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# OPENING REPORT

# QUO VADIS, TRIO?

WARSAW, JANUARY 2024





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**Institute for Social  
Policy Development**



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## Foreword



### **Małgorzata Bogusz**

*President of the Institute for Social Policy Development  
Member of the European Economic and Social Committee  
for 2020-2025*

Dear readers,

It is my great pleasure to present you the Report, serving as introductory material for the participants of our conference entitled “The Pathway to the Presidency”.

This is already the third event organized by the Institute for Social Policy Development in a series dedicated to the Polish presidency. Discussions conducted in this format aim to develop proposals for Poland’s health agenda during the Polish Presidency of the Council of the European Union in the first half of 2025. During this period, our country will help shape the EU’s political agenda, coordinate the work of the Council, and represent the interests of the Member States on the international stage.

The Polish Presidency comes at a crucial time for the future of the European Union – we will have to face numerous both external and internal challenges. Health issues will be of particular importance among them, especially in the context of the post-pandemic recovery. The implementation of the Green Deal, digital transformation, and strengthening solidarity within the Union, including in the context of the crisis related to the Russian invasion of Ukraine, will be extremely relevant.

There is no doubt that healthcare will be one of the key areas of the Polish Presidency. Health is the topic that affects every single citizen of the European Union and has an impact on many other areas, such as the economy, society, the environment, and security. Healthcare requires constant adaptation to changing conditions, challenges, and needs.

As representatives of Poland, we possess extensive expertise in the establishment and enhancement of healthcare systems. Over the past decades, we have made significant changes and improved the quality, efficiency, and availability of our system. We have increased healthcare spending, introduced new organisational and financial solutions, expanded

infrastructure and human resources, introduced technological and digital innovations, and promoted prevention and health education. While significant progress has been made, we have faced challenges and issues that continue to demand our attention and efforts.

Therefore, our goal as a Member State should be to strengthen the role of healthcare in the European Union and improve the health status and quality of life of citizens. We want our presidency to be a driving force, a catalyst for a resilient and accessible healthcare system for patients in need, regardless of national borders or income levels.

However, to optimally capitalise on this opportunity, we must show vision, initiative, and the ability to build compromises and coalitions, even with those representing different perspectives. Therefore, we are pleased that our events bring together representatives of public administration, decision-makers, and numerous European institutions. As a think tank working towards shaping health policy, we will do our utmost to create a field for cooperation and act across political boundaries to achieve the best results for Poland and Europe.

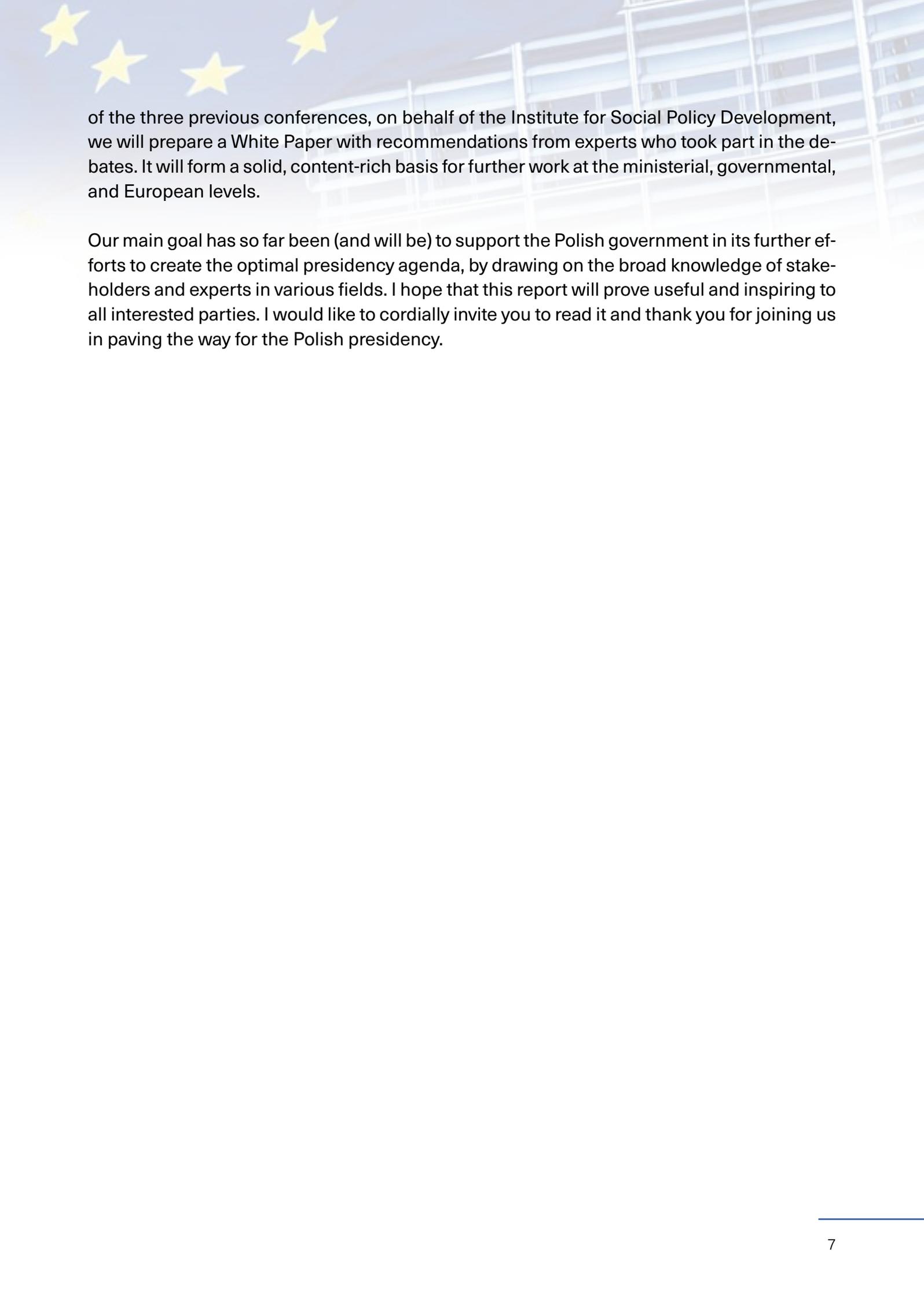
To use the time of our presidency effectively, it will be equally important to maintain close cooperation and dialogue with the EU institutions and civil society, and perhaps especially with other countries holding the rotating presidency together with Poland. It is therefore essential to start preparing the presidency agenda now, one year before taking over the presidency, drawing on the broad knowledge and involvement of stakeholders from different backgrounds.

This holds importance as conferences hosted by the Institute for Social Policy Development, focusing on the presidency, serve as a unique platform for developing proposals for a rotating presidency agenda. For the third time, we gather to work on these demands with a group of distinguished experts from a range of fields, representatives of public authorities, clinicians, healthcare industry representatives, and patient organizations. Our meetings are not only a source of valuable information and analyses, but also a place to exchange views and experiences, identify key issues, and develop a common position and standpoint.

To facilitate the implementation of these ambitious tasks, we have prepared this report, to serve as introductory material for participants at our conference entitled „The Pathway to the Presidency.” The following topics are covered in the report:

- the practical functioning of the rotating presidency of the Council of the European Union,
- the priorities of the countries that have held the rotating presidency in recent years,
- important legislative changes that will be the subject of the Polish Presidency's legislative and implementation work.

The purpose of this document is to provide you with knowledge that will serve as a starting point for discussion during the „Pathway to Presidency” event. Based on the conclusions



of the three previous conferences, on behalf of the Institute for Social Policy Development, we will prepare a White Paper with recommendations from experts who took part in the debates. It will form a solid, content-rich basis for further work at the ministerial, governmental, and European levels.

Our main goal has so far been (and will be) to support the Polish government in its further efforts to create the optimal presidency agenda, by drawing on the broad knowledge of stakeholders and experts in various fields. I hope that this report will prove useful and inspiring to all interested parties. I would like to cordially invite you to read it and thank you for joining us in paving the way for the Polish presidency.

## **From priorities to conclusions: preparing and implementing the EU Council presidency based on the experience of the 2011 Polish Presidency**



**Prof. Bolesław Samoliński MD Ph.D.**  
*Chairman of the Subcommittee on Health Priorities  
of the 2011 Polish Presidency Corps*

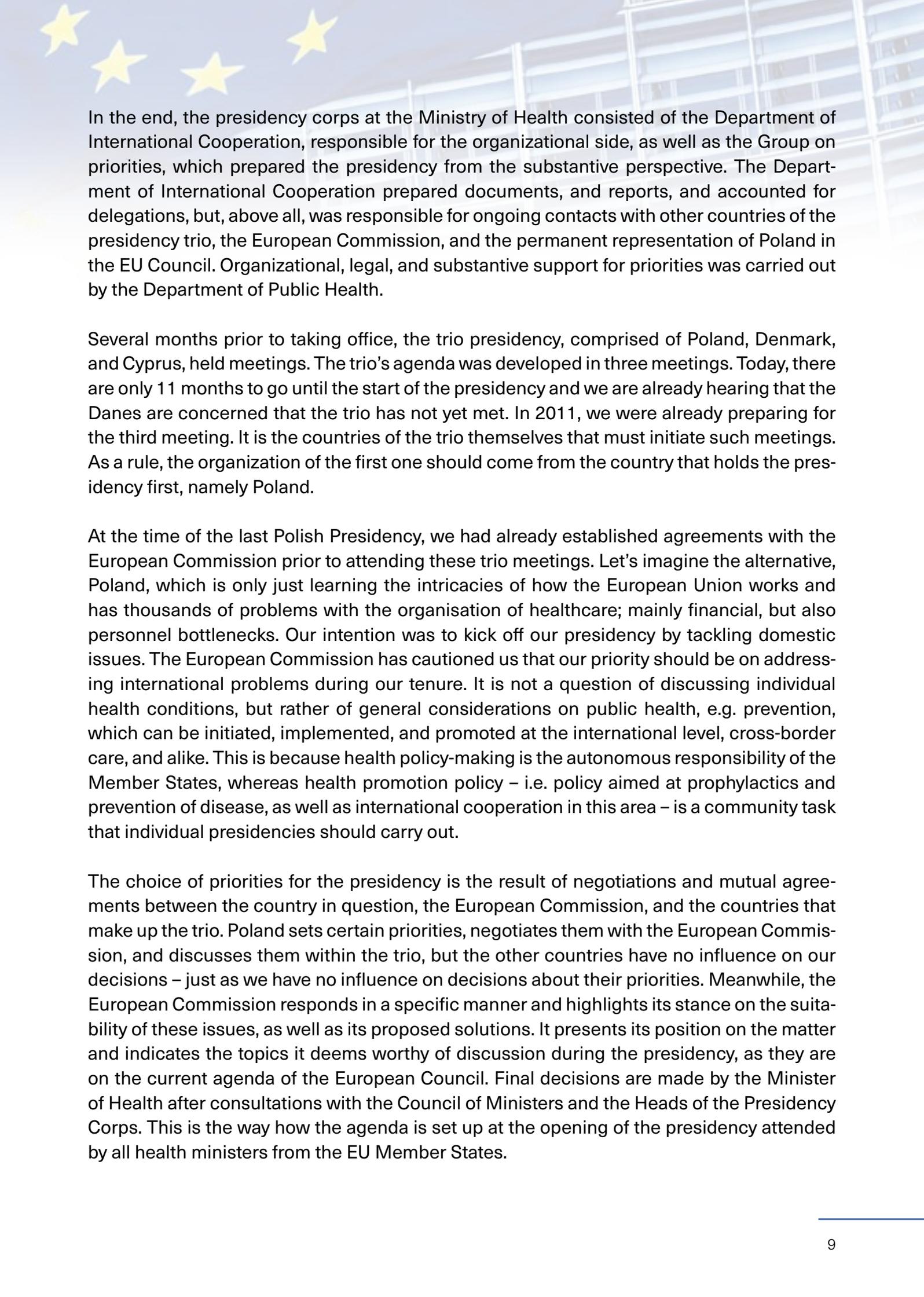
As Poland, we will soon be taking on another, the second EU Council presidency in history. It is therefore high time to reflect on the experience we gained in 2011 when we took over the presidency of the Union for the first time. It would be a shame if we did not utilise the lessons we learned from that period.

