century pandemic.

Based on the report's findings, pharmacists can play a key role in several cost-effective areas, including:

- 1. **Health education** focusing on eliminating risk factors for chronic diseases, such as smoking and obesity. Pharmacists, as one of the most accessible healthcare professionals, can participate in preventive health programmes, including those that provide support for smoking cessation.
- 2. **Increasing vaccination rates,** which vary significantly across EU member states. For example, the influenza vaccination rate in Europe remains below the target required to achieve herd immunity, with some countries reporting rates below 20%. Pharmacist-led vaccination services in community pharmacies represent a significant opportunity to improve vaccination coverage, strengthen the prevention of infectious diseases, and support coordinated EU-level actions to expand adult vaccination programmes.
- 3. **Prevention and improved management of chronic diseases:** community pharmacies can serve as accessible hubs for health education and disease prevention, screening programmes, and pharmaceutical services, such as medicines use review and the New Medicine service. The expected outcomes include early detection and prevention of chronic diseases, improved medication adherence and compliance, ensuring that patients follow medical recommendations and actively engage in their treatment. For instance, the Global Initiative for Asthma (GINA) highlights the potential role of pharmacists within therapeutic teams treating asthma patients. Their contributions may include educating patients on correct inhalation techniques or identifying patients with poor medication adherence through prescription monitoring. In addition, GINA experts recommend including pharmacists in regular monitoring and support for pregnant women with asthma, in close collaboration with doctors.

These practices help reduce the number of patients with chronic diseases, limit hospitalisations related to non-compliance with medical recommendations, drug interactions, or adverse drug reactions. US cost analyses have shown that every dollar spent on pharmaceutical care results in four dollars in healthcare savings. Polish studies estimate that non-compliance with medical recommendations, failure to initiate treatment, or improper medication use result in additional healthcare costs (including medical consultations, diagnostic tests, medications, and hospitalisations) of approximately PLN 6 billion annually.

A key priority during Poland's EU Council Presidency should be expanding pharmacists' competencies across Europe by promoting awareness of pharmaceutical care at both governmental and societal levels, integrating pharmaceutical services into national healthcare systems, and ensuring sustainable public funding for pharmaceutical care services. It is also important to integrate pharmaceutical services into healthcare systems while ensuring their financing from public funds.

#### Mental Health of Children and Adolescents – Key Challenges and Recommendations

One of the key challenges facing children and young people is violence – whether physical, psychological, sexual, or in the form of neglect. The report *Diagnosis of Violence Against Children in Poland 2023*, published by the Empowering Children Foundation, highlights the scale of the problem – as many as 79% of children and adolescents have experienced violence or neglect in their lives. The highest percentage was peer violence (66%), followed by violence from close adults (32%), sexual abuse without physical contact (26%), and emotional neglect (23%). These findings, along with incidents reported in the media and those observed in our communities, underscore how critical it is to develop the ability to respond to and prevent violent situations. An important issue in this context, particularly regarding minors' use of social media, is cyberbullying, which undoubtedly requires the attention of both parents and schools. Data from the *Teens 3.0* study (2020) show that 23% of children report having experienced cyberbullying firsthand, yet



only 10% of parents are aware of it. The lack of parental awareness of children's negative online experiences may stem from low awareness of cyber threats or a lack of personal experience with electronic aggression (only 7% of adults report such experiences). Additionally, teenagers often do not disclose their digital problems to adults. Exposure to harmful content and violent language on social media undoubtedly contributes to mental health crises among young people, including suicide attempts. It is particularly concerning that the number of suicide attempts among girls remains alarmingly high – according to data from the Polish Police Headquarters, of 2,054 reported suicide attempts in 2024, 1,599 involved girls.

Given these challenges, we support the introduction of mental health training for teachers, which has been implemented since 2024 as part of the EU-PROMENS project. Since children spend the majority of their day in school, teachers play a crucial role in recognizing and responding to signs of crisis, peer violence, and neglect. Above all, they must be sensitive to the experiences of children who suffer harm. Unfortunately, we frequently encounter cases where perpetrators of violence face no consequences, thereby sending the message that children have no control over difficult situations. In addition, we recommend that schools and kindergartens implement programmes aimed at developing emotional and social skills. Recognising the promotion of children's and adolescents' mental health as a policy priority will play a pivotal role in fostering social skills and emotional intelligence, ultimately helping to prevent mental health crises among minors. Suicide prevention should also be prioritised. Although 2024 has not seen a dramatic increase in suicides, the figures remain alarmingly high. Finally, we believe that providing support within a child's immediate environment is an effective approach, as demonstrated by NHF Centres for Community-Based Psychological and Psychotherapeutic Care, which offer local mental health support.

#### Sport and Physical Activity as a Key Pillar of Preventive Healthcare

In Europe, birth rates have been declining for years, and the population is ageing – the proportion of people aged 65 and older – was over 21% in 2023 and is projected to reach nearly 30% by 2050.<sup>269</sup> Life expectancy in Europe is also increasing, with the average individual now living more than 20 years past the age of 65. At the same time, more than 40% of people aged 65 and older suffer from at least two chronic diseases, often accompanied by disabilities. The prevalence of excess body weight is also rising, particularly among lower-income populations. Obesity, a major risk factor for many chronic diseases, is most common among older adults (20% in the 65–74 age group). Additionally, mental health problems are on the rise, affecting not only older individuals but also young people. These trends contribute to growing demand for healthcare services, while the working-age population capable of providing such care is shrinking. In response to these demographic shifts, ensuring that EU citizens live longer, healthier lives requires a paradigm shift in healthcare – moving away from a reactive (treatment-focused) model toward a proactive approach centred on comprehensive prevention. One of the key pillars of prevention, alongside a healthy diet, avoiding harmful substances, and regular medical check-ups, is physical activity.<sup>270</sup>

#### The Impact of Physical Activity on Health and Barriers to Participation

The health benefits of physical activity are indisputable. Exercise can replace many medications, but no medication can replace exercise. Regular physical activity is one of the most effective ways to prevent chronic diseases, including obesity, metabolic disorders (e.g., diabetes), and musculoskeletal conditions. Among individuals who are already affected by these conditions, exercise can slow disease progression and significantly improve overall health – physically, mentally, and socially.<sup>271</sup>

To maintain health, the World Health Organization (WHO) recommends engaging in 150-300 minutes of moderate-intensity exercise or 75-150 minutes of vigorous-intensity exercise per

<sup>269</sup> OECD, Health at a Glance: Europe 2024.

<sup>270</sup> Lifestyle is a major determinant of health and accounts for 30-50% of health risks.

<sup>271</sup> We use the definition of health developed by the WHO, see Constitution of the World Health Organization.



week.<sup>272</sup> The more, the better. However, statistics indicate that only a fraction of the population meets these recommendations. On average, only 15% of Europeans achieve the recommended levels of physical activity.<sup>273</sup> Women and older adults tend to be less active.<sup>274</sup> In 2021, 1.1 million deaths (21%) were attributed to smoking, excessive alcohol consumption, and high body weight – all of which are linked to physical inactivity. In Poland, only 28% of adults engage in any form of leisure-time physical activity, and a mere 10% exercise regularly.<sup>275</sup> Meanwhile, 53% of women and 68% of men aged 20 and older are overweight, with 23% of women and 25% of men classified as obese.<sup>276</sup> As a result, 74% of people fail to meet WHO physical activity guidelines.

Beyond physical health, exercise has profound mental health benefits. Physically active individuals report better mental well-being, higher life satisfaction, and greater self-esteem.<sup>277</sup> In Poland, 67% of employees experience stress at least once a week, and 1 in 7 (15%) experience stress daily. Among those surveyed, 31% reported that exercise helps improve their mood and relaxation, while 24% said it helps relieve stress. Additionally, physical activity fosters social health. Group workouts are becoming increasingly popular, as they enhance motivation and facilitate social connections. In 2024, 58% of people made new friends through fitness groups, with the percentage rising to 66% among Generation Z. For 48% of participants overall – and 55% of Generation Z participants – social interaction was the primary reason for joining a fitness group.<sup>278</sup> The trend suggests that people prefer exercising with others, and 40% of Gen Z participants plan to engage in more group workouts in 2025. Given this growing emphasis on the social aspects of physical activity, providing more opportunities for group-based exercise could encourage greater and more consistent participation, ultimately supporting public health and disease prevention.

#### Physical Activity as a Preventive Strategy and Corporate Social Responsibility (CSR)

Given these demographic challenges, which will increase healthcare costs and significantly impact EU economies, promoting health through physical activity is essential. However, the responsibility for prevention should extend beyond the public sector – businesses and employers should also play a role. Companies can encourage active lifestyles among employees by offering access to corporate fitness programs, workplace wellness initiatives, and structured sports programmes.

One example of integrating sports and physical activity into healthcare prevention is the Zdrowa OdWaga (Healthy Weigh Forward) programme, launched by Medicover in 2024. This 12-month initiative was implemented through multidisciplinary collaboration among physicians, trainers, and public health experts. The program targeted individuals with elevated BMI and additional health risk factors, providing personalized support at every stage – from initial health assessments to tailored physical activity plans and continuous motivation via workouts, webinars, and coaching sessions. Participants followed WHO exercise guidelines and trained under expert supervision in group settings, leading to significant improvements in fitness levels and overall health. Key results included a 33% improvement in endurance test performance (Cooper test), an 18% reduction in insulin resistance index, a 13% reduction in cardiovascular disease risk index, a 7% decrease in body mass index (BMI), and a 68% decrease in back pain complaints. The benefits of the program extended beyond weight loss, significantly reducing the risk of metabolic and cardiovascular diseases (e.g., diabetes, heart disease). Notably, positive results were observed within just a few months – after six months of training: Cooper test scores improved by 28%, Back pain symptoms decreased by 1.31 points, Visceral fat tissue was reduced by 6%, and the Body Roundness Index

<sup>272</sup> https://www.who.int/news-room/fact-sheets/detail/physical-activity.

<sup>273</sup> OECD, Health at a Glance: Europe 2024.

<sup>274</sup> WHO Off Track 2030 report.

<sup>275</sup> The Level of Physical Activity of Poles 2023. A report on a quantitative study for the Ministry of Sport and Tourism.

<sup>276</sup> National Health Fund, data for 2022.

<sup>277</sup> The impact of sports participation on mental health and social outcomes in adults: a systematic review and the "Mental Health through Sport" (conceptual model / Systematic Reviews /Full Text, biomedcentral.com.

<sup>278</sup> Strava Year In Sport Trend Report 2024.



(BRI) dropped by 4.6%.<sup>279</sup> Participants also reported 15.5% greater satisfaction with their overall health and a high 27.2% increase in daily functional fitness.<sup>280</sup> Based on reductions in health risk factors (HeartScore2) and subjective health improvements, participants' life expectancy in good health (Quality-Adjusted Life Years, QALY) increased by over one year. And all EU citizens want a longer life in better health. Expanding participation in Healthy Courage could improve public health, reduce chronic disease prevalence, and lower premature mortality rates across the EU.

#### FitSchool

FitSchool is an innovative educational and health program that integrates physical activity into daily school life, aiming to prevent lifestyle diseases, improve students' physical and mental wellbeing, and encourage healthy exercise habits from an early age. The programme aligns with the health prevention priorities of the Polish EU Presidency, offering comprehensive solutions that promote well-being through physical activity.

According to the World Health Organization (WHO), children and adolescents aged 5–17 should engage in at least 60 minutes of moderate-to-intense physical activity per day to support healthy physical development, mental well-being, and cognitive function. However, in many countries, including Poland, declining levels of physical activity among young people contribute to rising rates of obesity and other lifestyle diseases. FitSchool directly addresses these challenges by integrating movement into students' daily lives and promoting physical activity as a core component of education.

Beyond its role in preventive healthcare, FitSchool also serves as a health education tool, embedding physical activity into the learning process. By incorporating movement into everyday classroom activities, students not only enhance their physical fitness but also improve concentration, learning outcomes, and cognitive abilities. This holistic approach – which links education and health – reflects modern pedagogical strategies aimed at fostering student well-being.

Moreover, FitSchool promotes inclusivity by ensuring that all students, regardless of fitness level, socioeconomic background, or personal circumstances, have access to structured physical activity opportunities. The programme embraces diversity and equal access by providing schools with free educational and training materials, aligning with key Sustainable Development Goals (SDGs), particularly SDG 3 (Good Health & Well-Being) and SDG 4 (Quality Education).

FitSchool operates under the patronage of the Ministry of National Education, the Ministry of Sport and Tourism, and the Centre for Education Development. It has already been implemented in over 1,900 schools and kindergartens across Poland, Romania, and Sweden, with further expansion underway. The program includes a variety of age-appropriate and adaptable activities that seamlessly fit into school schedules, such as:

- Short interactive exercise breaks during classes designed to improve concentration and enhance learning.
- Eight- and 30-minute structured workouts encouraging students to engage in regular exercise.
- Nutritional education sessions led by dietitians to promote healthy eating habits.
- Mindfulness training supporting students' mental well-being.
- **Teacher training workshops** enhancing educators' ability to facilitate physical activity and motivate students.

Regular physical activity among children and adolescents is critical in reducing the risk of obesity, type 2 diabetes, and cardiovascular diseases. FitSchool seamlessly combines prevention, education, and physical activity, aligning with European policies aimed at promoting a healthy lifestyle and combating lifestyle diseases.

<sup>279</sup> Effects of a Six–Month Physical Activity Program on Health Risk Factors and Body Composition Among Overweight and Obese Middle-Aged Adults, Healthcare 2024.

<sup>280</sup> Assessment based on the WHOQOL-BREF questionnaire, https://www.who.int/tools/whoqol-bref/docs/default-source/publishing-policies/whoqol-bref/polish-whoqol-bref.