A presidency corps was set up about three years before the start of this period, within the framework of which we received language training in specialist terminology, as well as in the area of EU organisation and EU negotiations and 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 for us. It provided us with a thorough understanding of the Union's procedures at each stage and the presidency's key priorities, as well as the resulting conclusions.

In preparation for the presidency, we have begun to form a corps and conduct negotiations. I was approached by Deputy Minister Adam Fronczak, responsible for international policy and the Presidency on behalf of the Ministry of Health, who proposed that I lead a Group on priorities within the Ministry of Health. I accepted the responsibility. Thus, I additionally became the Deputy of Agnieszka Czapryniak, then Chairwoman of the Public Health Working Party at the European Commission.

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. Those trainings brought us on equal footing with major EU countries during our presidency.



In the end, the presidency corps at the Ministry of Health consisted of the Department of International Cooperation, responsible for the organizational side, as well as the Group on priorities, which prepared the presidency from the substantive perspective. The Department of International Cooperation prepared documents, and reports, and accounted for delegations, but, above all, was responsible for ongoing contacts with other countries of the presidency trio, the European Commission, and the permanent representation of Poland in the EU Council. Organizational, legal, and substantive support for priorities was carried out by the Department of Public Health.

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. Today, there are only 11 months to go until the start of the presidency and we are already hearing that the Danes are concerned that the trio has not yet met. In 2011, we were already preparing for the third meeting. It is the countries of the trio themselves that must initiate such meetings. As a rule, the organization of the first one should come from the country that holds the presidency first, namely Poland.

At the time of the last Polish Presidency, we had already established agreements with the European Commission prior to attending these trio meetings. Let's imagine the alternative, Poland, which is only just learning the intricacies of how the European Union works and has thousands of problems with the organisation of healthcare; mainly financial, but also personnel bottlenecks. Our intention was to kick off our presidency by tackling domestic issues. The European Commission has cautioned us that our priority should be on addressing international problems during our tenure. It is not a question of discussing individual health conditions, but rather of general considerations on public health, e.g. prevention, which can be initiated, implemented, and promoted at the international level, cross-border care, and alike. This is because health policy-making is the autonomous responsibility of the Member States, whereas health promotion policy – i.e. policy aimed at prophylactics and prevention of disease, as well as international cooperation in this area – is a community task that individual presidencies should carry out.

The choice of priorities for the presidency is the result of negotiations and mutual agreements between the country in question, the European Commission, and the countries that make up the trio. Poland sets certain priorities, negotiates them with the European Commission, and discusses them within the trio, but the other countries have no influence on our decisions – just as we have no influence on decisions about their priorities. Meanwhile, the European Commission responds in a specific manner and highlights its stance on the suitability of these issues, as well as its proposed solutions. It presents its position on the matter and indicates the topics it deems worthy of discussion during the presidency, as they are on the current agenda of the European Council. Final decisions are made by the Minister of Health after consultations with the Council of Ministers and the Heads of the Presidency Corps. This is the way how the agenda is set up at the opening of the presidency attended by all health ministers from the EU Member States.

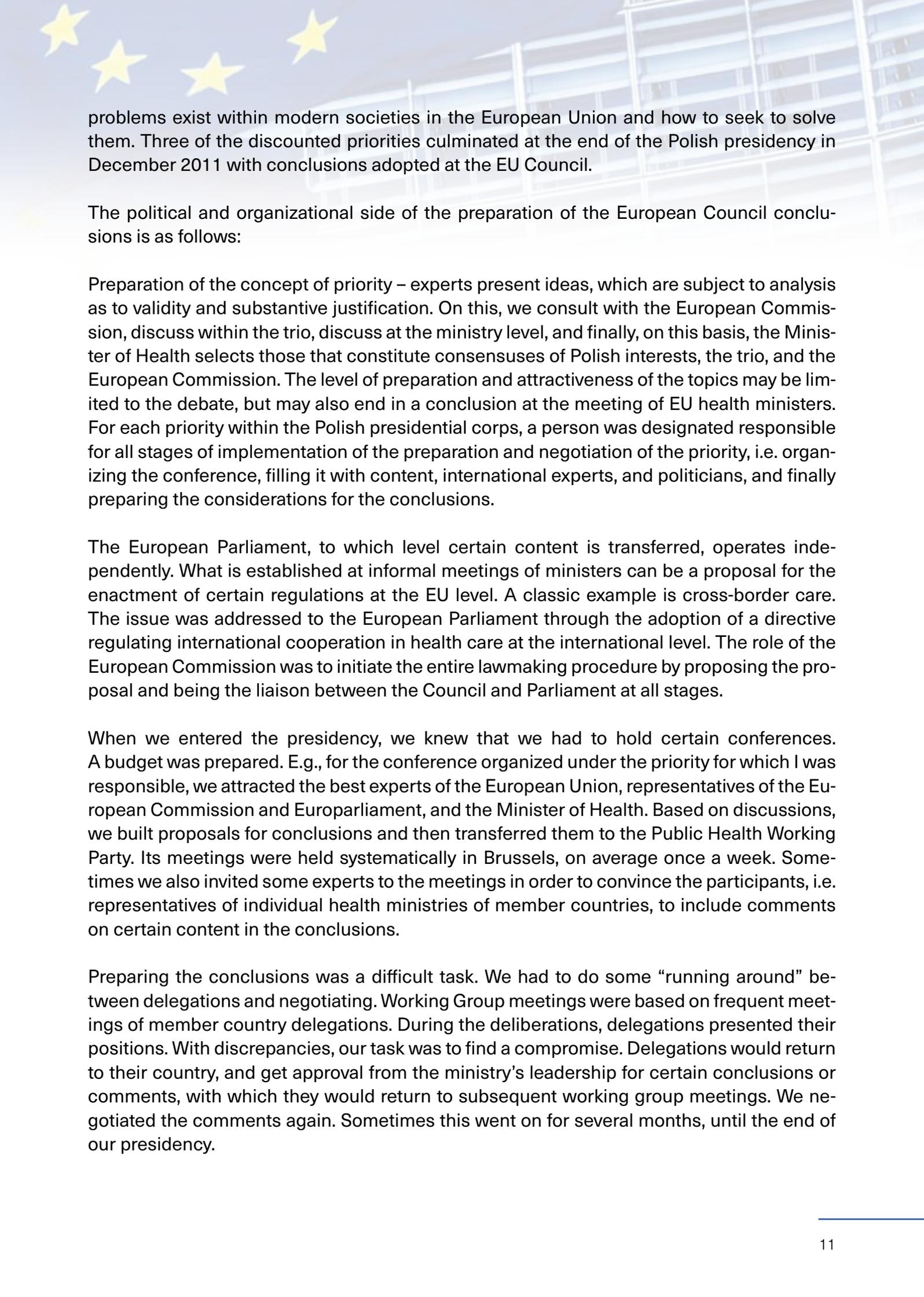
External experts, i.e. those invited to cooperate by the Ministry of Health, took part in the preparation of the substantive side of the Polish Presidency of the EU Council. Their proposals were discussed at meetings of the Group on priorities. Being the chairman of the Group, I managed the work of all the stakeholders on the topics raised and eventually presented a set of a dozen topics to the leadership of the Ministry. The final decision on which of them were to apply during our Presidency of the EU Council was made by Minister Ewa Kopacz, together with Deputy Minister in charge of the Presidency Adam Fronczak. This was still in the “pre-presidential” period. Within the sub-group for priorities, we met on average once a month for a year and a half and discussed these priorities. Initially, we had at least 15 of them!

At the Sopot meeting of ministers in early July 2011, we showed that we are a modern country that thinks innovatively on health issues at the international level and understands what might be of interest to the Member States and what is the most topical area that we should draw on and discuss. And I think that was incredibly important. Because the presidency plays an additional important role in promoting the country. If it's just about getting through, then I just see that as a waste of an opportunity – a loss of chances to show and promote ourselves, and above all to put on the table of the EU debates topics that are vital for Poland. We lose the opportunity to be present in the Union, to show ourselves again as a country that can play an important role in Central and Eastern Europe, that should be considered as a country with a certain level of diplomatic and political preparedness, that thinks in a modern and innovative way.

The opening of the presidency showcases certain priorities, while other matters that no longer originate from the European Commission are discussed. For example, when we started in Sopot in 2011, in addition to presenting and discussing our priorities, there was also a presentation on hearing disorders and the epidemiology of hearing disorders in Poland and around the world – one of priorities then. 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 therefore society. Backstage, prof. Skażynski set up stands for the delegation members to get their hearing tested, adding to the overall appeal of the meeting.

The implementation of the priorities should begin immediately after the inauguration ceremony of the presidency. Each priority involves a specific debate at the international and expert level organized as part of a conference. Poland prepared 5 conferences. We implemented two of them at the Medical University of Warsaw, and one in Poznan. The motto of the Polish Presidency was the slogan prepared by me and approved by the leadership of the Ministry: “Old age (aging) begins in childhood.” It combined issues of diseases of the central nervous system (2010 was the year of the brain in Europe), problems of senior citizen policy, public health, and issues of diseases of the developmental period, which were an important part of the prepared priorities of the presidency.

During the months of the presidency, we had to prepare and adopt positions that should be accepted by all health ministers of EU member states, called conclusions. These were presented and worked out at the above-mentioned conferences, signaling what transnational



problems exist within modern societies in the European Union and how to seek to solve them. Three of the discounted priorities culminated at the end of the Polish presidency in December 2011 with conclusions adopted at the EU Council.

The political and organizational side of the preparation of the European Council conclusions is as follows:

Preparation of the concept of priority – experts present ideas, which are subject to analysis as to validity and substantive justification. On this, we consult with the European Commission, discuss within the trio, discuss at the ministry level, and finally, on this basis, the Minister of Health selects those that constitute consensus of Polish interests, the trio, and the European Commission. The level of preparation and attractiveness of the topics may be limited to the debate, but may also end in a conclusion at the meeting of EU health ministers. For each priority within the Polish presidential corps, a person was designated responsible for all stages of implementation of the preparation and negotiation of the priority, i.e. organizing the conference, filling it with content, international experts, and politicians, and finally preparing the considerations for the conclusions.

The European Parliament, to which level certain content is transferred, operates independently. What is established at informal meetings of ministers can be a proposal for the enactment of certain regulations at the EU level. A classic example is cross-border care. The issue was addressed to the European Parliament through the adoption of a directive regulating international cooperation in health care at the international level. The role of the European Commission was to initiate the entire lawmaking procedure by proposing the proposal and being the liaison between the Council and Parliament at all stages.

When we entered the presidency, we knew that we had to hold certain conferences. A budget was prepared. E.g., for the conference organized under the priority for which I was responsible, we attracted the best experts of the European Union, representatives of the European Commission and EuroParliament, and the Minister of Health. Based on discussions, we built proposals for conclusions and then transferred them to the Public Health Working Party. Its meetings were held systematically in Brussels, on average once a week. Sometimes we also invited some experts to the meetings in order to convince the participants, i.e. representatives of individual health ministries of member countries, to include comments on certain content in the conclusions.

Preparing the conclusions was a difficult task. We had to do some “running around” between delegations and negotiating. Working Group meetings were based on frequent meetings of member country delegations. During the deliberations, delegations presented their positions. With discrepancies, our task was to find a compromise. Delegations would return to their country, and get approval from the ministry’s leadership for certain conclusions or comments, with which they would return to subsequent working group meetings. We negotiated the comments again. Sometimes this went on for several months, until the end of our presidency.

Once the conclusion was approved by the working groups, it was further discussed at the ambassadors' meeting, and only after their approval did it constitute the document that was adopted by EU health ministers at the end of the presidency. Every provision in the conclusions had to have the approval of all member states. Of course, the conclusions were not negotiated by the ministers, but by their representatives and the assembly of these representatives, i.e. the working group that negotiated the content of the conclusions.

The conclusion itself contained information about what the conclusion was about. Then the problems and solutions to these problems were defined, indicating tasks for the member states, for the European Commission, and the member states and the European Commission at the same time. The conclusions imposed further policy directions and recommendations on the European Commission, among other programs, with an indication of financial security for their implementation.

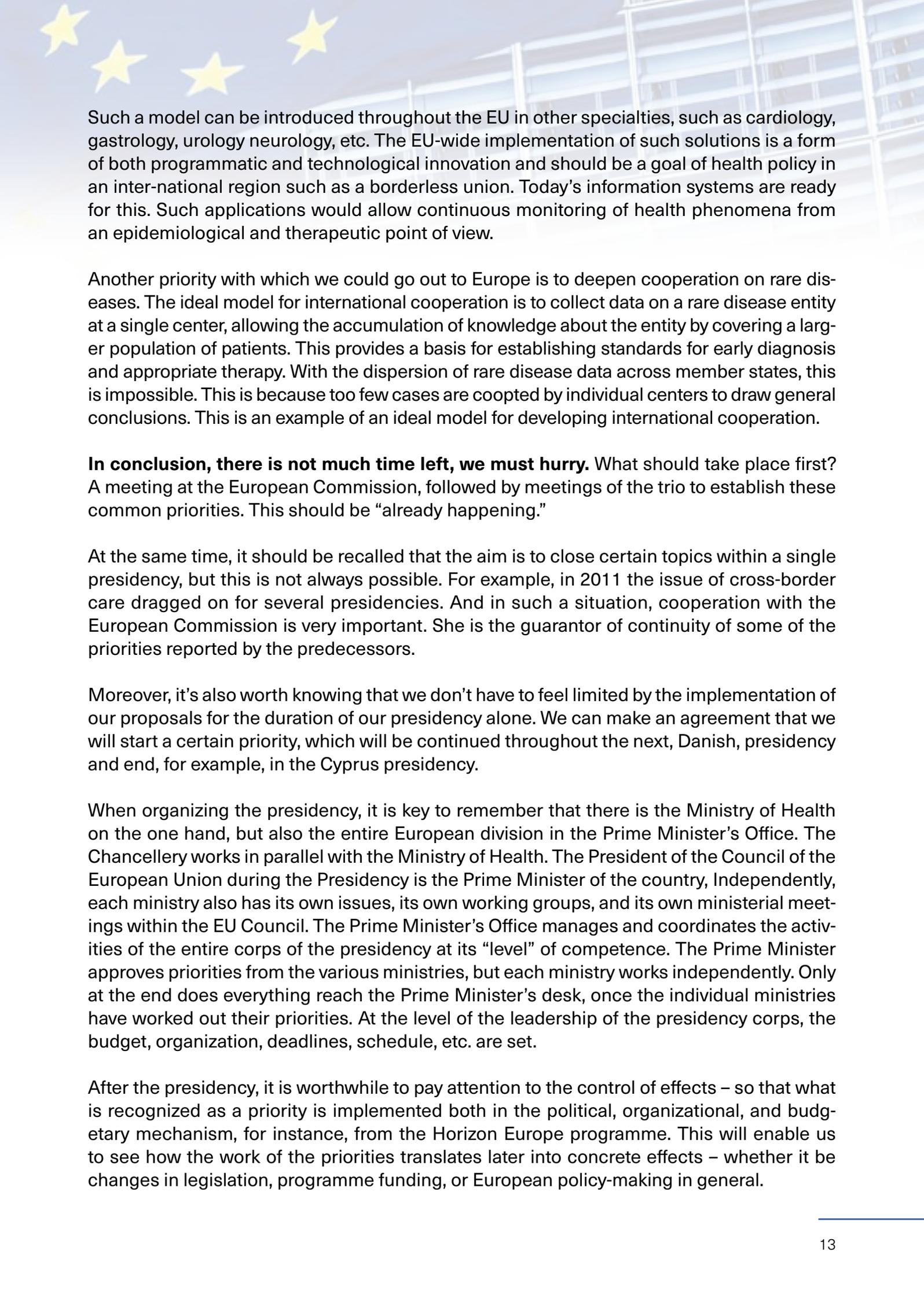
At the last meeting of EU health ministers closing the presidency period, the ministers voted on the conclusions.

The Polish Presidency of the Council of the European Union was considered the best presidency since the Lisbon Treaty was introduced. As Poles, we rose to the occasion.

**If I were to give advice to those preparing for the next presidency, I would start by reviewing the topics of the presidency for the last period, preferably the last 10 years. That's dozens of topics. Then I would find out from the European Commission, or more precisely its relevant department (DG SANTE), what the current European challenges are. The International Cooperation Department of the MZ should have current information on this subject. I would consider among experts what issues Poles and all Europeans would benefit from as priorities.**

In pointing out possible priorities to propose, it is worth mentioning that each EU country monitors epidemiological phenomena differently. In my opinion, this is a fantastic topic to lead after the COVID-19 pandemic. However, one of the essential needs is the continuous monitoring of certain health phenomena. All public statistics in the world are always inaccurate, so epidemiological surveys are being implemented to have real data on the state of the epidemic in terms of civilization diseases or infectious diseases within particular regions. This could be an interesting topic to raise at the EU-wide level. And frankly, it fits into the currently proposed concept of the three priority topics of our 2025 presidency.

If we talk about digitization as a priority, it would be worthwhile to concretize the content of this priority we have a Polish IT system, but perhaps we should strive to unify IT systems across the Union. Why can't a doctor in Italy, if he has a Polish patient, access his medical history? We, as allergologists, already have a good example of good practice in international cooperation on monitoring epidemiological phenomena, the effectiveness of therapy and prevention because there is already such a system in place, in which, for example, a Ukrainian on a visit to any doctor in the European Union, based on our application, fills out a health questionnaire in his language, and the doctor reads his history in his language.



Such a model can be introduced throughout the EU in other specialties, such as cardiology, gastrology, urology neurology, etc. The EU-wide implementation of such solutions is a form of both programmatic and technological innovation and should be a goal of health policy in an inter-national region such as a borderless union. Today's information systems are ready for this. Such applications would allow continuous monitoring of health phenomena from an epidemiological and therapeutic point of view.

Another priority with which we could go out to Europe is to deepen cooperation on rare diseases. The ideal model for international cooperation is to collect data on a rare disease entity at a single center, allowing the accumulation of knowledge about the entity by covering a larger population of patients. This provides a basis for establishing standards for early diagnosis and appropriate therapy. With the dispersion of rare disease data across member states, this is impossible. This is because too few cases are coopted by individual centers to draw general conclusions. This is an example of an ideal model for developing international cooperation.

**In conclusion, there is not much time left, we must hurry.** What should take place first? A meeting at the European Commission, followed by meetings of the trio to establish these common priorities. This should be “already happening.”

At the same time, it should be recalled that the aim is to close certain topics within a single presidency, but this is not always possible. For example, in 2011 the issue of cross-border care dragged on for several presidencies. And in such a situation, cooperation with the European Commission is very important. She is the guarantor of continuity of some of the priorities reported by the predecessors.

Moreover, it's also worth knowing that we don't have to feel limited by the implementation of our proposals for the duration of our presidency alone. We can make an agreement that we will start a certain priority, which will be continued throughout the next, Danish, presidency and end, for example, in the Cyprus presidency.

When organizing the presidency, it is key to remember that there is the Ministry of Health on the one hand, but also the entire European division in the Prime Minister's Office. The Chancellery works in parallel with the Ministry of Health. The President of the Council of the European Union during the Presidency is the Prime Minister of the country, Independently, each ministry also has its own issues, its own working groups, and its own ministerial meetings within the EU Council. The Prime Minister's Office manages and coordinates the activities of the entire corps of the presidency at its “level” of competence. The Prime Minister approves priorities from the various ministries, but each ministry works independently. Only at the end does everything reach the Prime Minister's desk, once the individual ministries have worked out their priorities. At the level of the leadership of the presidency corps, the budget, organization, deadlines, schedule, etc. are set.

After the presidency, it is worthwhile to pay attention to the control of effects – so that what is recognized as a priority is implemented both in the political, organizational, and budgetary mechanism, for instance, from the Horizon Europe programme. This will enable us to see how the work of the priorities translates later into concrete effects – whether it be changes in legislation, programme funding, or European policy-making in general.