### Electronic School Medicine System, Karolina Kryszkiewicz

Chronic lifestyle diseases such as obesity, type 2 diabetes, hypertension, and mental health disorders are an escalating challenge across Europe. Early detection of health risks and efficient communication between students, parents, school nurses, and doctors are key to prevention. In the era of digital transformation, innovative tools are essential to streamline health screening management and improve data flow. The Electronic School Medicine System (ESMS) addresses these needs by enhancing diagnostics, analysis, and the aggregation of student health screening data, thereby increasing the effectiveness of preventive healthcare measures.

### Key Challenges in Preventive Healthcare:

- Lack of digitised health screenings, making it difficult to track results and develop effective health strategies.
- No standardised interpretation of test results or health guidance for parents.
- Limited information flow between school nurses, parents, and doctors, delaying preventive and therapeutic interventions.
- Absence of centralized data aggregation at local and national levels, hindering evidence-based health policy planning.

The ESMS Solution: ESMS is an integrated system supporting student health screenings and medical check-ups, enabling:

- Automated data collection and analysis (height, weight, BMI, blood pressure, and screening results).
- Real-time transmission of results to parents, caregivers, and optionally to the Online Patient Account (IKP), allowing for timely follow-up actions.
- Creation of anonymised epidemiological databases, providing valuable insights for local and national public health programmes.

### **Benefits of ESMS:**

- The system enhances the speed and efficiency of health data exchange, enabling early detection of health risks.
- It provides parents and caregivers with tailored health recommendations based on screening results.
- It generates reliable epidemiological data, supporting evidence-based health policy decisions.
- It strengthens the prevention of lifestyle diseases through systematic health monitoring.

By integrating schools, families, and healthcare providers, ESMS enhances child and adolescent health outcomes while contributing to long-term cost reductions in chronic disease treatment. This data-driven approach to school medicine supports the development of a healthier society.

### The Role of Diet in Preventive Healthcare

Adhering to the principles of a healthy diet should be a core component of preventive healthcare. Establishing appropriate nutritional habits not only supports the body's daily functioning but also significantly reduces the risk of developing chronic diseases. According to the Central Statistical Office (GUS)<sup>281</sup>, in 2023, as in previous years, the leading causes of death in Poland were cardiovascular diseases (36.97%), followed by cancer (26.7%). The risk of both conditions can be effectively mitigated by adopting a healthier diet.

### The Mediterranean Diet

The Mediterranean Diet is recognized as one of the healthiest dietary patterns. A 2023 systematic review found that higher adherence to the Mediterranean Diet was associated with a lower risk of overall mortality, both in the general population and among individuals with pre-existing cardiovascular conditions. Additionally, research suggests that following a Mediterranean dietary pattern can reduce the risk of cardiovascular diseases, including heart attacks, various forms of



coronary artery disease, strokes, and cardiovascular-related mortality.<sup>282</sup>

A 2021 systematic review and meta-analysis also indicated that strict adherence to the Mediterranean Diet was correlated with a lower risk of cancer-related mortality in the general population, as well as a reduced risk of death from other causes among cancer survivors.<sup>283</sup> Similar conclusions were drawn in earlier studies, which attributed these positive health effects primarily to higher consumption of fruits, vegetables, and whole grains.<sup>284</sup>

The Mediterranean Diet emphasizes the consumption of vegetables and fruits, whole grains, legumes, healthy fats (e.g., olive oil), and fish and seafood. It also limits the intake of red meat and processed foods.

In Poland, national dietary guidelines are graphically represented by the Healthy Plate model, which closely aligns with the Mediterranean Diet principles. According to these guidelines vegetables and fruits should comprise half of the plate, and the minimum daily intake of fruits and vegetables should be at least 400 grams.

However, 2023 data from the Central Statistical Office (GUS) reveal that Poles fail to meet this target. Low consumption of fruits and vegetables is a growing public health concern, increasing the risk of chronic diseases. Raising awareness of basic nutritional guidelines is essential to improving the overall health of the Polish population. Furthermore, promoting education on the principles of the Mediterranean Diet could contribute to reducing the prevalence of many chronic diseases, which remain a significant public health challenge in Poland.

MediDieta promotes nutrition education and offers ready-made meals based on the Mediterranean Diet. This initiative provides practical solutions to support a healthier lifestyle and prevent lifestyle diseases, reinforcing the role of balanced nutrition in disease prevention.

### **Healthcare Priorities**

We propose that, as part of the European Union's health agenda and at the initiative of the Polish Presidency, actions be taken to develop and implement a standardized framework of unified healthcare quality indicators. This system should cover key areas of healthcare, such as:

• Treatment effectiveness: Indicators related to treatment outcomes in key therapeutic areas (e.g., cardiovascular diseases, cancers, chronic diseases), survival rates, and hospital readmission rates.

This also applies to the outpatient sector, for which no binding medical quality indicators currently exist in Poland. In particular, we propose introducing indicators for the management of chronic diseases such as hypertension and diabetes, as well as indicators for antibiotic prescription in respiratory infections. Antibiotic stewardship is crucial in addressing the growing issue of antimicrobial resistance.

A prerequisite for achieving treatment goals is close cooperation between patients and healthcare professionals, as well as adherence to medical recommendations, including lifestyle modifications and the elimination of harmful habits. Motivational interviewing, a proven communication technique, could be widely implemented in daily clinical practice to enhance patient engagement and adherence. This effective tool should be extensively implementated into the daily practice of all medical professionals.

- Patient safety: Indicators of adverse events, hospital-acquired infections, and medication safety. The identification, reporting, and analysis of adverse events should extend beyond hospitals to include outpatient care. The healthcare system should integrate tools to prevent polypharmacy and dangerous drug interactions.
- Access to and respect for patient rights.

<sup>282</sup> Nutrients. 2023 Jul 28;15(15):3356. doi: 10.3390/nu15153356.

<sup>283</sup> Eur J Nutr. 2021 Apr; 60(3):1561–1586. doi: 10.1007/s00394–020–02346–6.

<sup>284</sup> Nutrients. 2017 Sep 26;9(10):1063. doi: 10.3390/nu9101063.



In this area, we propose introducing Patient-Reported Outcome Measures (PROMs) – standardised, validated survey tools that assess patient-reported health outcomes in areas such as general health status, quality of life, specific symptoms, functional abilities, and physical, mental, and social well-being.

Cost-effectiveness: Indicators evaluating the efficient use of public funds for healthcare, comparing treatment costs with health outcomes.

The development of these indicators should be based on the collaboration of experts from various Member States, incorporating international best practices and the recommendations of organizations such as the OECD and WHO. It is crucial that the indicators are measurable, objective, comparable, and practical for implementation.

Once the set of indicators is developed, an EU-wide reporting and monitoring system should be established to ensure the regular collection of data from Member States. These data should be publicly accessible and analyzed to enable benchmarking and the identification of areas for improvement across countries.

### Lewiatan Confederation

### Kacper Olejniczak

Director of the Department of Healthcare and Life Sciences Sector, Lewiatan Confederation

In our opinion, the key areas of work for the Polish Presidency will include:

- a revision of the Pharmaceutical Package, and
- a potential legal instrument for strengthening pharmaceutical security in the EU.

Below, we present our recommendations in these areas.

Pharmaceutical Package and competitiveness concerns: The decline in the global competitiveness of the European pharmaceutical sector in terms of research and development (R&D) is not attributed to the erosion of intellectual property (IP) rights. Since the 1990s, the EU has consistently enhanced regulatory incentives and monopolies in the field of IP. Measures such as product patents under TRIPS, supplementary protection certificates (SPCs), regulatory and market exclusivity periods (the longest globally), orphan drug exclusivity, paediatric exclusivity, and SPC extensions have all been introduced with the aim of positioning Europe as a global leader in R&D innovation.

However, this enhancement of monopolistic protections coincides directly with the relative decline in R&D activities in Europe compared to China and the United States. This correlation challenges the assertion that "greater monopolies result in increased R&D". Even more worryingly, such monopolistic measures have contributed to the outsourcing of drug production outside Europe. While we commend the EU's recent reform efforts to address this issue, more work is needed.

Conversely, political measures fostering competition within the equivalent (generic) drug sector have successfully met expectations. Legislation supporting generic medicines has significantly boosted competition, doubled medication access across Europe, and alleviated pressure on healthcare budgets. Similarly, rules for biosimilar medicines have established Europe as a global leader in this technology, resulting in substantial investments in biological drug manufacturing within the EU.

Given the above, it is imperative that the European pharmaceutical strategy continues to support the generic and biosimilar drug sectors as pillars of Europe's pharmaceutical security framework.

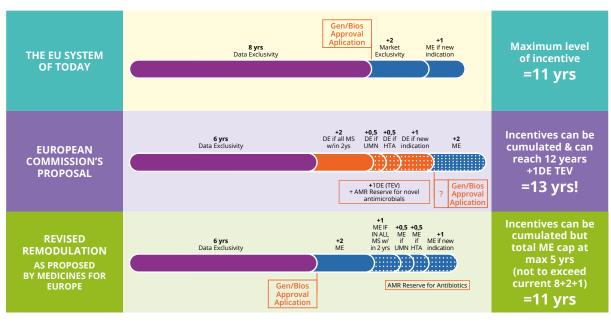
The impact assessment report accompanying the revision of the general pharmaceutical legislation underscores that: "a direct link between EU incentives and EU competitiveness is hard to establish because while the incentives make the EU markets more attractive, they are agnostic to the medicines' geographical origin. Around 20% of new medicines authorised in the EU are from the



EU, the others are mainly from US, UK, Switzerland and Japan that are equally eligible to all EU incentives. Equally EU based innovative companies can benefit from incentives elsewhere, if they sell their products there." In June 2016, the Council requested the European Commission to conduct an evidence-based analysis of the impact of incentive mechanisms, specifically SPCs. Two studies were subsequently commissioned: Max Planck Institute Study: This study questioned whether the availability of patent or SPC protection influences companies' decisions on the location of R&D facilities, emphasising that other factors, such as taxes, education, and infrastructure, likely hold greater significance. Copenhagen Economics Study: This study suggested that SPCs might play a role in attracting innovation to Europe but reiterated the importance of factors like tax policies and education systems in driving such decisions.

### **Regulatory Exclusivity and Exclusivity Voucher Periods**

The Pharmaceutical Package modifies the rules governing the granting of so-called regulatory exclusivity, i.e. the temporary protection of entities that first introduce a specific medicinal product to the market against market competition. The changes aim to extend the maximum protection period – already longer than in jurisdictions such as the United States – from the current 11 years to 13 years.

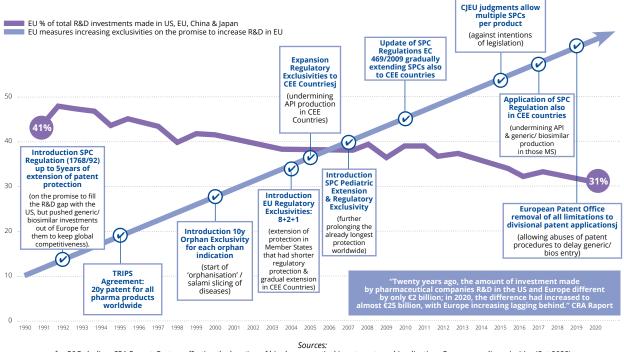


#### The regulatory exclusivities' remodulation in the E.U.

This regulatory protection system is complemented by Orphan regulatory exclusivities & by Parents (20yrs) and Supplementary Protection Certificate – SPC (up to +5,5yrs)

Meanwhile, there is no evidence to suggest a correlation between extending exclusivity-based protection and increased innovation levels – data on the origins of innovative medicines imported into the European Union (from the USA, Switzerland, the United Kingdom, and Japan) indicate quite the contrary.





#### Decline of R&D in Europe VS. European measures increasing exclusivities

for R&D decline: CRA Report, Factors affecting the location of biopharmaceutical investments and implications European policy priorities (Oct 2022) – prepared for EFPIA; for exclusivities increases: House of Commons, The Influence of the Pharmaceutical Industry (March 2005); EU legislation

In addition, the proposed new rules for granting protection are so unclear that they create uncertainty about when, in a particular case, it will be possible to market a competing drug. It should not be overlooked that the preparation of a generic product requires substantial research and development, clinical trials (bioequivalence studies), and the preparation of registration documentation. Generic manufacturers need to know several years in advance when they will be allowed to submit a marketing authorisation application in order to plan their work effectively. If, during the course of this work, it is suddenly announced that data exclusivity has been extended, some of the research conducted or documents prepared – initially compliant with the legal requirements on the date the six-year data exclusivity period was set to expire – may no longer meet the requirements at the new, extended expiry date. Moreover, during the period of data exclusivity in the EU, generic manufacturers may register medicinal products abroad and sell them there. However, in many countries, obtaining a marketing authorisation is contingent upon possessing marketing authorisation in the manufacturer's home country. Consequently, extending data exclusivity reduces the competitiveness of EU-based producers compared to those from India, China, or the United States, Where data exclusivity periods are shorter. For this reason, any additional protection periods should be granted exclusively in the context of market exclusivity, not data exclusivity.

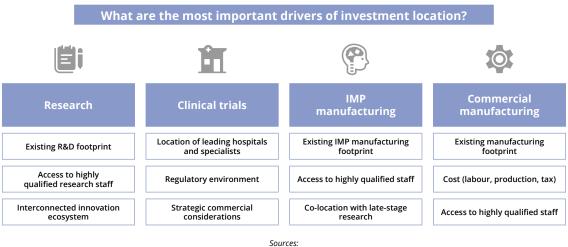
The pharmaceutical package also introduces the concept of a Transferable Exclusivity Voucher (TEV). Companies that launch new antimicrobial drugs would be granted a 12-month exclusivity right, which they could apply to another drug or sell to a third party. While this proposal is intended to incentivise research and development for new antibiotics, it may inadvertently create opportunities for abuse and anti-competitive practices. Alternative methods for supporting antibiotic development, such as those implemented in Sweden and the United Kingdom, should be considered. For example, the annual revenue guarantee programme has proven to be an effective tool to encourage investment in antibiotic research and development by offering guaranteed income streams. Both the Swedish and British models demonstrate that implementing income guarantees is a practical and viable approach, having been tested and shown positive outcomes.

It is also noteworthy that even the European Federation of Pharmaceutical Industries and Associations (EFPIA) – representing monopoly medicines producers – does not cite IP issues as a prerequisite for the relocation of production.



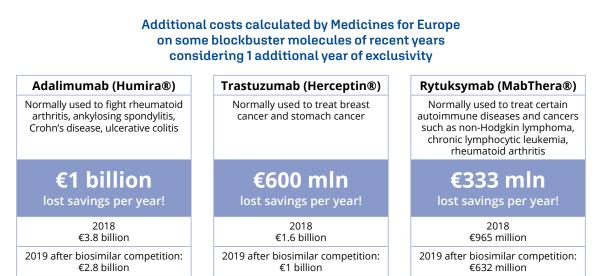
#### Indeed, IP is not even mentioned among factors stimulating localization of R&D investments in the CRA report prepared for EFPIA

#### Summary of factors driving the location of biopharmaceutical investments



CRA Raport, Factors affecting the location of biopharmaceutical investments and implications for European policy priorities act (2022)- prepared for EFPIA PATIENOTS • QUALITY • VALUE • SUSTAINABILITY • PARTNERSHIP

After all, each year of delayed competition results in tangible losses for patients and national payers, with a single year costing at least hundreds of millions of euros.



### Bearing the above in mind, we call for:

- Establishing a maximum uniform period of data exclusivity of six years and a basic market exclusivity of two years, with market exclusivity extendable through additional periods serving as incentives as currently provided for in the draft directive. However, the total duration of registration protection should not exceed the currently applicable periods, i.e., a maximum of 11 years.
- Clearly specifying in the regulations that, if the extension of data exclusivity or market exclusivity
  is contingent on ensuring the availability of the medicinal product on the market for patients,
  such availability must include not only placing the product on the market and ensuring sufficient
  supplies to meet patient demand, but also securing reimbursement for the product. Furthermore,
  the supply of the medicinal product to the EU market or the withdrawal of a reimbursement
  application in any Member State should result in the revocation of the granted exclusivity
- Abandoning the TEV mechanism and replacing it with the Annual Revenue Guarantee Scheme (as developed by the EU-Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections, EU-JAMRAI), which incentivises innovation while fostering responsible antibiotic consumption.



#### Changes relating to environmental protection

While supporting any directional actions aimed at improving the state of the natural environment, it should be emphasised that the European pharmaceutical industry must already meet the highest environmental standards. Due to changes in the Pharmaceutical Package, advanced legislative work is currently underway in the European Parliament and the Council in the field of, for example, municipal wastewater, which will significantly affect the European pharmaceutical industry producing equivalent drugs (generic and biological equivalents), which will translate into an increase in the costs of manufacturing these drugs. With this in mind, the perspective should also be considered so that the right goals and assumptions do not become a competitive barrier and do not lead to the elimination of this part of the pharmaceutical industry from Europe. This is particularly important due to the shortages of essential medicines in Europe and Asian competition, which, on the one hand, is subsidised financially by its governments and, on the other, is not subject to such stringent regulations.

#### Impact on competitiveness and SMEs

For SMEs, the impact assessment report stated,

- "In terms of effect on competitiveness, the proposed incentives do not make a geographic distinction, they equally offer regulatory protection for products developed in the EU, or anywhere in the world which ensures a level playing field between EU-based and third country-based companies. While the EU regulatory framework is attractive for developers, competitiveness also depends on many other factors e.g. tax system and incentives; available grants, loans and other funding (e.g. the European Innovation Council Accelerator); pool of talents; proximity of top academia; clinical trials infrastructures; market size; security of supply chains; favourable reimbursement decisions."
- It followed: "Similarly, incentives for UMN would benefit SMEs, which are generally willing to
  make early-stage investments in areas of high risk, by giving more value to their assets even if
  they are acquired by big pharma in late-stage development. SMEs already enjoy fee exemptions
  and reductions for regulatory procedures and through the new horizontal measures SMEs will
  benefit from optimised scientific support with a greater likelihood of success for authorisation.
  Overall, with the increasing investment in biopharmaceutical R&D and the increasing share
  of SMEs among developers, biopharma SMEs in the EU and elsewhere would have excellent
  prospects for the future."

On the one hand, the European Commission is talking about shortening the periods of exclusivity of medicines, but on the other hand, the proposed provisions de facto open up a whole range of possibilities for their extension. The maximum period of exclusivity on the market for a drug – of course, beyond 20 years of patent protection – under the new proposed directive and regulation is to be 13 years, and today it is 11 years.

In addition, the European Commission has also proposed the so-called IP package – currently pending in the Council and the European Parliament, in which monopoly companies are given the opportunity to introduce a single European procedure for SPC in all EU countries. Today, they have to apply for this state by state. And although the Pharmaceutical Package introduces regulations shortening registration procedures, the SPC mechanism introduced in the early 1990s, intended to compensate for the length of the registration process, is not shortened.

In addition, there are many projects dedicated to the development of research on new medicines, such as support for them by EU funds through IPCEI mechanisms or the largest public-private initiatives in the world – the Innovative Medicines Initiative, and now the Innovative Health Initiative, in which half of the funds come from all EU citizens, and half from monopoly companies represented by COCIR, EFPIA/Vaccines Europe, EuropaBio, MedTech Europe. The total budget of the IHI for 2021–2027 is EUR 2.4 billion.

All this – despite criticism from monopoly companies – indicates the EU's openness and support in this area. It is also worth supporting an industry producing drugs that compete on the market



at a competitive price, because these are the drugs in short supply in pharmacies. In this area, EU funds are no longer as generous.

Certainly, the monopoly period should not be extended, because European patients will wait longer for the emergence of price competition on the drug market, and national payers, including our National Health Fund, will be forced to bear higher reimbursement costs. Every day's delay in competition results in multimillion-euro losses for healthcare budgets.

As far as the EU's strategic autonomy is concerned, an important issue that should be addressed by the EU Council, chaired by Poland, is the restoration of pharmaceutical security in Europe and the Member States, including the resumption of the production of APIs and proprietary medicinal products in Europe. The topic is crucial for several reasons: it simultaneously fits into the objectives of the Polish and European economy, as well as strengthens public health at national and EU level.

The COVID-19 pandemic and Russia's aggression against Ukraine have shown that the dependence of access to medicines in the EU on global supply chains is too risky, because their disruption can occur quite rapidly, from week to week. Currently, 80% of APIs used in EU medicine production are sourced from India and China. Further production dependence may pose a threat to the health and safety of European and Polish patients. Therefore, it is necessary to take the lead on this subject to guarantee the strategic autonomy of the European Union based on the production capacities of individual Member States.

Drug shortages are a public health problem across Europe. Fortunately, the EU institutions are aware of this. The European Commission raised this issue in the Pharmaceutical Strategy; the European Parliament adopted a resolution on the lack of medicines; while the European Council drew attention to the recovery of drug production in the Versailles Declaration. In May, the future Belgian presidency, with the support of 18 Member States, including Poland, urged the European Commission to make urgent legislative changes to support API production in Europe. On 24 October, the European Commission issued a communication on the availability of medicines.

As evident, this topic is present in the discussions at the EU level. It is important for all Member States from the perspective of public health, but also from an economic point of view. Poland has a pharmaceutical industry and traditions in this area. We could develop the domestic industry so that it ensures the availability of medicines for the whole area of Central Europe. However, strengthening API production is a process that generates such huge costs that no company without state or EU support is able to do so. This is a transnational process and should be managed as such.

Therefore, it is also necessary to create a dedicated European legislative act containing financial and regulatory incentives to maintain and transfer the production of APIs and medicines ready for Europe. The Polish Presidency could make the declared strategic directions of all European institutions a reality.

### **Union of Entrepreneurs and Employers**

### Aleksandra Sienkiewicz

Director of the Health Forum, Union of Entrepreneurs and Employers

The Polish Presidency is a special time for Poland. Assuming the presidency on 1 January 2025 means that the eyes of the whole of Europe will be on us for the first half of the year. Among the many priorities in healthcare that have been mentioned for months as part of the preparations, four deserve special attention: **pharmaceutical security, health promotion and prevention, the digital transformation of healthcare, and the mental health of children and adolescents.** As the Union of Entrepreneurs and Employers, we are convinced that each of these is of critical importance and concerns issues that matter to Polish society as a whole.



The Polish Presidency should actively work towards implementing strategic directions in the field of healthcare, ensuring regulatory stability and predictability while supporting innovation and the development of the pharmaceutical sector. Improving the promotion of healthy lifestyles and preventing key risk factors could reduce the incidence of non-communicable diseases by up to 70%, which should be a priority in European health policy. Digitisation is a key element in rebuilding health systems after the pandemic and strengthening Europe's resilience. Despite overall progress, healthcare digitisation in the EU has been slower due to rigorous regulation and risks related to health data. The EU should support cooperation between Member States on the digitalisation of health by harmonising technological standards, promoting e-prescriptions, and countering disinformation, which would improve the accessibility and quality of healthcare. All of Europe, including Poland, faces shortages of raw materials, rising production costs, logistical challenges, and competition from Asian markets. There is a need to update pharmaceutical regulations to adapt them to modern realities and enhance the attractiveness of the European market for manufacturers. The return of API production and finished medicines to Europe entails high costs, necessitating financial support from national governments and the EU. This can be achieved through a businessfriendly legal and tax system, grants, and incentives. Particular emphasis should be placed on regulations that support pharmaceutical companies, particularly generic drug manufacturers, which increase availability and reduce the cost of pharmacotherapy.

In the face of numerous health threats, it is crucial to strongly promote health prevention and patient adherence to treatment. Everyone should understand that failing to take care of their health from an early age may lead to becoming a patient later in life, possibly to the extent of being unable to work, which would mean ceasing to contribute to GDP and instead relying on social benefits. All these factors together increase costs for the state, employers, and household budgets. A responsible approach to health through early prevention helps avoid many preventable diseases. Patients must be encouraged to stay active and eat properly to do everything possible to prevent avoidable diseases. Taking care of one's health reduces both direct and indirect costs, including presenteeism and absenteeism. If one becomes a patient, it is essential to follow prescribed therapies, comply with medical recommendations, and undertake the prescribed treatment. A healthy society translates into a healthy economy.

Non-communicable diseases account for nearly 90% of all deaths in the European Region of the World Health Organisation (WHO). A significant portion of this disease burden is preventable and largely dependent on risk factors such as tobacco use, harmful alcohol consumption, unhealthy diets, physical inactivity, air pollution, and exposure to carcinogens and radiation. Promoting healthy lifestyles, combined with measures to prevent and counteract key risk factors for non-communicable diseases, has the potential to reduce their incidence by up to 70%.<sup>285</sup> Actions aimed at eliminating these risk factors through prevention and health promotion, as well as addressing the fundamental socio-economic determinants of these diseases, should continue to be a priority in European health policy.

Non-communicable diseases not only impose a heavy burden on public health and well-being but also negatively impact economies, strain healthcare professionals, and place disproportionate pressure on health systems, which in many European countries are significantly understaffed and underfunded. People with comorbid conditions are also more vulnerable during public health crises. They are more susceptible to infectious diseases and experience weakened immune responses, including an increased risk of severe illness from infectious diseases such as COVID-19. The rationale for investing in eliminating NCD risk factors is clear: they generate high healthcare and pharmaceutical costs in all countries and lead to significant social expenditure, such as productivity loss.

<sup>285</sup> Pan American Health Organization (PAHO), Healthy Aging and Non-Communicable Diseases, https://www3. paho.org/hq/index.php?option=com\_ content&view=article&id=9979:healthy-aging-noncommunicable-diseases&Itemid=0&lang=en#gsc. tab=0.



With ageing populations in Europe, healthcare costs are expected to rise. The return on investment in prevention is well documented, yet the proportion of health spending allocated to prevention remains low, accounting for only 3% of overall health expenditure in the EU.<sup>286</sup>

Meanwhile, the predominant focus of healthcare systems in many Member States on curative rather than preventive measures has resulted in healthcare being perceived primarily as a cost. However, a well-functioning healthcare system – not merely one that provides treatment – is essential for a country's socio-economic development, including GDP growth. This can be achieved through health education and prevention, which help reduce future costs, increase productivity, enhance well-being, and improve quality of life. The objective of healthcare policy should be to ensure the mental and physical well-being of citizens, which directly translates into workforce participation and healthy life expectancy. Supporting pro-health attitudes in a multidimensional way is therefore essential.

Psychological and psychiatric care has long been a neglected area. In 2019, one in six people in the EU and the broader WHO European region was estimated to suffer from a mental health condition. This figure has risen by approximately 25% due to the COVID-19 pandemic, and access to psychiatric care remains a key issue in many Member States. Although most countries have policies to improve population mental health, their implementation continues to face challenges. These include a growing shortage of healthcare professionals and the need for more extensive and robust programmes to prevent mental health problems and promote well-being. Additionally, individuals with lived experience of mental health conditions should play a greater role in shaping these programmes to ensure they meet actual needs.

A lack of education and access to assistance not only generates high costs for the healthcare system but also has a significant impact on business expenses, the financial sustainability of social security systems, and the wider economy. Data from 2022 indicate that the number of sick leave certificates issued due to mental and behavioural disorders in Poland alone amounted to 1.29 million, equating to 23.8 million days of work absence. This increasing trend is concerning, and limited access to mental health support, along with long waiting times for assistance, only exacerbates the problem.

The digital transformation of healthcare is a critical priority. The development of digital technologies has been strongly supported by the European Union over the past decade, with EU policymakers making digital transformation a political priority and introducing a comprehensive legislative package to facilitate it. However, digitalisation in healthcare has lagged behind other sectors due to stringent regulatory environment related to healthcare services, as well as risks related to technological failures, and concerns over handling sensitive health data.