## Principles governing the exercise of the Presidency of the Council of the European Union



**Jakub Gierczyński MD Ph.D, MBA**  
*European Health Network*



**Małgorzata Bogusz**  
*Institute for Social Policy Development*

The Council of the European Union, which plays a key role as the EU's decision-making body, focuses on a variety of tasks, including

1. the negotiation and adoption of European Union law,
2. the coordination of Member States' policies in the fields of economic and fiscal policy, education, culture, youth and sport, and employment,
3. the development of 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. the conclusion of international agreements, which may cover broad areas (such as trade, cooperation and development aid) or specific subjects (such as textiles, medicines, vaccines, human products, fisheries, customs, transport, research or technology),
5. the adoption of the European Union budget.<sup>1</sup>

The presidency of the Council of the European Union is not elected. 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>2</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.

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

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

Table. The Presidencies of the Council of the European Union from 2011 to 2026 – from the first to the second Polish Presidency.

Timeframe	Presidency of the Council of the European Union by groups (trios)
January 2025 - June 2026	<b>Poland</b> , Cyprus, Denmark
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	Netherlands, Slovakia, Malta
July 2014 - December 2015	Italy, Latvia, Luxembourg
January 2013 - June 2014	Ireland, Lithuania, Greece
July 2011 - December 2012	<b>Poland</b> , Denmark, Cyprus

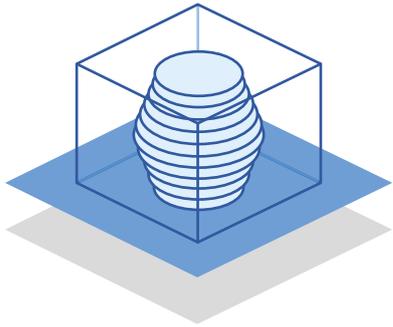
Source: Own elaboration based on materials from the Council of the European Union

Each trio sets long-term goals and prepares a common agenda of topics and issues that the Council will address for 18 months. On the basis of the common agenda, each of the three countries develops its own, more detailed programme for its six-month Presidency of the Council.<sup>3</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 chairs most meetings of the Council, committees and working parties. The aim of 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 6-month period of its Presidency of the Council of the European Union. 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>4</sup>

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

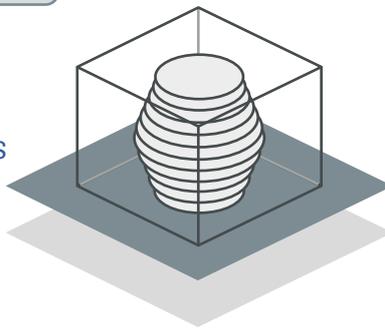
<sup>4</sup> <https://www.consilium.europa.eu/pl/council-eu/presidency-council-eu/>



## European Council

27 EU leaders

sets political directions

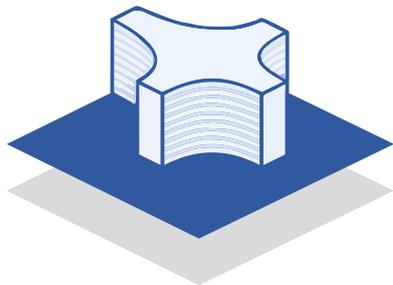


## Council of the EU

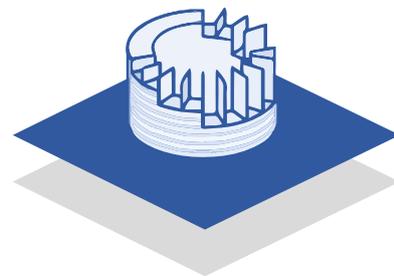
27 ministers

## Rotating presidency

represents the Council  
in its dealings with other  
EU institutions

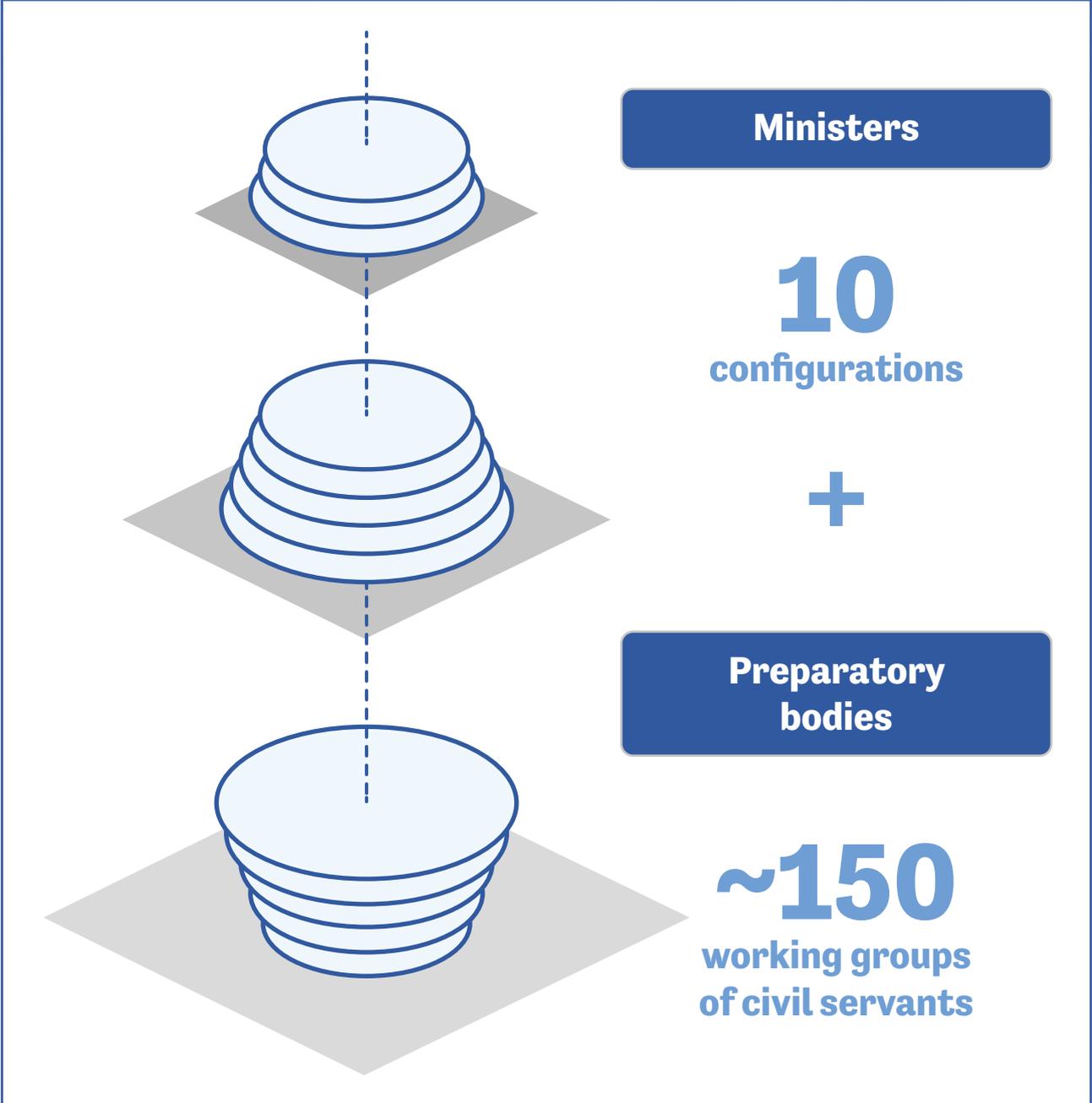


## European Commission



## European Parliament

Source: <https://www.consilium.europa.eu/en/presidency-council-eu/>



Source: <https://www.consilium.europa.eu/en/presidency-council-eu/>

## Health in the priorities of the countries holding the EU Council Presidency 2011–2024



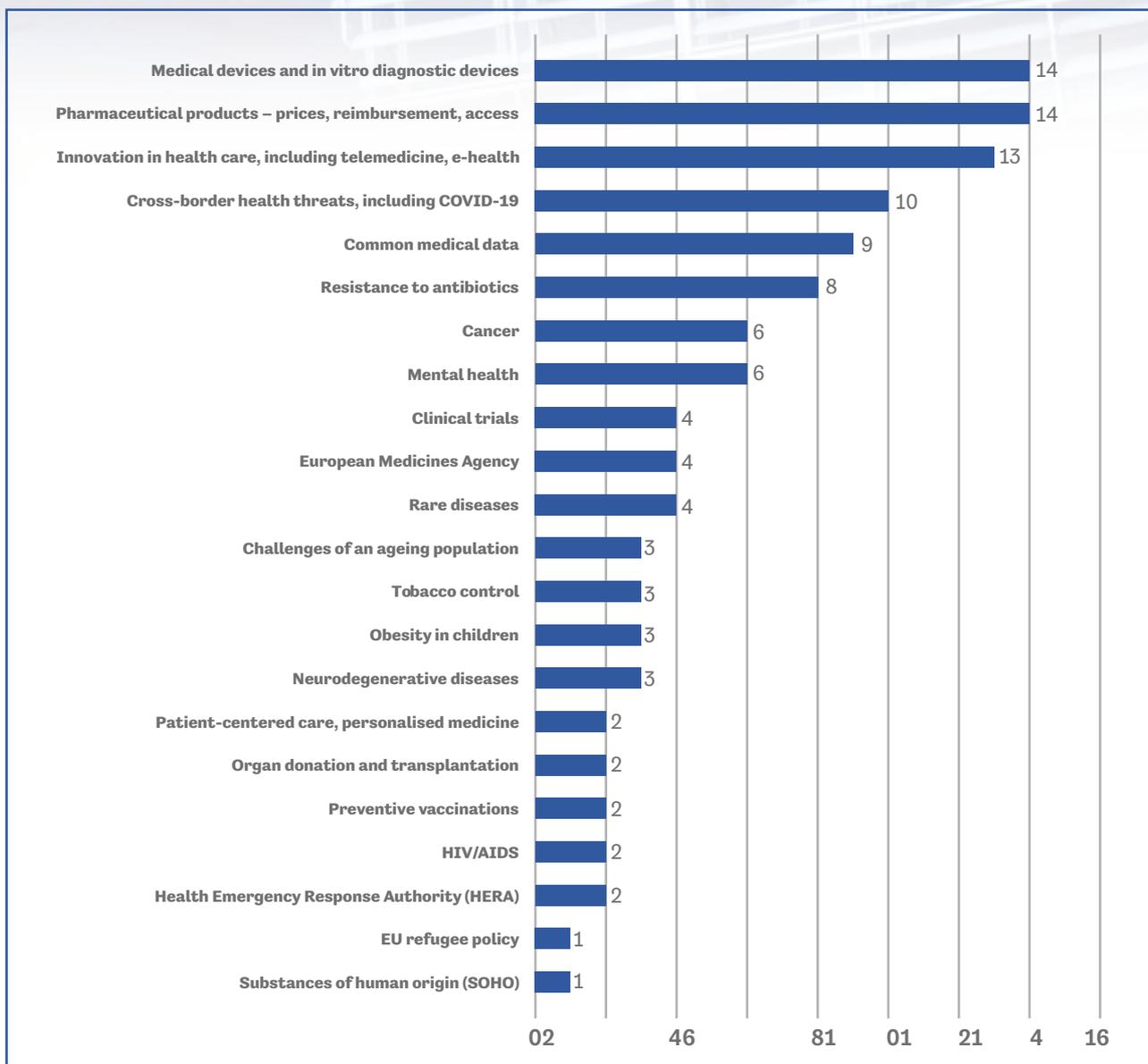
**Jakub Gierczyński MD Ph.D, MBA**  
*European Health Network*