The COVID-19 pandemic forced patients, medical professionals, and healthcare institutions to restructure almost all care pathways. As medical practices and hospitals restricted in-person visits to essential consultations, teleconsultations and telemedicine became the new standard of care across Europe, despite the fact that for 84% of patients, it was their first experience with virtual healthcare.<sup>287</sup> The pandemic also highlighted weaknesses in both the health and digital sectors in Europe, as reliance on non-European products and technologies led to supply chain disruptions and shortages of medicines and medical equipment.

Today, this new momentum for digitalisation could play a key role in accelerating the recovery of health systems following the COVID-19 pandemic and enhancing Europe's resilience to future crises. Looking beyond the pandemic and its consequences, the current moment presents a historic opportunity to finally make digital technologies an integral part of public health services – making them more equitable and accessible to all European citizens, while also offering greater personalisation and value for individual patients.

<sup>286</sup> Eurostat, Preventive health care expenditure statistics (a database), 2023. https://ec.europa. eu/eurostat/statisticsexplained/index. php?title=Preventive\_health\_care\_expenditure\_st atistics#:~:text=Highlights&text=EU proc.20 Member proc.20States proc.20spent proc.20,of proc.20the proc.20 Covid proc.2D19 proc.20crisis.&text=Preventive proc.20 health proc.20care proc.20expenditure proc.20in,0.37 proc.20 proc.25 proc.20of proc.20GDP proc.20in proc.202020.

<sup>287</sup> European Parliamentary Research Service, 2021.



However, significant disparities in access to services persist across the European Union, and the financing of healthcare by Member States, measured as a percentage of GDP, also varies. This highlights the need for a localised approach when implementing digital solutions in the health sector, as levels of digital preparedness across EU countries remain uneven. Expanding the use of mobile health (mHealth) beyond pilot programmes and integrating it with clinical and public health initiatives will be a major challenge, particularly in countries with limited economic resources.

From a technological perspective, it is essential to establish a reliable public infrastructure in Member States that enables the seamless integration of mobile healthcare into routine health activities. These innovative digital solutions should form part of "integrated health services", defined as "health services managed and delivered in such a way that people receive continuity of health promotion, disease prevention, diagnosis, treatment, disease management, rehabilitation and palliative care, coordinated across different levels and settings of care, both within and beyond the health sector, according to their lifelong needs".

The European Union should support Member States in the digital transformation of healthcare, particularly by fostering cooperation among EU countries in health digitalisation. This should include the exchange of best practices, joint research projects, and, most importantly, the harmonisation of technological standards, enabling, for example, the cross-border implementation of e-prescriptions across all Member States. It is also essential to introduce appropriate information campaigns to combat health-related disinformation and enhance transparency in public health communication, which would encourage greater public engagement with digitalised health processes.

Digital technologies can enhance citizens' access to healthcare and drive progress in healthrelated matters, particularly as healthcare becomes more personalised. While modern technologies cannot fully resolve all challenges in healthcare, they can add substantial value, particularly in areas where effective and accessible solutions are lacking. However, numerous barriers remain to the digitalisation of healthcare systems, including resistance from healthcare professionals and patients. The key priority is to understand what is required to accelerate healthcare digitalisation, beyond the fundamental need to advance the information society.

Restoring medicines security in Europe and among Member States – including the revival of API and finished medicine production in Europe – has become a strategic imperative. The events of recent years, particularly the COVID-19 pandemic and Russia's military aggression against Ukraine, have underscored the critical importance of medicines security, especially in times of crisis, and have highlighted the urgent need to reduce Europe's dependence on API production in the Far East. Further production dependence may pose a threat to the health and safety of European and Polish patients. The need to restore the production of APIs and finished medicines to Europe is a strategic objective of all European institutions, as reflected in key policy documents, including the opinion of the European Economic and Social Committee of December 2023, the Versailles Declaration of the Council of 11 March 2022, the European Parliament resolution on medicine shortages of 17 September 2020, and the European Commission's Pharmaceutical Strategy of 25 November 2020.

It is important to highlight that locating the entire medicine manufacturing process within a country, including API production, entails significant costs (such as the construction of new infrastructure, workforce training, and environmental protection), making financial support from national governments and the EU essential. Such support may be provided indirectly, through the establishment of a business-friendly legal and tax framework, or directly, via subsidies, grants, or other incentives. Notably, Polish pharmaceutical companies are primarily engaged in the production of generic medicines, which contributes to increased availability and lower costs of pharmacotherapy. Therefore, particular emphasis should be placed on creating regulatory conditions that facilitate the efficient operation of companies, ensuring stability, predictability, and return on investment. Some of the solutions currently being implemented will require further development in the future.



Examples of proposed reimbursement and registration measures include:

- 1. Full exemption from statutory payback requirements for medicines manufactured in Poland and/ or from substances produced in Poland.
- 2. Priority listing, particularly for free medicines, for medicines manufactured in Poland and/or from substances produced in Poland.
- 3. Ensuring the possibility of obtaining comparable reimbursement conditions for medicines manufactured in Poland and/or from substances produced in Poland.
- 4. Reduction of data exclusivity and market exclusivity periods for originator medicines.
- 5. Closing regulatory loopholes that allow for the abuse of exclusivity rights and negative patent linkages that delay the market entry of generic alternatives.

It is necessary to take the lead on this subject to guarantee the strategic autonomy of the European Union based on the production capacities of individual Member States. It is also necessary to create a dedicated European legislative act containing financial and regulatory incentives to maintain and transfer the production of APIs and medicines ready for Europe. The Polish Presidency could make the declared strategic directions of all European institutions a reality.

### **Federation of Polish Patients**

### Stanisław Maćkowiak

President of the Federation of Polish Patients and President of ORPHAN, the National Forum for Rare Disease Therapies

### The Situation of Rare Disease Patients in Poland in the Context of the European Union and the Need for a European Action Plan for Rare Diseases

From 1 January 2025, Poland took over the six-month Presidency of the Council of the European Union as part of a trio consisting of Poland, Denmark, and Cyprus. The Polish Ministry of Health has defined the key health priorities of its Presidency as the digital transformation of healthcare, mental health for children and adolescents, the promotion of preventive measures, and pharmaceutical security. Taking into account Poland's recent advancements in rare disease care, the country should also promote and support the optimisation of rare disease care during its Presidency. It is worth recalling that the Presidencies of France, the Czech Republic, Sweden, Spain, Belgium, and Hungary actively promoted the challenges and optimisation of care for rare disease patients. Stella Kyriakides, Commissioner for Health and Food Safety, has repeatedly stressed that: "The fight against rare diseases is not only a matter of healthcare but also a reflection of values and solidarity in the European Union". She added: "We have a duty to support people living with rare diseases and their families. Our efforts will continue to make a difference to all those in need".<sup>288</sup>

A disease is considered rare if it affects fewer than 5 individuals per 10,000 inhabitants. More than 10,000 rare diseases have been identified. Eighty per cent of rare diseases have a genetic basis. Within the EU, about 36 million people -8% of the total population of ca. 450 million – live with a rare disease.<sup>289</sup>

In recent years, the situation of rare disease patients in Poland has significantly improved. The second Rare Disease Plan (2024–2025) was adopted, the Council for Rare Diseases was established, and the Parliamentary Team for Rare Diseases remains active in the Sejm. The forty-four active Polish clinical centres have joined the European Reference Networks (ERNs). From 2021 to January 2025, 157 new molecule-indications for rare disease treatments were publicly reimbursed, constituting 32% of all new drug reimbursements. Poland's national newborn screening covers 30 rare conditions, and its SMA (Spinal Muscular Atrophy) screening programme is among the

<sup>288</sup> RareDiseases – The EU needs a strategy that will help 36 million people in Europe, https://www.eesc.europa.eu/pl/news-media/eesc-info/112023/articles/114044.

<sup>289</sup> Eurostat, EU research on rare diseases, 2023, https://research-and-innovation.ec.europa.eu/research-area/health/rare-diseases\_en.

best in the world, supporting over 1,000 patients. Thanks to the public reimbursement of all three therapies, Poland can boast one of the world's best models for the diagnosis and treatment of SMA.

Poland's journey to improving the situation in the field of diagnosis and treatment of rare diseases has been difficult and long. Let us recall this journey, the efforts that have been made globally, in Europe, and in Poland over the past forty years, to optimise care of rare disease patient and their families. The first significant international milestone was the Orphan Drug Act of 1983 in the United States, signed by President Ronald Reagan, marking the first time that the issue of rare disease patients was formally recognised. On 16 December 1999, Regulation No 141/2000 of the European Parliament and of the Council of the European Union was published, stating that patients suffering from rare diseases should be entitled to the same quality of treatment as other patients.<sup>290</sup> On 11 November 2008, the European Commission published a communication to the European Parliament, the Council of the European Union, the European Economic and Social Committee, and the Committee of the Regions, Rare diseases: Europe's challenges.<sup>291</sup> On 8 June 2009, the Council Recommendation on an action in the field of rare diseases (2009/ C151/02) was issued, recommending that Member States establish and implement plans for rare diseases to ensure patients suffering from rare diseases have access to high-quality healthcare, including diagnosis, treatment, rehabilitation, and access to orphan drugs. It was recommended that a European framework for national plans, developed under the EUROPLAN Project, be adopted by 2013, following the recommendations of the European Commission.<sup>292</sup> On 10 July 2020, the European Parliament published a resolution calling for the development of an EU Action Plan on Rare and Neglected Diseases.<sup>293</sup> In 2021, at the initiative of the European Parliament, the report Rare2030. Forsight in rare diseases policy was published, containing recommendations for integrating European and national action plans in the field of rare diseases.<sup>294</sup>

In Poland, the Regulation of the Minister of Health of 22 November 2021 on health priorities includes the provision: "(11) Improvement of the diagnosis and treatment of rare diseases".<sup>295</sup> This priority led to the adoption of the Operational Plan for Rare Diseases for 2021–2023, focusing on six key areas: Rare Disease Expert Centres; rare disease diagnostics, including access to modern diagnostic methods such as large-scale genomic testing; access to medicines and special nutritional products for rare diseases; the Polish Register of Rare Diseases; the Rare Disease Patient Passport; the Rare Diseases Information Platform. The budget allocated for the Plan's implementation amounted to approximately PLN 130 million.<sup>296</sup> In May 2022, the Minister of Health appointed the Council for Rare Diseases, whose role was to provide substantive support for the implementation of the Plan for Rare Diseases for 2021–2023.<sup>297</sup>

In 2021, the trio of France, the Czech Republic, and Sweden declared that during their Presidencies of the Council of the European Union, they would create a discussion platform to prioritise rare diseases at the political level. At the Prague Conference on 25-26 October 2022, a Call to Action

294 Rare2030. Forsight in rare diseases policy, https://www.rare2030.eu/.

- 295 Regulation of the Minister of Health of 22 November 2021 amending the Regulation on health priorities, https://isap.sejm. gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210002144.
- 296 Resolution No. 110 of the Council of Ministers of August 24, 2021 on the adoption of the Plan for Rare Diseases, M.P. [Polish Official Gazette] 2021 item 883, https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WMP20210000883.
- 297 Council for Rare Diseases established under the Plan for Rare Diseases 2021–2023, https://chorobyrzadkie.gov.pl/pl/zespol-portalu/rada-do-spraw-chorob-rzadkich.

<sup>290</sup> Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, https://eur-lex.europa.eu/eli/reg/2000/141/oj.

<sup>291</sup> European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 11 November 2008 on Rare Diseases – Europe's challenges, https://eur-lex.europa.eu/EN/legal-content/summary/rare-diseases-europe-s-challenges.html.

<sup>292</sup> Council Recommendation of 8 June 2009 on an action in the field of rare diseases (2009/C 151/02), https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:151:0007:0010:EN:PDF.

European Commission, Tackling rare diseases. Challenges, opportunities and gaps for action on rare diseases in the European Union, 2020, https://www.europarl.europa.eu/RegData/etudes/STUD/2024/754210/IPOL\_STU(2024)754210\_EN.pdf.



and a proposal for a coordinated European Action Plan for Rare Diseases were formulated.<sup>298</sup> On 28 February 2023, marking World Rare Disease Day, 48 Members of the European Parliament (MEPs) appealed to European Commission President Ursula von der Leyen, urging the European Commission to adopt a European Action Plan for Rare Diseases as soon as possible.<sup>299</sup>

On 23 October 2024, the European Economic and Social Committee (EESC) published an opinion titled *Leaving No One Behind: European Commitment to Tackling Rare Diseases*, calling on the European Commission to adopt a Rare Diseases Action Plan with clearly defined and achievable goals.<sup>300</sup> At the Hungarian Presidency's concluding conference, titled *For an EU Commitment to Tackling Rare Diseases*, the EESC once again urged the adoption of a European Action Plan for Rare Diseases.<sup>301</sup>

The Council of Ministers adopted the Plan for Rare Diseases for 2024–2025 on 13 August 2024.<sup>302</sup> Its aim is to continue work on introducing comprehensive solutions and improving the healthcare system for patients with rare diseases, the implementation of which was initiated by the Plan for Rare Diseases carried out in 2021-2023. The actions proposed in the document for rare disease patients are scheduled for implementation in 2024-2025, with the goal of continuing work in six key areas:

- 1. Establishing Specialist Centres for Rare Diseases (OECR) and analysing settlement products introduced for them;
- 2. Improving access to diagnostic tests used in diagnosing and treating rare diseases;
- 3. Improving access to medicines and special nutritional products for rare diseases;
- 4. Developing the Polish Register of Rare Diseases (PRCR);
- 5. Introducing the Rare Disease Patient Card;
- 6. Managing the Rare Diseases Information Platform (<u>https://chorobyrzadkie.gov.pl</u>) and developing and disseminating knowledge about rare diseases.

On 29 November 2024, the Minister of Health established the Council for Rare Diseases to implement the Plan for Rare Diseases for 2024–2025.<sup>303</sup>

Currently, the healthcare system in Poland provides assistance to patients with rare diseases in an incomplete and fragmented manner. We are working to ensure that assistance to rare disease patients in Poland is provided comprehensively. We want systemic assistance to be legally defined and adopted in the highest legal form – an act, the implementation of which will be reported annually in the Sejm. This act will cover benefits for patients with rare diseases in the areas of healthcare, education, employment and social care. We want every patient with a rare disease to know the pathway they will follow within the healthcare, education, employment and social care systems. Patients with rare diseases do not expect special or priority treatment. They want the opportunity to access benefits and be treated like other citizens.