**Małgorzata Bogusz**  
*Institute for Social Policy Development*

Below you will find a cross-country analysis of the health priorities of the presidencies of the Council of the European Union from the Polish Presidency in 2011 to the Belgian Presidency in 2024. Of the health priorities analysed in the context of each Member State's Presidency agenda, most countries (14) have identified activities in the field of health technologies, both in the area of medical devices and pharmaceuticals. Thirteen countries indicated activities related to health innovation, including e-health, in their agendas. Ten countries' agendas addressed the issue of cross-border health threats, including the COVID-19 pandemic, and resistance to antibiotics. Nine countries included the need for a European Health Data Space in their agendas. Out of the eight countries, antimicrobial resistance was given top priority, followed by cancer and mental disorders in six countries. Four countries prioritised rare diseases, clinical trials and EMA. Neurodegenerative diseases, childhood obesity, tobacco control and the challenges of an ageing population were the priorities pursued by four countries each. Two countries each defined the presidency's health priorities with reference to the Health Emergency Preparedness and Response Authority (HERA), HIV/AIDS, preventive vaccination, organ donation and transplantation, patient-centred care and personalised medicine. The EU's health policy for refugees and the SOHO regulation were also among the priorities.

Chart. Health priorities in the agendas of the Presidency of the Council of the European Union by thematic area and number of countries that chose them, 2011-2024



It is worth recalling that **Poland's priorities in the field of health during its first Presidency of the Council of the European Union from 1 July to 31 December 2011** included the following issues:

- \* Disease prevention and early detection, treatment of chronic respiratory diseases in children;
- \* Healthy aging begins in childhood;
- \* Early detection and treatment of communication disorders in children;
- \* E-health and innovation in the health sector;
- \* Promotion of healthy lifestyles;

- \* Prevention of neurodegenerative diseases, including Alzheimer's disease
- \* Research on the brain diseases;
- \* Pharmacovigilance.<sup>5</sup>

### **What health priorities will Poland choose for its second Council of the European Union Presidency from January to June 2025?**

- \* Rare diseases? Poland has a rare disease plan, an excellent newborn screening programme covering 30 rare diseases and improving access to reimbursable therapies.
- \* Cardiology? This area of medicine has not yet been identified as a health priority by any presidency. Moreover, Poland runs the National Cardiovascular Programme and an excellent comprehensive care system for heart attack patients (KOS-Zawał).
- \* Treatment of solid tumours and blood cancer? The number of diagnosed cancer cases is increasing in ageing societies, and at the same time many innovative therapies are being discovered and approved.
- \* Diseases of the brain – neurology and psychiatry? One in three inhabitants of the European Union will suffer from these conditions.
- \* Infectious diseases, antibiotic resistance and vaccinations throughout life? Infectious diseases are still a major threat to the functioning of citizens and societies.
- \* Diseases of the respiratory system? The increasingly common respiratory diseases can be life-threatening or lead to disability.
- \* Autoimmune diseases in rheumatology, dermatology, gastroenterology or allergology? These diseases affect young people at the time of diagnosis and last a lifetime. Rapid diagnosis and effective treatment allow patients to lead a normal life.
- \* Health prevention and education addressing lifestyle diseases to reduce risk factors such as smoking, alcoholism, smog or obesity?
- \* EU and national drug safety? Supply chains for raw materials and finished medicinal products can be impacted by pandemics and geopolitical factors.
- \* Healthy ageing from birth? As patients, we not only want to live longer, we also want to live as long as possible in good health.
- \* Genetic diagnostics? Without an accurate diagnosis, it is not possible to fully utilise all therapeutic methods.
- \* Digitisation and the use of artificial intelligence in health care systems? No healthcare system is efficient without a perfectly functioning IT system that supports the collection and analysis of data as well as the support of patients, medical staff and auxiliary personnel.

The priorities of the Polish EU Council Presidency will be discussed by all system stakeholders in Poland in the coming months.

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<sup>5</sup> [http://oide.sejm.gov.pl/oide/en/images/files/prezydencja/Raport\\_koncowy.pdf](http://oide.sejm.gov.pl/oide/en/images/files/prezydencja/Raport_koncowy.pdf)

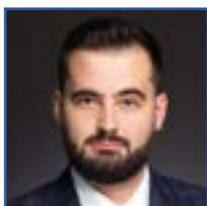
## Health priorities in the Spain-Belgium-Hungary trio agenda and their consequences



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To enhance the consistency and effectiveness of the presidency, the Lisbon Treaty introduced a system of “trio presidencies” in 2009, whereby three consecutive presidencies cooperate closely and agree on a common programme for their 18-month term.

The trio programme sets out the main objectives and priorities of the trio, based on the strategic agenda of the EU for 2019-2024. The programme covers six thematic areas: general affairs, foreign affairs, economic and financial affairs, justice and home affairs, employment, social policy, health and consumer affairs, and environment, transport, energy and telecommunications.

The programme reflects the trio’s commitment to addressing the challenges and opportunities facing the EU, such as the recovery from the pandemic, the green and digital transitions, the social dimension of Europe, the resilience and strategic autonomy of the EU, the international partnerships and multilateral cooperation, and the dialogue with citizens. The programme also takes into account the end of the current institutional cycle and the preparation for the next one, as well as the integration of new members in a manner that strengthens key European policies.

The current trio has started operating since the 1st of July 2023. It includes Spain, Belgium, and Hungary. If Belgium, and previously Spain, can somehow share a main vision on certain political and social issues, working with Eurosceptic Hungary is much more difficult.

Nevertheless, the overall idea of the trio is based on cooperation to ensure a smooth continuation of the activities implemented earlier in a range of sectors, including healthcare. The common threats and problems, among others, the war in Ukraine, coupled with the chaotic and not entirely regulated health consequences that have resulted after COVID-19 are there to be addressed.

The main areas that the three countries will focus on are presented below. Having said that it is clear that the level of involvement may differ from country to country considering the needs and specific perspectives of the Presidency.

- \* The trio aims to work to further strengthen the EU Health Union and the resilience of health systems that are accessible to all, build preparedness for future health emergencies, and promote health and healthy lifestyles. The trio intends to continue the work on antimicrobial resistance and on the accessibility of medicines that meet our public health needs. It will also strive to improve the prevention of health risks through a comprehensive “one health” approach to the prevention of health risks, demonstrating a commitment to a comprehensive strategy for addressing health challenges from various perspectives, inter alia, on mental health, cardiovascular disease, and rare diseases, as well as the global health initiative. During its presidency, Spain declared mental health as one of its priorities. This pillar will be taken over, as based on the new initiative of the Commission on Mental Health, the trio was to pay particular attention to stress and occupational burnout, emphasizing the importance of mental health in the workplace.
- \* The trio aims to actively contribute to the formulation, acceptance, and execution of the Strategic Agenda for the 2024-2029 period. Drawing lessons from the previous challenging times, the overarching objective is to sustain European integration, ensuring peace, stability, and prosperity for Member States and citizens for over 70 years.
- \* Demographic challenges are also on the priority programme for the current trio.<sup>6</sup> This is especially visible in the plans of the Hungarian Presidency.<sup>7</sup> According to the work programme, special attention was to be devoted to addressing the demographic challenge by focusing on developing strategies aimed at overcoming this issue. While many regions anticipate population growth, the EU is undergoing population decline, a pattern projected to persist – this phenomenon is attributed to the EU’s average fertility rate, which has decreased from 2.37 in 1970 to 1.53 in 2021. Maintaining a stable population typically requires an average fertility rate of 2.1. As indicated, the countries will continue efforts towards effective implementation of the European Pillar of Social Rights action plan and the Commission’s action plan for the social economy.
- \* The trio prioritized enhancing fair mobility in the labor market within the European Union, emphasizing access to social protection and labor rights.<sup>8</sup> The aim was to ensure

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6 <https://ec.europa.eu/social/main.jsp?langId=en&catId=1226&furtherNews=yes&newsId=10714>

7 <https://www.euractiv.com/section/politics/news/hungary-to-push-for-family-policy-during-eu-council-presidency/>

8 <https://ec.europa.eu/social/main.jsp?langId=en&catId=1226&furtherNews=yes&newsId=10718>



health and safety, promote inclusive policies, and prevent discrimination in the workplace. The trio will pay particular attention to stress and burn-out at work, in line with the new Commission initiative on mental health. It intends to support inclusion, in particular by facilitating the integration of those categories that are most vulnerable or at risk of exclusion. The trio also plans to take forward discussions on the initiative from the Commission on the European Disability Card.

- \* The trio tries to demonstrate its commitment to boosting the European cultural and creative sectors by promoting cultural diversity, stimulating its digital and green transformation and improving access to culture. The trio undertakes to implement the European work plan for culture. The trio aims to place the aspirations of young people at the centre of European policies, with a special focus on those with fewer opportunities. The trio intends to assess the current European work plan for sport and adopt its successor, focusing efforts on promoting sport, including non-organised sport. In line with the European Tourism Agenda 2030, the trio also aims to focus on the resilience, sustainability, circularity and data-driven governance of the tourism ecosystem.

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The health priorities of the **Spanish Presidency for the period from 1 July to 31 December 2023** are as follows:

- \* improving the protection of vulnerable patient groups,
- \* fostering preparedness and response initiatives for facing new health alerts,
- \* aligning the European health agenda with the 2030 Agenda for Sustainable Development (Agenda 2030) and the One Health approach,
- \* creation of a European Health Data Space (EHDS),
- \* a Regulation on standards of quality and safety for substances of human origin intended for human application (SoHO),
- \* strengthening the European Medicines Agency (EMA),
- \* disease prevention and health promotion culture in the European Union with respect to issues such as childhood obesity and lifelong vaccination,
- \* strengthening the capabilities of health systems in areas where the pandemic has exposed shortcomings, such as strategic autonomy in healthcare provision,
- \* new actions on HIV and mental illness.<sup>9</sup>

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The health priorities of the **Belgian Presidency (1 January to 30 June 2024)** focus on three overarching themes: preparedness, care and protection.