A single patient with a rare disease has virtually no influence. Patient organisations, however, have far more opportunities than individual patients, which is why they strive to be visible in the media and administrative spheres. They also often seek support in the Sejm and the Senate, within the

- 301 EESC, For an EU commitment to tackling rare diseases, 2024, https://www.eesc.europa.eu/en/agenda/our-events/events/ eu-commitment-tackling-rare-diseases.
- 302 Polish Council of Ministers, Rada Ministrów przyjęła Plan dla Chorób Rzadkich na lata 2024–2025 [Council of Ministers adopted the Plan for Rare Diseases 2024-2025], https://www.gov.pl/web/zdrowie/rada-ministrow-przyjela-plan-dla-chorob-rzadkich-na-lata-2024-2025.
- 303 Internal directive of the Minister of Health of 29 November 2024 repealing the internal directive on the appointment of the Council for Rare Diseases, https://dziennikmz.mz.gov.pl/legalact/2024/119/.

<sup>298</sup> Czech Presidency's Call to Action from the Expert Conference on Rare Diseases, https://www.eurordis.org/publications/ czech-presidencys-call-to-action-from-the-expert-conference-on-rare-diseases/.

<sup>299</sup> MEPs call on Commission President to deliver overdue strategy on rare diseases, https://www.eurordis.org/publications/ czech-presidencys-call-to-action-from-the-expert-conference-on-rare-diseases/.

<sup>300</sup> EESC, ESC calls for European flagship initiative for health and action plan on rare diseases. Leaving No One Behind: European Commitment to Tackling Rare Diseases, 2024, https://www.eesc.europa.eu/pl/news-media/press-releases/eesccalls-european-flagship-initiative-health-and-action-plan-rare-diseases.



parliamentary space. Efforts are made to communicate the needs of rare disease patients through all available channels. However, it should be emphasised that this is only possible because they are united, as individual patients with rare diseases have practically no influence. From a political or even social standpoint, a single rare disease entity often remains unnoticed. The National Orphan Forum is an association of organisations representing dozens of rare and ultra-rare diseases through its member associations and foundations acting on behalf of patients. We are present where decisions about people living with a rare disease are made, and our activities are aimed at broadly improving the quality of life of rare disease patients in Poland.

The Polish National Forum for Rare Disease Therapy ORPHAN is a patient umbrella organisation bringing together patient associations and foundations working for rare disease patients in Poland.<sup>304</sup> In January 2025, the ORPHAN National Forum brought together 79 rare disease patient organisations.<sup>305</sup> The activities of ORPHAN focus on the overarching goal of improving the quality of life of over three million people affected by rare diseases in Poland. As an umbrella organisation, we ensure that the voice of rare disease patients is heard. We support and organise awareness campaigns, facilitate fast and effective diagnostics, promote research into new medicines and innovative therapies, advocate for access to treatment, and campaign for equal treatment of rare disease patients in society across all aspects of life. ORPHAN organises regular conferences, workshops, patient training sessions and debates to optimise the care of patients with rare diseases and their families in Poland. Every year, the Forum participates in the celebration of World Rare Disease Day, organising a conference attended by leading rare disease experts, including doctors, diagnosticians, lawyers, government and parliamentary representatives, manufacturers of medicines, diagnostic tools and medical devices, patient representatives and patients themselves. This event always takes place on the last day of February. ORPHAN regularly participates in the work of the Parliamentary Team on Rare Diseases, representing the voice of rare disease patients. The Forum is a member of the international umbrella patient organisation EURORDIS-Rare Diseases Europe.<sup>306</sup> EURORDIS is a non-governmental alliance of patient organisations and individuals active in the field of rare diseases, promoting research into rare diseases and the commercial development of orphan drugs. The aim of EURORDIS is to improve the quality of life for all people suffering from rare diseases in Europe. ORPHAN is also a member of the Federation of Polish Patients (FPP), participating in meetings of the Council of Patient Organisations at the Ministry of Health<sup>307</sup> and the Council of Patient Organisations at the Commissioner for Patient's Rights<sup>308</sup>.

At this point, it should be noted that for the past four years, at the initiative of ORPHAN, the ORPHAN national audit has been conducted in Poland. This audit is an annual, cross-sectional, and comprehensive study of the actual needs of rare disease patients and their families. Poland is among the few countries in the European Union where a regular and thorough audit of rare disease patient needs is conducted. The first ORPHAN audit was launched in 2021, and the latest one was conducted in 2024, marking the fourth study of patient needs. Previous reports have been published and are available on ORPHAN website.<sup>309</sup> In 2021, 35 patient organisations participated (73% of 48 ORPHAN members). In 2022, 36 organisations took part (72% of 50 members). In 2023, responses were obtained from 47 organisations (81% of 58 members). In 2024, the audit saw participation from 54 organisations (70% of 77 organisations cooperating with KFO). A particularly notable achievement is the nearly twofold increase in the number of organisations collaborating

<sup>304</sup> Polish National Forum for Rare Disease Therapy ORPHAN, http://rzadkiechoroby.org/o-kfo/.

 <sup>305</sup> Polish National Forum on the Treatment of Orphan Diseases – ORPHAN, Members, http://rzadkiechoroby.org/czlonkowie/.
 306 EURORDIS–Rare Diseases Europe, https://www.eurordis.org/.

<sup>307</sup> Patient Organisations Council, https://www.gov.pl/web/zdrowie/rada-organizacji-pacjentow.

<sup>308</sup> Patient Organisations Council at the Polish Commissioner for Patient's Rights, https://www.gov.pl/web/rpp/radaorganizacji-pacjentow.

<sup>309</sup> Gierczyński J., Maćkowiak S., Audyt krajowego forum Orphan 2024. Potrzeby pacjentów z chorobami rzadkimi w zakresie dostępu do technologii medycznych i optymalizacji opieki w Polsce, National Forum for Rare Disease Therapy ORPHAN, Warszawa, August 2024, http://rzadkiechoroby.org/audyt/.



with KFO between 2021 and 2024 – rising from 48 organisations in 2021 to 77 in 2024. Key findings of the 2024 Audit are presented below:

- All patient organisations (54 entities) assessed the National Forum ORPHAN Audit as a highly effective tool for identifying the needs of rare disease patients.
- 15% of the respondents (8 organisations) indicated that the situation of rare disease patients had been prioritised in the past year. However, 85% (46) reported that the needs of rare disease patients in Poland are not treated as a priority.
- 28% of the organisations (15) stated that the situation of rare disease patients had improved since the implementation of the Plan for Rare Diseases (2021–2023). In contrast, 72% (39) indicated that there had been no improvement.
- 26% of the participating organisations (14) observed improvements in the situation of rare disease patients following the introduction of the Medical Fund. However, 74% (40) reported that there was no improvement.
- All patient organisations agreed that rare diseases should be one of the health priorities of the Polish Presidency of the Council of the EU from January to June 2025.
- 61% of the patient organisations (33) confirmed that they were aware of a dedicated rare disease expert centre, while the remaining 39% (21 organisations) were not aware of such a centre.
- 70% of the respondents (38 organisations) stated that they were familiar with the rare diseases information platform, whereas 30% (16 organisations) indicated they were not familiar with such a platform.
- 91% of patient organisations called for improvements in social care, including increasing the working hours and responsibilities of assistants for people with disabilities, introducing respite care for families, providing financial support for families of patients in financial difficulties, offering psychological support for patients and their families.
- 91% of patient organisations called for improvements in education, And specifically for: adapting schools to accommodate students with disabilities, assigning assistants for students with disabilities, adjusting teaching methods to meet the needs of students with disabilities, changing qualifications for teachers, including introducing legal provisions allowing educational staff to administer life-saving medication. At the same time, it was proposed to enhance training for medical assessors and healthcare personnel (including specialists, primary care physicians, nurses, paramedics, and emergency department staff) on the specifics of rare diseases.
- 89% of the surveyed patient organisations identified an urgent need for improved reimbursement access to diagnostic tests, particularly genetic testing, newborn screening and cyclical tests for disease progression monitoring.
- 87% of the patient organisations stressed the need to optimise the rare disease care model in Poland, particularly through coordinated and comprehensive care, establishing reference centres, setting up multidisciplinary teams in these centres.
- 74% of the patient organisations called for improved reimbursement access to 62 new drug technology molecule indications.
- 52% of the patient organisations identified the need for improved reimbursement access to medical devices for 25 clinical indications.

The second flagship research project of ORPHAN is the Clinical Audit, Designed to highlight the perspectives of clinicians. Together with the patient perspectives expressed in the 2024 ORPHAN Audit, this project aims to present a complete picture of the needs and directions for optimising rare disease care in Poland, in the broader EU context. The methodology of the 2024 Clinical Audit followed a two-step process: the first step was the preparation of key and up-to-date data on three areas of the Plan for Rare Diseases 2024-2025: Specialist Centres for Rare Diseases (OECR), diagnostics and registered and reimbursed orphan drugs in the European Union and in Poland. The second step was qualitative research conducted among selected clinical experts specialising in rare disease diagnosis and treatment across different medical fields. The findings from this research will serve as the scientific basis for a series of reconciliation workshops in January 2025,



culminating in the launch of the final report in February 2025, and a conference under the Polish EU Presidency on 10–11 April 2025.

I invite everyone to work together towards improving care for rare disease patients and their families through the National Forum for Rare Disease Therapy ORPHAN and EURORDIS-Rare Diseases Europe. Our joint efforts to enhance the situation of rare disease patients in the EU should contribute to the adoption of a European Action Plan for Rare Diseases.

### **Parents for Climate**

### Kamila Kadzidłowska

Co-founder and Vice-President of the Board of the Parents for Climate Foundation

The health, future, and safety of the youngest generations are priorities that occupy a central place in the activities of Parents for Climate. Like many parents in Poland, Europe, and around the world, we are increasingly concerned about the impact of multiple crises (pandemics, armed conflicts, climate, energy, ecological, economic, and humanitarian crises) on young people's lives and health. Although these crises result from the political and economic decisions of those who are older and in power, it is the youngest and most vulnerable who will bear their harshest consequences.

Poland assumes the EU Council Presidency at a particularly challenging time of multiple crises, which requires the European Union to make strategic and bold decisions. Despite geopolitical pressures, the health, future, and safety of the youngest generation should remain at the heart of the political agenda. The future of the European Union as a crisis-resilient and sustainable community depends on the well-being of the young generation – currently under significant strain.

As an independent social movement and foundation serving on the Council of Non-Governmental Organisations for the Polish Presidency of the Council of the European Union, we present nine recommendations addressing contemporary health challenges for children and young people. These proposals include the right to live in a clean environment, improving air quality, protecting mental health, ensuring access to healthy food and nature, advancing health education, and combating disinformation and unfair marketing practices. Our postulates are based on the principles of sustainable development, integrating health initiatives with climate and environmental education.

The proposed actions, following the principle of "prevention is better than cure", focus on eliminating harmful environmental factors and strengthening children's resilience to health, climate, and societal challenges. We hope that the Polish Presidency will incorporate these priorities into its EU agenda, giving them a strategic and long-term dimension.

### Prioritising Child Health. EU4KidsHealth initiative

Children's health is fundamental to the future of European societies, yet it is currently in an alarming state. Therefore, addressing this issue must be at the centre of responsible political decision-making. Poland has a unique opportunity to become a leader in child health protection during its EU Presidency. As an organiser of EU legislative work, it could initiate the development of the EU4KidsHealth principle, which would require legislators to assess the impact of legal regulations on children's health and revise laws contributing to the EU's health crisis. This initiative would foster policy development that prioritises sustainable development, public health, and children's health education.

# Postulate: Poland should initiate the EU4KidsHealth initiative as a key component of European preventive healthcare policies, ensuring that legislative decisions prioritise children's health.

Placing children's health at the centre of EU policy will bring direct benefits by improving young people's health while also reducing the social and healthcare costs associated with treating lifestyle diseases.



### EU Climate Policy as a Preventive Healthcare Tool

Fundamental biological needs – breathing, eating, and sleeping – determine human life. Their quality determines our health and well-being, with key factors including: **clean air** – air pollution is one of the leading health risk factors, contributing to respiratory and cardiovascular diseases, asthma, allergies, immune system disorders, cancer, and neurological and mental health issues; **a balanced diet** – a diet based on diverse, natural, and minimally processed foods, rich in vegetables, fruits, legumes, healthy fats, proteins, and whole grains, positively affects bodily functions, prevents obesity, type 2 diabetes, hypertension, and atherosclerosis, protects against nutritional deficiencies, and strengthens immunity and mental health; **a sustainable lifestyle** – regular outdoor physical activity, digital hygiene, and avoiding harmful substances have a direct impact on the physical and mental health of all generations; **a healthy environment** – lack of access to clean water, soil contamination with pesticides and heavy metals, and the negative effects of climate change, such as heatwaves, floods, and wildfires, directly impact health and life expectancy; **contact with nature** – proximity to nature supports mental health and overall immunity, reduces stress, improves quality of life, and enhances the ability to adapt to the negative effects of climate change, including heatwaves.

Improving public health in Poland and the EU requires the implementation of regulations addressing:

- Air quality improvement (enforcing directives on pollutant limits, including PM2.5, PM10, and nitrogen oxides, which are particularly harmful to children).
- Low-emission transport and sustainable mobility (promoting electric mobility, public transport, rail networks, and active mobility to reduce air pollution and improve urban living conditions).
- The **"Farm to Fork"** strategy (supporting sustainable agriculture, reducing pesticide and antibiotic use in agriculture, and minimising food waste).
- **Biodiversity protection** (expanding and protecting green urban spaces and forests, and conserving ecosystems).
- Greenhouse gas reduction (supporting climate neutrality efforts, including renewable energy and energy efficiency measures that lower exposure to smog and climate change effects).

Postulate: The Polish EU Presidency should prioritise climate policies as part of its strategy for ensuring children's health security, emphasising the European Green Deal's role in preventing lifestyle diseases and enhancing future-oriented societal resilience.

Failure to implement the European Green Deal's climate policies will lead to substantial health and social costs, undermining the basis of EU stability and security.

### Clean Air. Transposition of the Ambient Air Quality Directive (AAQD) for Vulnerable Groups

According to the World Health Organisation (WHO), air pollution is the most significant environmental health threat in the EU.<sup>310</sup> Poland remains among the European countries with the highest air pollution levels, leading to the premature deaths of over 41,000 people annually and generating approximately PLN 130 billion in healthcare costs due to increased hospitalizations.

Studies<sup>311</sup> indicate that inhaling air with high levels of pollutants – primarily from coal and wood combustion in residential heating systems and road transport emissions – can have health impacts comparable to smoking several cigarettes daily. It significantly increases the risk of **respiratory, cardiovascular, and neurological diseases, as well as cancer**, with particularly harmful effects on children, starting from the prenatal stage. Harmful pollutants can cross the placental barrier, **disrupting fetal development** and leading to low birth weight, congenital

<sup>310</sup> Source: European Court of Auditors, Air pollution: Our health still insufficiently protected (Special Report), https://op.europa.eu/webpub/eca/special-reports/air-quality-23-2018/en.

<sup>311</sup> For an example of such a study, see *Air pollution can accelerate lung disease as much as a pack a day of cigarettes*, University of Washington, 2019, https://www.washington.edu/news/2019/08/13/air-pollution-can-accelerate-lung-diseaseas-much-as-a-pack-a-day-of-cigarettes/.

defects, and an increased risk of preterm birth. In later childhood, air pollution weakens the immune system, making children more susceptible to infections and chronic conditions, while also damaging the brain, impairing cognitive functions and increasing the prevalence of neurodevelopmental disorders.<sup>312</sup>

Importantly, there is no safe threshold for exposure to the toxins present in air pollution and its effects are not felt equally by everyone. However, certain groups – older adults, individuals with chronic cardiovascular and respiratory diseases, pregnant women, and children – are particularly vulnerable to its effects. **To protect the health of these groups, it is crucial to implement the Ambient Air Quality Directive (AAQD) without delay**. This directive requires EU Member States to meet air quality standards in line with WHO guidelines, setting maximum permissible concentrations for pollutants such as particulate matter (PM2.5, PM10), nitrogen oxides (NOx), sulfur dioxide (SO<sub>2</sub>), and ozone. It also mandates the development and enforcement of air protection plans in cases where air quality limits are exceeded. Furthermore, it guarantees access to justice for patients suffering from diseases caused by poor air quality. Additionally, this mechanism will motivate local authorities to take ambitious action, ensuring that the interests of **patients remain a priority.** 

# Postulate: The Polish Presidency should lead international and interdepartmental cooperation to develop the strongest possible legal framework for transposing the Ambient Air Quality Directive (AAQD) into national legislation, with a particular focus on protecting children, older adults, and individuals with chronic illnesses.

Interdepartmental actions to implement AAQD should include:

- **public education** on the sources of air pollution and its health impacts;
- **training medical professionals** in environmental health, with an emphasis on diagnosing, treating, and preventing air pollution-related diseases;
- strengthening patients' access to justice;
- expanding air quality monitoring networks, particularly near schools and healthcare facilities;
- **supporting the establishment of green buffer zones** around schools and healthcare institutions to minimize exposure to pollution;
- requiring detailed health impact assessments for investments that may increase air pollution levels.

The Polish Presidency could also initiate an international exchange of best practices and policies aimed at improving air quality across the EU.

### Healthy Food and the Farm to Fork Strategy: A Preventive Approach to Cancer and Lifestyle Diseases

An unhealthy diet is a major factor contributing to the rising prevalence of lifestyle diseases and cancer, particularly among children. Across Poland and other EU countries, inadequate nutrition has led to a surge in obesity, neurodevelopmental disorders, type 2 diabetes, hypertension, dental decay, vitamin and mineral deficiencies, antibiotic resistance, and cancer.

Children's diets, starting as early as preschool age, are often deficient in vegetables while being overly reliant on processed meats, such as sausages and cold cuts. The International Agency for Research on Cancer (IARC) has confirmed that consuming these products increases the risk of cancer, especially **colorectal and gastric cancers**.<sup>313</sup> Additionally, toxic chemicals used in food production – such as pesticides and glyphosate – have been linked to endocrine system disruptions. Industrial meat production, which relies heavily on antibiotics, further exacerbates the issue. The

<sup>312</sup> Institute of Environmental Protection – National Research Institute, Jak smog wpływa na mózgi dzieci? [How does smog affects children's brains?], 2023, https://ios.edu.pl/informacje-prasowe/jak-smog-wplywa-na-mozgi-dzieci/.

<sup>313</sup> For more information on this topic, see National Centre for Nutrition Education, Spożycie mięsa a ryzyko nowotworów [Meat consumption and cancer risk], https://ncez.pzh.gov.pl/choroba-a-dieta/spozycie-miesa-a-ryzyko-nowotworow/?utm\_source=chatgpt.com.



WHO warns that growing **antibiotic resistance**, driven in part by their overuse in the food industry, is one of the most pressing global health threats today. Reducing these harmful practices is critical both for creating sustainable food systems and for safeguarding public health.

Despite increasing awareness of the need for dietary change, major barriers to adopting a healthy diet persist. These include the limited availability of nutritious food compared to the abundance of highly processed, sugar-laden, and salty products, as well as the high cost of organic foods and limited access to fresh vegetables and fruits. Unhealthy food marketing – particularly in advertisements targeting children – further exacerbates the issue, along with the widespread availability of unhealthy snacks in schools and vending machines.

A key solution to these challenges is implementing the Farm to Fork Strategy, which promotes sustainable food production, reduces pesticide and antibiotic use, and supports short supply chains to improve the accessibility of nutritious food. Additionally, the EAT-Lancet diet – a science-backed model emphasizing whole grains, legumes, fruits, vegetables, nuts, and seeds while limiting ultra-processed foods, refined sugars, and red meat – should be widely promoted.

# Postulate: As part of cancer and lifestyle disease prevention efforts, the Polish Presidency should lead collaboration on implementing the Farm to Fork Strategy, with a particular emphasis on increasing access to healthy food and promoting the EAT-Lancet diet as a foundation for sustainable nutrition.

Recommended actions in this area include:

- working with the European Commission to accelerate reductions in pesticide and antibiotic use while promoting organic farming;
- action to eliminate harmful substances in food and packaging, including pesticides, preservatives, and toxic plastics;
- restricting the promotion and availability of highly processed foods in schools and vending machines, as well as in advertising targeted at children;
- **incorporating the EAT-Lancet** diet into school and healthcare institution menus, increasing plant-based food consumption while limiting processed meat intake;
- **supporting short food supply chains and local organic food producers** through green public procurement in government institutions;
- educating children, parents, and teachers on the benefits of a sustainable diet and its impact on both health and the environment;
- expanding access to nutritional counselling, including training healthcare professionals in dietary guidance and disease prevention;
- redirecting subsidies from industrial meat and dairy production to support sustainable farming and healthy food alternatives;
- **funding scientific research** on the links between diet, environmental factors, and the risk of lifestyle and cancer diseases.

Implementing these measures will improve public health, support environmental sustainability, and strengthen local organic agriculture across the EU.

### Green Prescriptions for a Mental Health Crisis in Children and Adolescents

The mental health crisis is one of the EU's most pressing challenges. Problems such as **depression**, **anxiety**, **and cognitive difficulties** are becoming increasingly common among younger generations. Their escalation is influenced by climate change, the pandemic, the security crisis caused by war, civilizational stress, urbanization, and a lack of social interaction and contact with nature. At the same time, excessive use of digital devices, social media addiction, exposure to harmful content, cyberbullying, and disinformation further exacerbate mental health problems, negatively impacting the emotional development and well-being of young people. While **digital threats** are already on the agenda of the EU Presidency, insufficient attention has been given to one of the primary causes of these mental health challenges – **the lack of contact with nature**.



In today's fast-paced world, dominated by technology, it is easy to overlook the fundamental role that nature plays in human health and well-being. Time spent in nature not only **rejuvenates the body** but also plays a crucial role in **proper neurodevelopment**, **fostering creativity, cognitive function, and emotional resilience in children.** Research findings published in the Journal of Environmental Psychology<sup>314</sup> confirms that exposure to green spaces significantly **reduces stress levels, improves mood, and even alleviates pain**. Additionally, findings from the Polish research project NeuroSmog indicate that proximity to green spaces **reduces ADHD symptoms, mitigates behavioural problems, and improves overall well-being in children**.<sup>315</sup> Regular exposure to nature also encourages physical activity and **strengthens social bonds**, both of which are essential for mental health.

Over the past two decades, however, children's time spent outdoors has decreased by more than 50%, while their average daily screen time has risen to over seven hours. This trend is not only driven by the digital world's allure but also by poor urban planning that has reduced children's access to natural spaces for free play and relaxation. The modern urban environment, full of parking lots, shopping centres and monotonous green planning, is often not conducive to outdoor activity, especially in the era of climate change. Research also highlights that the quality of green spaces – e.g., the presence of diverse vegetation, access to shade, and the ability to explore safely – is critical to health benefits.

A highly effective tool for improving mental health is **Green Care**, which integrates nature-based health and social services. This approach includes green prescriptions, which involve medical recommendations for spending time in nature while reducing screen exposure, as well as the expansion of urban green spaces and the revitalization of school and kindergarten surroundings. These measures contribute to the development of healthier and more resilient societies.

Furthermore, Green Care, combined with emotional support, education on pro-environmental behaviours, and the promotion of outdoor activity, serves as an effective intervention for **climate anxiety** – the distress experienced by young people regarding climate change. If left unaddressed, this form of anxiety can develop into chronic stress and depression.

# Postulate: The Polish Presidency should initiate cooperation aimed at integrating Green Care, which utilizes contact with nature as a key tool for preventing and treating mental health issues, into national healthcare systems.

The key actions in this area include:

- **introducing "green prescriptions**" as a standard component of preventive healthcare and mental health treatment in national healthcare systems;
- **promoting nature-based therapies** in healthcare and educational institutions, including through EU-funded health programmes;
- strengthening international collaboration for the exchange of best practices on Green Care and nature-based therapies;
- creating and revitalizing green spaces in urban areas, particularly near schools, kindergartens, nursing homes, and hospitals;
- developing infrastructure that encourages physical activity and interaction with nature, such as community gardens and sensory parks;
- **implementing health education** programmes on the benefits of regular contact with nature and its role in mental well-being;

The systematic adoption of nature-based therapies, green prescriptions, and urban greening initiatives will yield long-term health and social benefits while enhancing Europe's resilience to climate-related challenges.

<sup>314 &</sup>quot;Stress recovery during exposure to natural and urban environments", Journal of Environmental Psychology, 1991, https://www.sciencedirect.com/science/article/abs/pii/S0272494405801847?viaproc.3Dihub.

<sup>315 &</sup>quot;Nurturing attention through nature", Environmental Research, 2024, https://www.sciencedirect.com/science/article/abs/pii/ S0013935124019315?viaproc.3Dihub.



### Counteracting Disinformation and Unfair Marketing Practices that Threaten Health Security

The phenomenon of massive disinformation, which distorts the perception of real threats and weakens trust in science and public institutions, is a serious challenge for the security of the EU. Experts point out that both false narratives on climate change (including undermining the scientific consensus on its anthropogenic nature) and those on health (e.g. the COVID-19 pandemic, vaccine safety, and drug efficacy) have common features and sources.<sup>316</sup> This is pro-Russian disinformation (understood as messages originating from Russia or distributed on behalf of the services of the Russian Federation), which is part of a strategic and planned cognitive warfare campaign against NATO and EU countries.<sup>317</sup>

The mechanisms of these disinformation campaigns rely on simple, emotionally charged messages designed to instill fear, distrust, and a sense of threat. An example of such narratives is the portrayal of environmental regulations as "green totalitarianism" or an "ideology," as well as an alleged threat to jobs and economic growth. In the health sector, these include false claims about the harmfulness of vaccines, the promotion of pseudoscientific treatments, or the denial of the existence of the COVID-19 pandemic. Such content spreads through social media, amplified by automated bot networks, and is used to manipulate public opinion. The consequence of these actions is the deepening of societal divisions, making it harder to take coherent political actions at both the national and EU levels, ultimately undermining key climate policies, which are crucial to Europe's independence from fossil fuel imports from Russia.

The problem of eroding trust in health and climate policies is further exacerbated by economic actors who frequently employ unfair marketing tactics, including greenwashing. This practice misleads consumers by falsely attributing ecological characteristics to products. As a result, many harmful products – such as highly processed foods, sweets, beverages, and snacks – are marketed as harmless or even beneficial. These deceptive practices not only mislead consumers but also contribute to rising healthcare costs.

Children, as a group particularly vulnerable to marketing manipulation and disinformation, require special protection. Addressing these phenomena is a key element of the strategy for building healthy, resilient, and informed societies. Coordinated actions at the EU and national levels are necessary, such as supporting the implementation of the Anti-Greenwashing Directive (2024/825), the Audiovisual Media Services Directive (AVMSD), the Digital Services Act (DSA), and the Green Claims Directive. Schools and the media, particularly public broadcasters, have a critical role to play in this process, as their mission should include health and climate education.

# Postulate: The Polish Presidency should initiate intergovernmental and interdepartmental cooperation to protect children from digital threats, including disinformation and greenwashing.