- \* Preparedness
  - Strengthening the EU framework for managing preparedness and response to health emergencies

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<sup>9</sup> <https://spanish-presidency.consilium.europa.eu/media/e4ujaagg/the-spanish-presidency-programme.pdf>

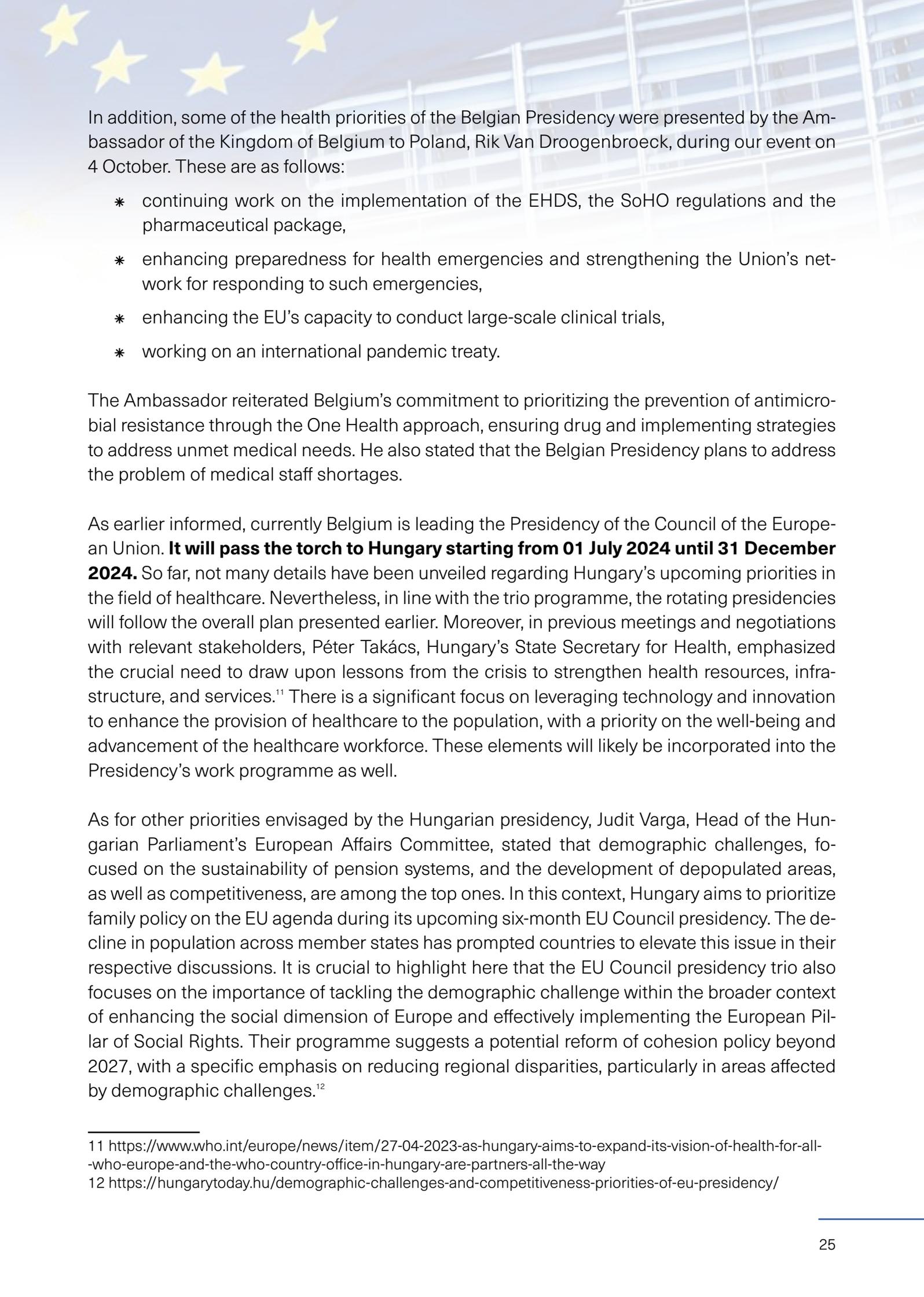
- Enhancing the EU's capacity to conduct large-scale clinical trials
  - Negotiating the international pandemic treaty and the international health regulations, under the World Health Organisation's purview
  - Fighting antimicrobial resistance
- \* Care
- Strengthening and supporting Member States' health systems and health workforce strategies, including shortages
  - Improving policies for innovation and health care policy to better address unmet health needs
  - Advancing health promotion and disease prevention to enhance overall population health
- \* Protection
- Revising pharmaceutical legislation to provide faster access to high-quality, safe, affordable and greener medicines in all Member States
  - Supporting innovation and boosting the EU's competitiveness and attractiveness in the pharmaceutical sector
  - Strengthening the EU's health security by moving forward new proposals to effectively address medicines shortages
  - Enhancing the EU's strategic autonomy concerning medicines
- \* The Belgian Presidency will aim to complete legislative work on:
- the EU Health Data Space (EHDS),
  - Regulation on Substances of Human Origin (SOHO),
  - EU pharmaceutical legislation.
  - the Presidency will highlight the significance of Health in All Policies (HiAP).<sup>10</sup>

The Belgian Presidency will only have 4 months to realise its priorities. Due to the elections to the European Parliament in June, the legislative term will end at the end of April with the last plenary session.

Belgium will also be dealing with current issues, including the consequences of the war unleashed by Russia beyond Poland's eastern border.

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<sup>10</sup> [https://belgian-presidency.consilium.europa.eu/media/3kajw1io/programme\\_en.pdf](https://belgian-presidency.consilium.europa.eu/media/3kajw1io/programme_en.pdf)



In addition, some of the health priorities of the Belgian Presidency were presented by the Ambassador of the Kingdom of Belgium to Poland, Rik Van Droogenbroeck, during our event on 4 October. These are as follows:

- \* continuing work on the implementation of the EHDS, the SoHO regulations and the pharmaceutical package,
- \* enhancing preparedness for health emergencies and strengthening the Union's network for responding to such emergencies,
- \* enhancing the EU's capacity to conduct large-scale clinical trials,
- \* working on an international pandemic treaty.

The Ambassador reiterated Belgium's commitment to prioritizing the prevention of antimicrobial resistance through the One Health approach, ensuring drug and implementing strategies to address unmet medical needs. He also stated that the Belgian Presidency plans to address the problem of medical staff shortages.

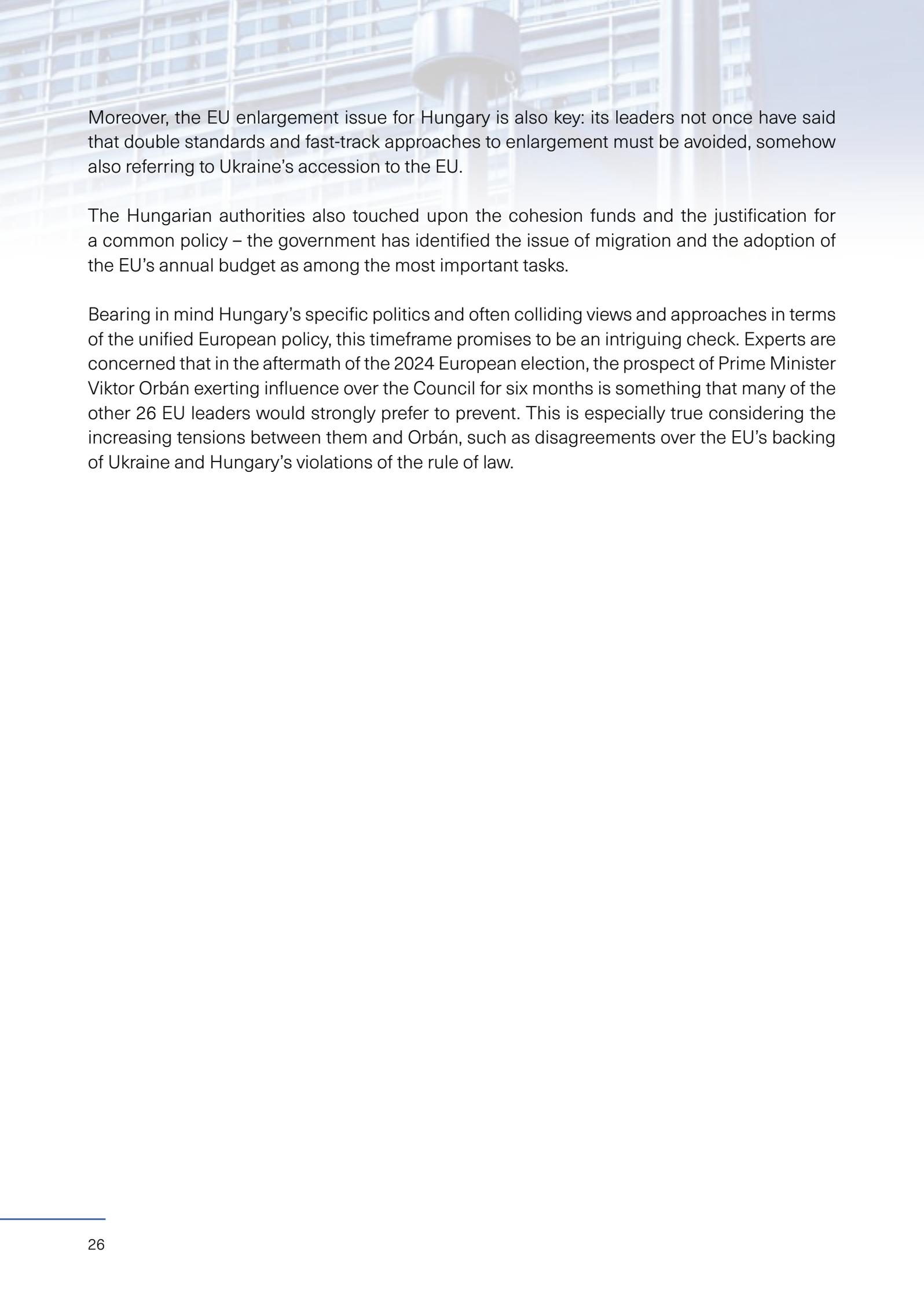
As earlier informed, currently Belgium is leading the Presidency of the Council of the European Union. **It will pass the torch to Hungary starting from 01 July 2024 until 31 December 2024.** So far, not many details have been unveiled regarding Hungary's upcoming priorities in the field of healthcare. Nevertheless, in line with the trio programme, the rotating presidencies will follow the overall plan presented earlier. Moreover, in previous meetings and negotiations with relevant stakeholders, Péter Takács, Hungary's State Secretary for Health, emphasized the crucial need to draw upon lessons from the crisis to strengthen health resources, infrastructure, and services.<sup>11</sup> There is a significant focus on leveraging technology and innovation to enhance the provision of healthcare to the population, with a priority on the well-being and advancement of the healthcare workforce. These elements will likely be incorporated into the Presidency's work programme as well.