The key actions in this area include:

- supporting the implementation of the Anti-Greenwashing Directive (2024/825 of 28 February 2024), the Audiovisual Media Services Directive (AVMSD), and the Digital Services Act (DSA) to restrict children's access to harmful content and counter disinformation;
- **implementing strict regulations for technology companies (Big Techs)** that design their products to be addictive, ensuring accountability for their impact on children;
- enforcing strict regulations on traditional and digital media that act as conduits for disinformation and greenwashing;
- **supporting the Green Claims Directive** to promote transparent and verifiable standards for environmental declarations;

<sup>316</sup> NATO, Climate Change and Security Impact Assessment, 2024, https://www.nato.int/nato\_static\_fl2014/assets/pdf/2024/7/pdf/240709-Climate-Security-Impact.pdf.

<sup>317</sup> Team for Addressing Disinformation, Raport Komisji ds. badania wpływów rosyjskich i białoruskich [Report of the Committee for the Investigation of Russian and Belarusian Influence], 2025, https://www.gov.pl/web/sprawiedliwosc/raportzespolu-ds-dezinformacji-komisji-ds-badania-wplywow-rosyjskich-i-bialoruskich.



- prohibiting the advertising of products harmful to health similar to restrictions on tobacco products, bans should be placed on the advertising of highly processed foods, sweetened beverages, and products containing toxic substances. It is worth recalling Article 16B of the Polish Broadcasting Act of 1991, which already prohibits such advertising, though its provisions remain unenforced;
- introducing health warnings on packaging, making them visible and understandable for children on products containing excessive sugar, trans fats, or salt modelled on the labeling system for tobacco products;
- enhancing consumer education and social campaigns aimed at raising awareness about disinformation and greenwashing.

The introduction and effective enforcement of these proposed regulations into national law will reduce the harmful impact of marketing manipulation and disinformation on public health across the EU.

### Environmental Health as the Foundation of Health Education and Training of Medical Staff

Despite alarming data on the impact of environmental factors on public health, this topic is still not given due importance in many EU countries, including Poland, even by healthcare professionals. Research by Prof. Tadeusz M. Zielonka from the Department of Family Medicine at the Medical University of Warsaw<sup>318</sup> indicates that as many as 70% of medical specialists in Poland consider their knowledge about smog to be insufficient. This lack of awareness results in limited discussions with patients about factors that could effectively support treatment. Furthermore, many doctors lack information on the risks associated with consuming processed foods, antibiotic resistance, and excessive use of digital devices.

When conducting patient interviews, doctors rarely ask about daily eating habits and environmental factors, such as living near busy streets or coal-burning stoves. Patients are often not informed that toxins in the air and food can cause chronic and sometimes irreversible health problems. Pregnant women and those planning pregnancy should be particularly aware of these risks to make informed choices about their diet, workplace, and place of residence. These gaps in environmental health education also contribute to patients' and sometimes even medical professionals' susceptibility to health and climate-related disinformation. To effectively counter these challenges, **postgraduate education for doctors and other healthcare professionals must be introduced and expanded** to include mandatory modules on the impact of air pollution and climate change on public health, the diagnosis and treatment of climate-related and vector-borne diseases, nutritional prevention, the fight against antibiotic resistance, and lifestyle medicine.

A crucial step towards preparing society to take responsibility for public health is the Polish government's initiative to **introduce health education as a mandatory subject in schools.** The health education curriculum covers key environmental health topics such as air quality and climate change, the importance of a healthy diet and physical activity, digital hygiene, and the consequences of excessive electronic device use. Although the concept of health education has been criticised by some political circles, it is essential to depoliticize this issue, as children's health should be treated as a non-partisan priority.

**Public media** should play a key role in this process, as their statutory obligation to support civic and health education is often neglected. Polish and EU public media should provide reliable information on environmental health, promote pro-health attitudes, and encourage preventive measures. Medical professionals should actively participate in disseminating knowledge and promoting preventive strategies. Within the framework of educational activities, doctors could also provide recommendations on prevention, such as advising patients to avoid exposure to smog during peak pollution periods.

<sup>318</sup> The study was conducted in 2017 on a sample of 500 specialist doctors with an average age of 55. For more information, see "70 procent lekarzy uważa swoją wiedzę o smogu za niewystarczającą. Dr Zielonka: "Zaskakująca jest skala problemu" [Seventy per cent of doctors consider their knowledge of smog insufficient. 'The scale of the problem is surprising,' says Dr Zielonka.], Smoglab, 2021, https://smoglab.pl/70-procent-lekarzy-uwaza-swoja-wiedze-o-smogu-za-niewystarczająca-doktor-tadeusz-zielonka-zaskakująca-jest-skala-problemu/.



## Postulate: The Polish Presidency should initiate actions to promote awareness of environmental health, risk factors for lifestyle and cancer diseases, and effective prevention methods to build informed and resilient communities.

Key actions should include:

- introducing health education as a mandatory subject in school curricula across Poland and other EU countries;
- integrating environmental health into medical training programmes by incorporating modules on environmental health impacts into university curricula and specialised training for healthcare professionals;
- including health education in the mission of public media at both national and EU levels to raise public awareness of environmental health impacts;
- promoting interdepartmental public awareness campaigns on the risks associated with air pollution, poor diet, sedentary lifestyles, and excessive digital device use;
- **implementing EU educational programmes** that integrate public health and environmental issues.

Health education and awareness of environmental impacts on public health are crucial for making informed health decisions and effectively countering threats resulting from environmental and lifestyle factors.

### Schools as a Hub for Comprehensive Prevention to Meet 21st-Century Challenges: A Review and Implementation of the Most Effective European Programmes

As health challenges affecting children and adolescents continue to grow in complexity, comprehensive school-based prevention programmes must be implemented. The starting point for these efforts should be **a review of the best European preventive practices in schools**, which not only educate students but also influence entire local communities. Particularly noteworthy are programmes implemented in Nordic countries under the **NordicHealth** concept, which integrates educational, environmental, and health initiatives to promote both individual and community well-being.

Denmark provides numerous best-practice examples, such as the creation of green zones around schools to protect children from smog, exhaust fumes, and noise, while simultaneously promoting physical activity and contact with nature. This initiative benefits both the physical and mental health of students, enhancing their concentration and academic performance. Sweden has improved air quality in schools by introducing modern ventilation systems and reducing car traffic around school premises, leading to a significant decrease in asthma, allergies, and respiratory infections. Finland has developed a comprehensive school programme integrating healthy nutrition, physical activity, and digital hygiene. Regular physical education classes and lessons on responsible technology use help prevent digital addiction and support healthy habits.

Western European countries have also taken important steps. France has introduced a policy requiring 50% organic food in school canteens, ensuring that half of all school meals come from organic and local sources. This initiative supports local farmers while reducing childhood obesity and improving nutrition quality. German and Dutch initiatives focus on tackling childhood obesity through integrated educational activities. Additionally, many school areas now feature air quality monitoring, speed limits of 30 km/h, and special school streets (**Streets4Kids**), which are closed to traffic during student drop-off and pick-up hours. These programmes serve as models that could be adapted across the EU, taking into account local challenges and conditions, to integrate educational and environmental measures aimed at improving public health and safety.

Postulate: The Polish Presidency should initiate a European review of best preventive health practices for children and adolescents and develop a catalogue of recommended actions at the local community level.



The key components of school-based prevention programmes for student health are as follows:

- safe streets and school surroundings strategies to enhance traffic safety near schools, including car-free zones;
- Streets4Kids designated zones closed to car traffic during drop-off and pick-up hours to improve safety and protect children from smog and noise pollution;
- air quality monitoring measuring air pollution levels inside and outside educational institutions, paired with a communication and education system for both children and adults;
- creation and revitalisation of green zones near schools ensuring students have access to high-quality green areas that promote physical activity, interaction with nature, and mental health;
- promotion of environmentally friendly investments infrastructure projects supporting active lifestyles, such as bicycle lanes, playgrounds, parks, and sports facilities, which enhance children's health and learning environments;
- healthy meals and eating habits incorporating nutritional education and setting higher food standards in school canteens, including the EAT-Lancet diet;
- **EAT-Lancet diet and local public procurement** ensuring schools source fresh, healthy foods while supporting local agriculture;
- sustainable resource and waste management implementing efficient practices to reduce energy and food waste;
- **promotion of active mobility** encouraging **walking** and **cycling** to school among students, parents, and staff;
- digital hygiene;
- education on health and environmental issues.

The implementation of these measures will strengthen the resilience of younger generations, foster healthier and more informed local communities, and reduce the economic burden of lifestyle diseases.

### Coalition for Children's Health. Strategic Partnership with Denmark and Cyprus

Achieving real progress in improving children's health in the EU requires building a coalition of countries committed to this goal. The Polish Presidency of the Council of the EU has a unique opportunity to initiate this process by inviting the countries taking over the Presidency in the coming months, such as Denmark and Cyprus.

Particular attention should be paid to the partnership with Denmark, which for years has set high standards for the integration of health and environmental policies, developing modern health systems and a health-conscious society. The partnership with Denmark could include joint actions to promote best practices in the areas outlined in previous proposals, including the implementation of the Ambient Air Quality Directive, the review of school prevention programmes, the promotion of a planetary diet, and counteracting greenwashing and health disinformation. Joint actions based on Denmark's best practices could become the cornerstone of a modern EU strategy for children's health.

Similarly, it is important to include Cyprus, which – despite its geographical specificity – can play a key role in developing sustainable policies in areas sensitive to climate change. This is crucial in protecting the health, future, and security of the youngest generation. Cooperation between Poland, Denmark, and Cyprus would ensure a comprehensive approach to health and environmental challenges, encompassing diverse climatic, social, and economic conditions in the European Union.

# Postulate: The Polish Presidency should launch a coalition for children's health, in which a strategic partnership with Denmark and Cyprus will become the foundation for integrating health and climate policies, building more resilient and healthier EU societies.

This coalition should not only enhance children's health in Europe but also facilitate the integration of health and climate policies, strengthening societal resilience to contemporary challenges.



Finally, it is essential to emphasise that programmes and solutions for the prevention of lifestyle diseases are inextricably linked to climate policies. While the primary focus is on children's health, it is worth noting that what benefits children – clean air, healthy food, access to nature, and education – also serves society as a whole. These measures improve overall quality of life and strengthen the foundations of sustainable development. Many of the proposed actions can also support the prevention of diseases of old age, as older individuals, alongside children and pregnant women, are particularly vulnerable to lifestyle and environmental diseases.

However, implementing these recommendations requires moving beyond traditional approaches and establishing interdepartmental cooperation that integrates health, environmental, and educational policies in a cohesive, long-term manner. We call for bold and strategic decisions in which, regardless of geopolitical circumstances, the priority of children's health, future, and safety remains at the centre. Public health policy, particularly in the face of contemporary challenges, must transcend ideological divisions and be treated as a cross-party priority, aimed at securing the well-being of future generations. We believe that the Polish Presidency, supported by experts and the non-governmental sector, can serve as a catalyst for groundbreaking actions on a European scale in this area.

"We don't inherit the Earth from our ancestors, we borrow it from our children." This thought by Antoine de Saint-Exupéry should guide all our actions.

### Women at the Centre Association

### Wiesława Rybicka-Bogusz

President of the Mazovia Regional Branch of the Women at the Centre Association

Women at the Centre Association is a national civil society organisation that focuses on supporting and strengthening the role of women in various aspects of social, political, economic, and healthrelated life. It was created on the initiative of women who recognised the need to act for equality, preventive healthcare, and the development of local communities. Currently, the organisation consists of 16 regional branches, including the largest, the Mazovia Regional Branch. Magdalena Sobkowiak-Czarnecka serves as the Association's President.

The members of the Association include:

- 1. Local community leaders: Women actively engaged in their communities, undertaking initiatives to improve the quality of life of residents and supporting women in achieving their goals.
- 2. Experts in various fields: Women representing a range of professions and specialisations, such as education, medicine, business, law, culture, and public administration. This diversity enables them to offer comprehensive support and undertake initiatives across a wide spectrum of topics.
- 3. Ambassadors of social change: they promote the idea of women's solidarity, potential building, and involving women in decision-making processes at local, regional, and national levels.

The Association is not only a leader in social and preventive healthcare activities but also a space where every woman can find support, develop her skills, and actively participate in public life. Through its activities, Women at the Centre transforms the lives of many women for the better, inspiring them to take action and advocate for their rights.

### **Key Initiatives and Projects**

### **Breast Cancer Prevention**

The Association organises events such as the Pink March, mammography screenings in mobile units, and workshops on breast self-examination. It educates women about health through lectures, social media campaigns, and the distribution of educational materials.



### A Healthy Polish Woman in Europe

This project aims to raise awareness of women's health in the European context. The Association promotes best practices that can be implemented in Poland during its Presidency of the Council of the EU.

### **Supporting Women in Politics and Business**

The Association runs a mentoring programme for women who wish to advance their professional careers or become involved in public life. It also organises discussion panels featuring experts from various fields.

### **Promoting Gender Equality**

The Association conducts workshops on women's rights, equal employment opportunities, and work-life balance. It supports women in building self-confidence and assertiveness.

### Support for Women in Difficult Life Situations

The Association collaborates with social welfare centres, organises fundraisers for women in need of material or financial assistance, and provides crisis intervention services addressing, for instance, domestic violence.

### **Regional Leadership Academy**

The Regional Leadership Academy is a flagship programme designed to strengthen the role of women as leaders in their communities. The project focuses on developing leadership, social, and organisational skills while inspiring participants to take on new challenges.

The Academy organises workshops, training sessions, mentoring, and networking opportunities. The most engaged participants receive distinctions and opportunities to participate in national and international projects. The Academy has already helped hundreds of women become leaders in their regions, engaging in initiatives related to education, health, environmental protection, and gender equality.

### How Women at the Centre Can Contribute to Poland's EU Council Presidency

### Leadership in Preventive Healthcare

Poland, through the Association's activities, could propose the establishment of a common EU standard for breast cancer prevention. A project could be initiated in which each Member State commits to improving population-level access to screening programmes.

### **Promoting Education and Cooperation**

The Association could organise an international conference featuring experts, health ambassadors, educators, prevention specialists, and government representatives to share best practices and develop joint solutions.

### **Proposing Legislative Actions**

Introducing an EU Council Resolution on equal access to screening and support for women affected by breast cancer.