As for other priorities envisaged by the Hungarian presidency, Judit Varga, Head of the Hungarian Parliament's European Affairs Committee, stated that demographic challenges, focused on the sustainability of pension systems, and the development of depopulated areas, as well as competitiveness, are among the top ones. In this context, Hungary aims to prioritize family policy on the EU agenda during its upcoming six-month EU Council presidency. The decline in population across member states has prompted countries to elevate this issue in their respective discussions. It is crucial to highlight here that the EU Council presidency trio also focuses on the importance of tackling the demographic challenge within the broader context of enhancing the social dimension of Europe and effectively implementing the European Pillar of Social Rights. Their programme suggests a potential reform of cohesion policy beyond 2027, with a specific emphasis on reducing regional disparities, particularly in areas affected by demographic challenges.<sup>12</sup>

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<sup>11</sup> <https://www.who.int/europe/news/item/27-04-2023-as-hungary-aims-to-expand-its-vision-of-health-for-all-who-europe-and-the-who-country-office-in-hungary-are-partners-all-the-way>

<sup>12</sup> <https://hungarytoday.hu/demographic-challenges-and-competitiveness-priorities-of-eu-presidency/>



Moreover, the EU enlargement issue for Hungary is also key: its leaders not once have said that double standards and fast-track approaches to enlargement must be avoided, somehow also referring to Ukraine's accession to the EU.

The Hungarian authorities also touched upon the cohesion funds and the justification for a common policy – the government has identified the issue of migration and the adoption of the EU's annual budget as among the most important tasks.

Bearing in mind Hungary's specific politics and often colliding views and approaches in terms of the unified European policy, this timeframe promises to be an intriguing check. Experts are concerned that in the aftermath of the 2024 European election, the prospect of Prime Minister Viktor Orbán exerting influence over the Council for six months is something that many of the other 26 EU leaders would strongly prefer to prevent. This is especially true considering the increasing tensions between them and Orbán, such as disagreements over the EU's backing of Ukraine and Hungary's violations of the rule of law.

## Key EU initiatives in development during the Polish European Union Council Presidency



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## Regulation on Standards of Quality and Safety for Substances of Human Origin Intended for Human Application (SoHO Regulation)

### Context and role of the regulation

Substances of human origin play an important role in medicine, biotechnology and pharmacy, which can contribute to improving human health and quality of life. Directives on blood, tissue and cells were introduced in response to the transmission of communicable diseases in the 1980s and 1990s. However, a recent review of legislation has shown that patients, donors and children born from donated eggs, sperm or embryos were not fully protected from avoidable risks, as the current framework is not up to date with scientific development. In addition, Member States use different monitoring systems, which hinders the cross-border exchange of blood, tissues and cells and does not encourage innovation in this area.

On 19 July 2022, the European Commission presented a draft regulation on quality and safety standards for substances of human origin intended for human use.<sup>13</sup> The text is based on the conclusions drawn from the recent COVID-19 pandemic and takes into account the risk of disease transmission through blood, tissues and cells and the need for adequate supplies.

<sup>13</sup> [https://health.ec.europa.eu/blood-tissues-cells-and-organs/overview/proposal-regulation-substances-human-origin\\_en](https://health.ec.europa.eu/blood-tissues-cells-and-organs/overview/proposal-regulation-substances-human-origin_en)

This draft recognises that substances of human origin can be dangerous to public health or the environment if they are a source of financial profit or do not meet the appropriate quality and safety standards.

## **Objectives and principles**

The SoHO Regulation is a piece of European Union legislation that aims to ensure high standards of quality and safety for substances of human origin (SoHO), such as organs, tissues, cells, blood and blood derivatives used for medical or scientific purposes. This regulation replaced two directives from 2002 and 2004, which dealt with the same issues but were considered inadequate and inconsistent.

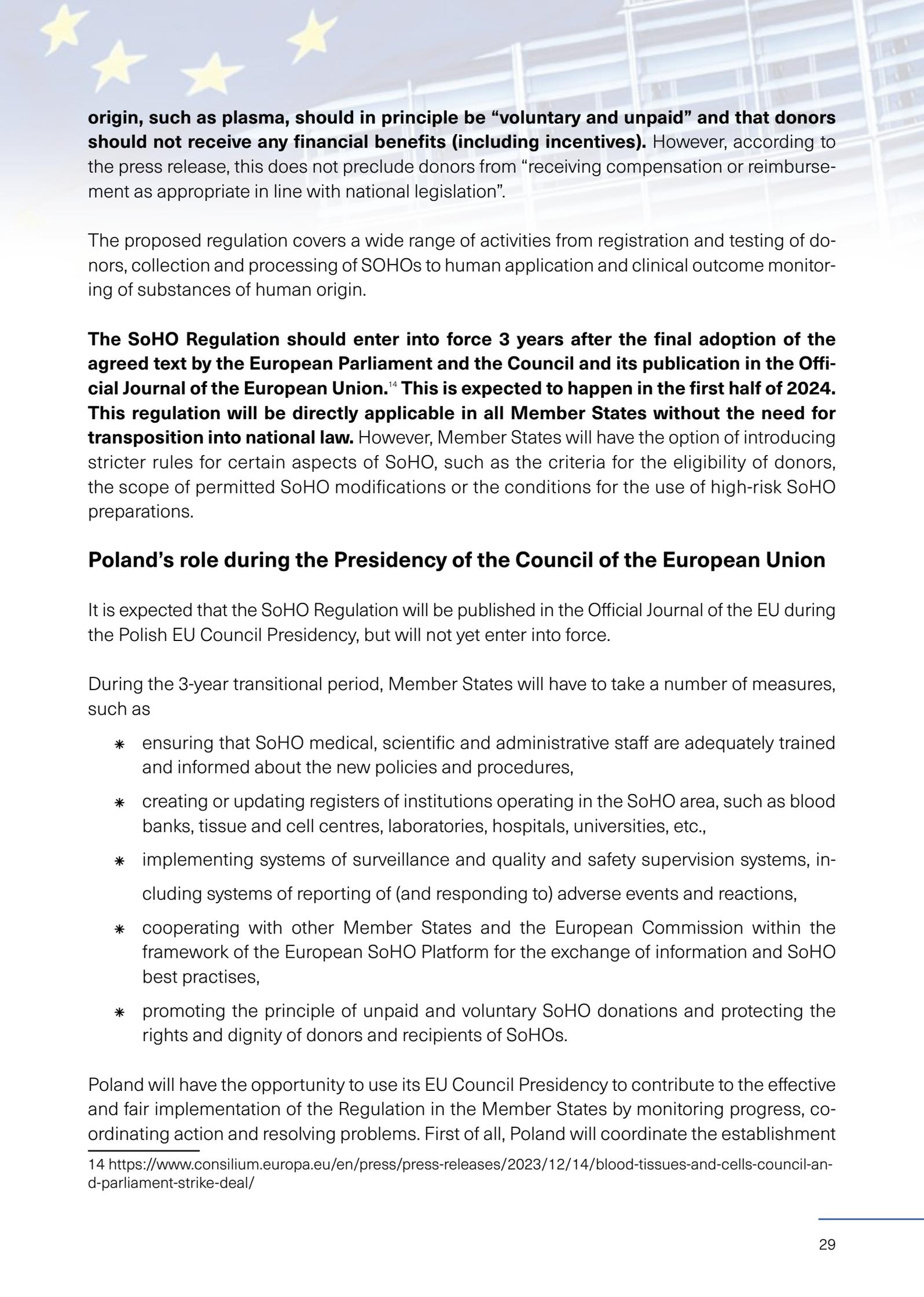
The objectives and principles of the SoHO regulation are as follows:

- \* establishing harmonised rules for the marketing and use of SoHOs on the EU market to ensure the free movement of these products and services while avoiding risks to public health and patient safety,
- \* introducing a system to categorise SoHOs according to the degree of risk associated with their use, to ensure an appropriate level of monitoring and control of these products and services and facilitate access to innovative solutions,
- \* enhancing quality and safety requirements for SoHO at all stages of the supply chain, from procurement, storage, processing, testing, distribution to use, to ensure the protection of donors and recipients and to prevent the transmission of infectious diseases or adverse immunological reactions,
- \* introducing mandatory tracing of SoHOs from donor to recipient and vice versa to enable the identification and localisation of SoHOs when needed and to ensure transparency and accountability for all actors involved in the supply chain,
- \* introducing an obligation to report serious adverse events or incidents related to SoHO to a common EU system to enable rapid response and corrective action and to improve knowledge and experience on the quality and safety of SoHO,
- \* strengthening the role of social partners and patient organisations in the development and implementation of the SoHO Regulation to ensure that all stakeholders are more involved and consulted and that their needs and expectations are taken into account.

## **State of work**

On 14 December 2023, after the third trialogue, the European Parliament and the Council of the European Union finally agreed on a draft regulation on quality and safety standards for substances of human origin intended for human use.

**Although the provisionally agreed text is not yet publicly available, the Council's press release emphasises that the draft stipulates that donations of substances of human**



**origin, such as plasma, should in principle be “voluntary and unpaid” and that donors should not receive any financial benefits (including incentives).** However, according to the press release, this does not preclude donors from “receiving compensation or reimbursement as appropriate in line with national legislation”.

The proposed regulation covers a wide range of activities from registration and testing of donors, collection and processing of SOHOs to human application and clinical outcome monitoring of substances of human origin.

**The SoHO Regulation should enter into force 3 years after the final adoption of the agreed text by the European Parliament and the Council and its publication in the Official Journal of the European Union.<sup>14</sup> This is expected to happen in the first half of 2024. This regulation will be directly applicable in all Member States without the need for transposition into national law.** However, Member States will have the option of introducing stricter rules for certain aspects of SoHO, such as the criteria for the eligibility of donors, the scope of permitted SoHO modifications or the conditions for the use of high-risk SoHO preparations.

## **Poland’s role during the Presidency of the Council of the European Union**

It is expected that the SoHO Regulation will be published in the Official Journal of the EU during the Polish EU Council Presidency, but will not yet enter into force.

During the 3-year transitional period, Member States will have to take a number of measures, such as

- \* ensuring that SoHO medical, scientific and administrative staff are adequately trained and informed about the new policies and procedures,
- \* creating or updating registers of institutions operating in the SoHO area, such as blood banks, tissue and cell centres, laboratories, hospitals, universities, etc.,
- \* implementing systems of surveillance and quality and safety supervision systems, including systems of reporting of (and responding to) adverse events and reactions,
- \* cooperating with other Member States and the European Commission within the framework of the European SoHO Platform for the exchange of information and SoHO best practises,
- \* promoting the principle of unpaid and voluntary SoHO donations and protecting the rights and dignity of donors and recipients of SoHOs.