### **Main Areas of Activity**

### **Preventive Healthcare and Health Education**

The Association actively promotes preventive healthcare, particularly in the areas of breast cancer and cervical cancer. It organises educational campaigns, outdoor events, workshops, and conferences to raise women's awareness of the importance of preventive screenings. It also supports women post-diagnosis by offering psychological assistance and information on available treatments.



### **Empowering Women**

The Association provides training and workshops for women looking to develop their professional and social skills. It promotes gender equality and combats discrimination in the workplace and public life. It also supports women in difficult life circumstances, including survivors of domestic violence and single mothers.

### **Civic and Social Engagement**

The Association encourages women to participate in civic activities, including public consultations, local projects, and collaboration with local authorities. It also promotes women's participation in politics and their presence in decision-making structures.

### **Development of Local Communities**

Women at the Centre works with local organisations and governments to implement projects targeting local communities. It builds support networks for women in small towns and rural areas.

### **International Cooperation**

The Association establishes partnerships with similar organisations across Europe and globally, exchanging experiences and best practices. It advocates for the adoption of European standards in preventive healthcare and women's rights.

### Core Values of Women at the Centre

The Association is guided by values such as solidarity, equality, education, development, and commitment. Mutual support among women, regardless of age, place of residence, or life experience, is the foundation of its work. It promotes equal opportunities for women and men in all aspects of life, prioritises education as a key to personal and social development, and actively engages in shaping local communities by driving meaningful change in policy and the economy.

### **GrowSPACE** Fundation

### Dominik Kuc

Member of the Board of the GrowSPACE Foundation

### Polish Presidency of the Council of the European Union Recommendations in the Area of Healthcare – the System Through the Eyes of a Young Patient

The Polish Presidency of the Council of the European Union 2025 presents an excellent opportunity to highlight the priorities of the younger generation in the field of health. As the GrowSPACE Foundation, we monitor the needs of the youngest patients and assess systemic responses to the challenges faced by Generation Z and Generation Alpha. The Polish Presidency should therefore focus on agency, strengthening mental health, and ensuring continuous efforts to promote the wellbeing of young people.

Young patients require adequate support from the mental health care system. But how does this system look from their perspective? What actions should be taken to make it truly effective for young people? Below are the key challenges and recommendations.

### Key Challenges in the Mental Health System

The primary challenges young people face in the mental health care system include the lack of early intervention and a sense of confusion, which delays access to appropriate support. These elements should be at the heart of the solutions and recommendations put forward during the Polish Presidency.

First and foremost, schools should actively collaborate with the healthcare system to monitor, detect, and respond at an early stage. Coordinating education and healthcare is crucial in developing what is known as the Ground Level - a framework encompassing all preventive,

psychoeducational, and mental health monitoring activities that take place before a young person formally enters the healthcare system. These efforts should be implemented in schools, ensuring that the widest possible group benefits from early support. School psychologists can play a key role in early intervention, but emotional first aid and the identification of initial symptoms can also be carried out by form teachers. It is important to focus on monitoring mechanisms – not only assessing individual well-being but also tracking the collective well-being of groups, classes, and school communities. In August 2024, the **GrowSPACE Foundation** published a report revealing that 308 municipalities in Poland still lacked a single school psychologist (based on public data collected from local governments and school organizational reports). While employment in this area increased by three percentage points compared to 2023, there remains a 23% national shortfall in school psychologist positions. There is still significant work to be done in building a sustainable early prevention framework. Beyond the issue of availability, there are also concerns regarding the quality of psychological support provided in schools. Key improvements could include clear professional standards, access to supervision, dedicated psychological offices in schools, and greater autonomy for school psychologists within educational teams.

Another major concern is the prevalence of **secondary stigmatisation** of young people experiencing mental health crises. This additional burden exacerbates the challenges already faced by children and adolescents in distress. From a young age, they may encounter peer rejection for visiting the school psychologist or misunderstanding of their struggles by adults. According to research conducted as part of the **Straighten Your Gaze** campaign, 25% of respondents witnessed instances of mistreatment towards individuals with mental health disorders, and 4% experienced such treatment themselves. Manifestations of secondary stigmatisation include social exclusion, lack of respect, and dismissal of a young person's opinions. Staying in a day ward or a stationary ward is a particularly difficult moment. Particularly vulnerable are **children and adolescents returning to school after hospitalisation or treatment in day psychiatric wards**. These individuals often face ridicule, rejection, or isolation from their peers. Additionally, they experience heightened academic pressure, with expectations to quickly catch up on missed tests, assignments, and exams. This transition period demonstrates a critical area for collaboration between the healthcare and education systems – ensuring that young people move seamlessly from medical facilities back into educational settings.

Secondary stigmatisation is often reinforced by deep-seated **stereotypes** surrounding mental health in child and adolescent psychiatry. From an early age, students are exposed to harmful narratives such as "going to the psychologist is a punishment" or "depression can be cured by exercise". If someone has a panic attack, they are told to "pull themselves together" and focus on their studies. These misconceptions create barriers to seeking help, encourage the trivialisation of mental health concerns, and delay early intervention. According to data from Dr Aleksandra Lewandowska, the National Consultant for Child and Adolescents Psychiatry, as many as 70% of children and young people in crisis should receive support through psychosocial interventions. Only around 10% require hospitalisation. This underscores the urgent need for stronger early intervention strategies and greater mental health awareness among young people and their communities.

### Recommendations and Priorities of the Polish Presidency of the Council of the European Union

Since January 2025, Poland has held the Presidency of the Council of the European Union. The foundation of our country's initiatives will be security in various aspects. The key health priorities include the mental health of children and adolescents, public health, prevention, the digitisation of healthcare, and pharmaceutical security. Particularly significant is the fact that **mental health is finally becoming one of the key issues and priorities on the European Union's agenda**. As the GrowSPACE Foundation, we present several key recommendations on health protection within the framework of the Polish Presidency's priorities for the Council of the EU in 2025, with a particular focus on mental health. It is important to note that these issues require long-term action at the EU level, serving as a compass for future years.



Our recommendations stem from direct engagement and psychoeducational work with young people. They are based on the challenges faced by young patients and propose systemic solutions that should be considered during the Polish Presidency.

Key recommendations for the Polish Presidency include the following:

- Strengthening Prevention and Ground Level care. From the perspective of preventing mental health crises, universal psychoeducation is key. It serves as a protective barrier, helping to avert many severe cases. Health education should be a compulsory part of the curriculum in schools, not only in Poland but across the entire European Union. Knowledge about health should be delivered in a reliable and age-appropriate manner to all students.
- Destigmatisation of Mental Health Issues. Tackling Societal Challenges The Polish Presidency should focus on supporting people in crisis while also launching EU-wide social campaigns aimed at educating the broader population. The primary objectives should include increasing awareness, reducing stigma, and promoting the importance of mental health support.
- Improving Access to Psychological and Psychiatric Care Young people should have unhindered access to outpatient psychological and psychiatric care. The most effective support is that which is integrated into their immediate environment. The Polish Presidency should focus on equalising access to mental health services across regions, ensuring that young people in rural areas and small towns receive the same level of care as those in major cities. In many EU countries, there is a growing shortage of mental health specialists, as many are moving to the private sector or relocating to larger urban centres. Expanding access to care should involve several strategic approaches, including ensuring the presence of school psychologists in all schools, increasing access to psychiatric consultations, and introducing regulatory frameworks for the profession of psychologist to maintain high standards of care.
- **Psychological Safety Standards for Online Spaces** For Generation Z and Generation Alpha, the online world and the physical world have merged into a single reality. This shift has redefined core aspects of human interaction, including relationships, social connections, and peer support. However, the digital environment also exposes young people to new risks, such as online bullying and violence, access to harmful and inappropriate content, smartphone addiction, disinformation and misleading content. Given that the digitalisation of healthcare is one of the Polish Presidency's priorities, efforts should be made to develop EU-wide psychological safety standards for children and adolescents online. This should encompass policies on smartphone use in schools as well as broader measures addressing the psychological impact of digital technologies on youth.
- Strengthening Cooperation Between the Health and Education Systems Addressing mental health challenges effectively requires close collaboration between the healthcare and education sectors. Schools play a crucial role in providing young people with their first point of access to mental health support, including preventive measures and early interventions. Cooperation must occur at multiple levels, including direct collaboration between schools and mental health services, but also interdepartamental coordination to ensure comprehensive policy implementation. This is a crucial aspect of the Polish Presidency's priorities: mental health is an interdisciplinary issue so responsibilities must be shared between multiple governmental departments to create an effective and cohesive support system.

### Summary

The Polish Presidency of the Council of the European Union 2025 presents a unique opportunity to prioritise youth agency in the healthcare system. The GrowSPACE Foundation has outlined the most pressing challenges and key recommendations for Poland's Presidency. The most significant challenge is the lack of early intervention for mental health crises among children and adolescents. This issue is exacerbated by insufficient investment in Ground Level prevention and early intervention mechanisms, as well as social stigma and stereotypes surrounding mental health. To address these challenges, the Polish Presidency should focus on: strengthening mental health prevention and education, fostering cooperation between the healthcare and education systems, expanding access to mental health support services, and implementing psychological safety standards for online spaces.



### **Summary and Conclusions**

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"In the area of health security, every citizen of Poland and the European Union has the right to health, which means equal access to healthcare..."

Lech Wałęsa

"Poland has the potential to become a leader in developing solutions that will have a tangible impact on the lives of Europeans. By making responsible use of this opportunity, Poland will contribute to building a stronger, healthier, and more secure Europe."

Magdalena Sobkowiak-Czarnecka

"The Polish Presidency of the Council of the European Union marks a pivotal moment for the EU's future, particularly in the area of health security. Our role as a Member State is to bolster the role of healthcare within the EU and to enhance the health and quality of life of EU citizens."

Małgorzata Bogusz

These are quotes from Lech Wałęsa, Magdalena Sobkowiak, and Małgorzata Bogusz from the opening pages of the White Paper *Polish Presidency of the Council of the European Union 2025. Healthcare Policy Recommendations.* They highlight the significance of our Presidency at this crucial moment and underscore the central role of health within it.

New risks to European security have emerged: Russia's aggression and the pandemic. They have disrupted peace and stable development, adding to the existing challenge of lifestyle diseases – long-recognised factors influencing health and life expectancy on our continent and in Poland. Both new and longstanding threats now collectively pose a significant challenge, not only to the security of every citizen but also to various communities, nations, and the entire European society.

The extension of life expectancy is one of humanity's greatest achievements, particularly evident in European Union countries. However, what truly matters is the quality and security of old age, which depends on state organisation, including healthcare systems and economic potential, but above all on generational replacement. This presents yet another major challenge. When we factor in a low birth rate, a growing proportion and number of people in post-working age, and both longstanding and emerging risk factors – traditional lifestyle-related risks such as diet, physical activity, alcohol, and tobacco use, alongside new threats with profound implications for population health, including climate change, the escalating mental health crisis, and widespread distrust in medical advances fuelled by misinformation and fake news on social media – Europe's health security remains a formidable challenge.

Therefore, while the overarching priority of the Polish Presidency of the Council of the European Union is Europe's security – primarily in response to Russia's aggression in Ukraine and the potential threats facing other countries, particularly in Central and Eastern Europe – it must also encompass health security. A strong, healthy population is essential for tackling new challenges and addressing mounting economic and international issues. It is also key to driving the innovations



that propel global change, including in healthcare systems. As a Member State, Poland's role will be to strengthen the position of healthcare within the EU and to improve the health and quality of life of its citizens – through the development and application of new technologies, particularly artificial intelligence.

Meeting these challenges is also dependent on health, as a healthy state is built on healthy citizens. Without the well-being of our European communities, there will be no promising prospects for development, problem-solving, or addressing new challenges. A nation that prioritizes the health of its people fosters economic growth – essential not only for overall progress but also for sustaining and advancing healthcare systems. This creates an important feedback loop from organizational, financial, and political perspectives, offering a positive outlook for European nations and ensuring a sense of well-being for their citizens.

All participants in the debates held as part of the Road to the Presidency series, which has been ongoing for two years, emphasise the importance of preventive healthcare. This is reflected in the contributions of the authors of this White Paper. Politicians are also writing and speaking about it, marking a significant shift. The fight against disease – once the exclusive domain of public health specialists – is now increasingly recognized by clinicians, a wide range of healthcare professionals, and representatives of nations within EU institutions, Member States, and even local communities. It is worth recalling an important yet somewhat overlooked principle: **health is a national asset and warrants special state protection**. Equally relevant is another guiding motto from Poland's first Presidency of the Council of the European Union: **old age begins in childhood**. Therefore, during the current Presidency, Poland is addressing some of the most pressing health challenges: health innovation, with a strong focus on e-health, disease prevention, based on universal health education from an early age, and mental health, as a fundamental pillar of well-being and the sustainable development of European societies.

Pharmaceutical security should be added to the list of key EU priorities pursued during our Presidency. In recent years, the European Union has shifted its approach to health, drawing on new experiences, including those from the pandemic. Health is no longer solely delegated to the policies of individual Member States but is increasingly regarded as a common good that should also be managed at the EU level, both by the European Commission and the European Parliament. This perspective is reflected in the contributions of Polish representatives within these institutions, as well as in the insights of Polish politicians, whose chapters can be found in this extraordinary and comprehensive publication that we proudly present to you.

Everyone involved in this work, as well as those who have observed this dedication, are grateful for the efforts undertaken to ensure that the Polish Presidency of the Council of the European Union leaves a lasting mark, paving the way for a new era in health policy across our continent. I would like to extend my deepest gratitude to the Institute for Social Policy Development for its commitment to fostering a two-year-long debate, which has served as the foundation for the document you now hold in your hands. Let us all work to ensure that its influence continues to shape health policies not only within the European Union and its Member States but, above all, in our homeland, Poland.

fai

Bolesław Samoliński

The White Paper summarizes the series of debates and conferences titled "Path to Presidency" held from 2023 to 2025 under the patronage of:



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