Poland will have the opportunity to use its EU Council Presidency to contribute to the effective and fair implementation of the Regulation in the Member States by monitoring progress, coordinating action and resolving problems. First of all, Poland will coordinate the establishment

<sup>14</sup> <https://www.consilium.europa.eu/en/press/press-releases/2023/12/14/blood-tissues-and-cells-council-and-parliament-strike-deal/>

of a European SoHO platform (if this measure has not already been taken by its predecessors). Poland should also monitor the progress of individual Member States in preparing the competent authorities to maintain a register of SoHO operators and the procedure for their registration and authorisation of SoHO preparations. Finally, our task will be to coordinate the preparation of Member States to carry out inspections of installations and other facilities operating in the SoHO area.

In addition, we should not forget to raise public awareness and involvement in SoHO issues by organising information and education campaigns and participating in the public and ethical debate on SoHO.

## **EU4Health Programme 2021-2027**

### **Context of the programme**

The EU4Health programme was adopted as a response to the COVID-19 pandemic and to reinforce crisis preparedness in the EU. The pandemic has highlighted the vulnerability of national healthcare systems and shown the need for greater cooperation and solidarity at European level. The EU4Health programme will bring a contribution to the long-term health challenges by building stronger, more resilient and more accessible health systems. Health is an investment and, with a EUR 5.3 billion budget during the 2021-27 period, the EU4Health programme is an unparalleled EU financial support in the health area.<sup>15</sup> EU4Health is a clear message that public health is a priority for the EU. The programme is a key instrument to pave the way to a European Health Union.

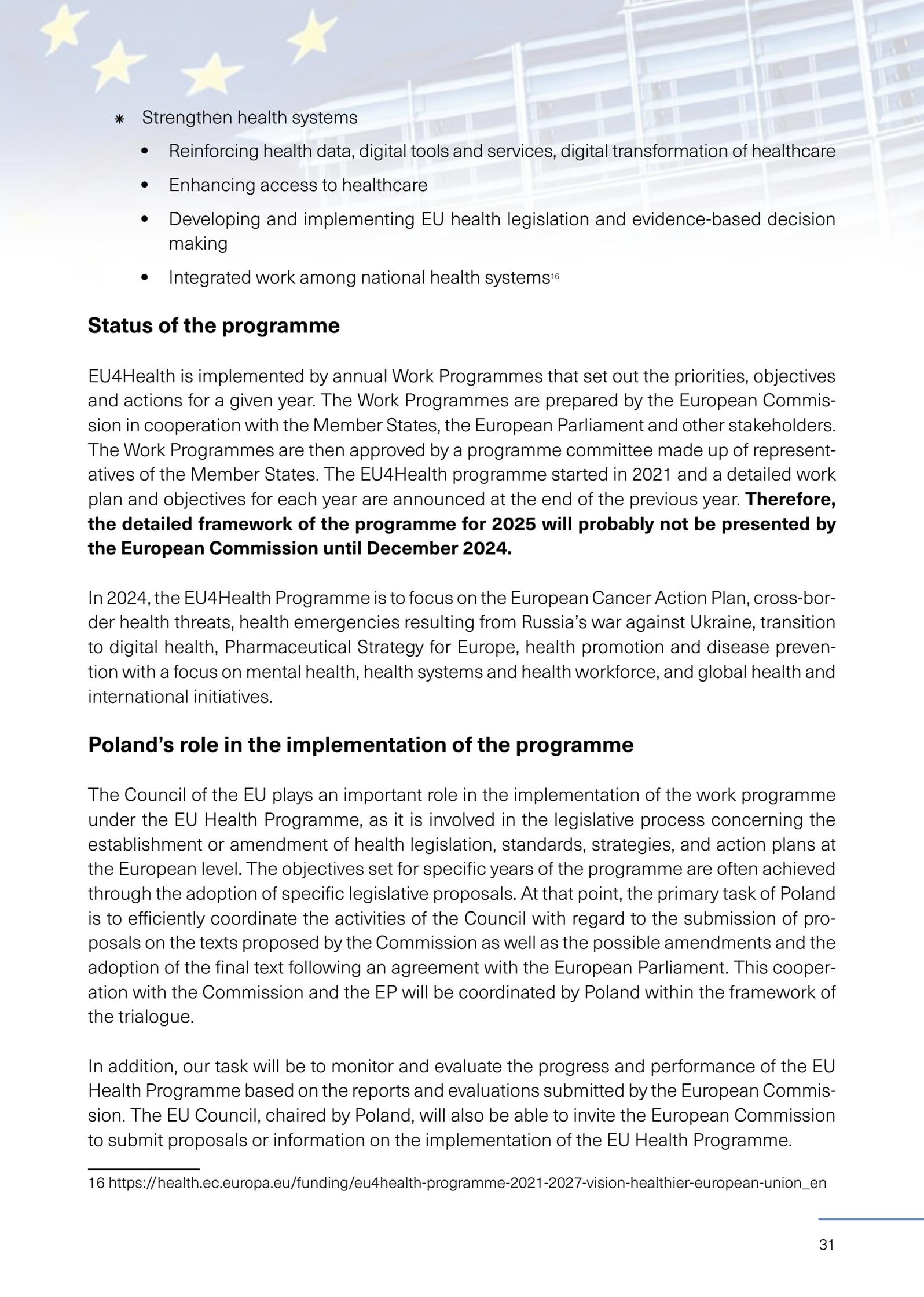
### **Principles of the programme**

The EU4Health programme has four general objective representing the ambitions of the programme and ten specific objectives representing the areas of intervention:

- \* Improve and foster health
  - Health promotion and disease prevention, in particular cancer
  - International health initiatives and cooperation
- \* Protect people
  - Prevention, preparedness and response to cross-border health threats
  - Complementing national stockpiling of essential crisis-relevant products
  - Establishing a reserve of medical, healthcare and support staff
- \* Access to medicinal products, medical devices and crisis-relevant products
  - Ensuring that these products are accessible, available and affordable

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<sup>15</sup> [https://health.ec.europa.eu/publications/factsheet-european-health-union-eu4health-work-programme-2024\\_en](https://health.ec.europa.eu/publications/factsheet-european-health-union-eu4health-work-programme-2024_en)



- \* Strengthen health systems

- Reinforcing health data, digital tools and services, digital transformation of healthcare
- Enhancing access to healthcare
- Developing and implementing EU health legislation and evidence-based decision making
- Integrated work among national health systems<sup>16</sup>

## Status of the programme

EU4Health is implemented by annual Work Programmes that set out the priorities, objectives and actions for a given year. The Work Programmes are prepared by the European Commission in cooperation with the Member States, the European Parliament and other stakeholders. The Work Programmes are then approved by a programme committee made up of representatives of the Member States. The EU4Health programme started in 2021 and a detailed work plan and objectives for each year are announced at the end of the previous year. **Therefore, the detailed framework of the programme for 2025 will probably not be presented by the European Commission until December 2024.**

In 2024, the EU4Health Programme is to focus on the European Cancer Action Plan, cross-border health threats, health emergencies resulting from Russia's war against Ukraine, transition to digital health, Pharmaceutical Strategy for Europe, health promotion and disease prevention with a focus on mental health, health systems and health workforce, and global health and international initiatives.

## Poland's role in the implementation of the programme

The Council of the EU plays an important role in the implementation of the work programme under the EU Health Programme, as it is involved in the legislative process concerning the establishment or amendment of health legislation, standards, strategies, and action plans at the European level. The objectives set for specific years of the programme are often achieved through the adoption of specific legislative proposals. At that point, the primary task of Poland is to efficiently coordinate the activities of the Council with regard to the submission of proposals on the texts proposed by the Commission as well as the possible amendments and the adoption of the final text following an agreement with the European Parliament. This cooperation with the Commission and the EP will be coordinated by Poland within the framework of the triad.

In addition, our task will be to monitor and evaluate the progress and performance of the EU Health Programme based on the reports and evaluations submitted by the European Commission. The EU Council, chaired by Poland, will also be able to invite the European Commission to submit proposals or information on the implementation of the EU Health Programme.

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<sup>16</sup> [https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union\\_en](https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en)

### Context and role of the regulation

On May 3, 2022, the European Commission adopted a proposal for the regulation establishing the European Health Data Space (EHDS).<sup>17</sup> This regulation aims to provide individuals with access to their electronic health data and control over them, as well as to define the principles of secondary use of data in the European Union. The European Health Data Space constitutes a fundamental element of the European Health Union, extending and enhancing the General Data Protection Regulation (GDPR) and the NIS 2 Directive.

### Objectives and principles of the regulation

If effectively executed, individuals' health information would be accessible throughout the EU, empowering researchers and policymakers to leverage the extensive medical data within the EU for enhancing healthcare.

### State of play

Up to this point, the discussions have primarily focused on determining the extent of patient involvement in the sharing of their health data for research. However, concerns have also arisen regarding the financial aspects of the legislation, along with significant apprehensions about the practical implementation of the proposed measures. Despite the apparent complexity, Parliament is committed to finalizing an agreement before the EU election. Whether the EU MS shares the same level of determination is yet to be observed.

The current progress can be presented as follows: On November 28, 2023, the ENVI and LIBE Committees of the European Parliament adopted a report on a proposal related to health data regulation, supporting most provisions and suggesting amendments. On December 6, 2023, the Council of the European Union agreed on its position, introducing changes like limiting data scope and establishing a European advisory body for health data. The Parliament approved its position on December 13, initiating trilateral negotiations with the Council and the Commission. The Parliament's position mostly aligns with committee-approved measures but includes an amendment allowing patients to object to health data registration. Negotiations have started, but concerns exist, as both the Parliament and Council positions lack full acknowledgment of social partners and worker involvement. The Parliament stresses the need for funding, capacity building, and training for healthcare workers, emphasizing digital skills. While both texts improve consent to data sharing, concerns remain, including the introduction of a data use opt-out, with the Council decentralizing the decision to individual countries, while the Parliament treats it as a built-in general mechanism.

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<sup>17</sup> <https://www.consilium.europa.eu/en/press/press-releases/2023/12/06/european-health-data-space-council-agrees-its-position/>



## Poland's implementation role

Poland will kick off its Presidency most probably after the regulation is in place. Therefore, once in this leadership role, Poland's primary responsibility will be to closely monitor and oversee the implementation of the regulation across different EU member states. This is essential, as the European Health Data Space stands as a crucial component of the European Health Union, marking the inaugural creation of a unified EU data space dedicated to a specific domain. This development is a direct outcome of the European data strategy, illustrating the commitment to fostering cooperation and coherence in health-related data within the EU. Hence, the role of upcoming Presidencies will be to ensure its proper execution to achieve the planned results.

## Reform of the EU pharmaceutical legislation

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### Context

As Bono once said, "Where you live should not determine whether you live, or whether you die" – this statement was used by the Health Stella Commissioner Kyriakides when launching the EU pharmaceutical legislation.

On 26 April 2023, the European Commission unveiled proposed changes to EU pharmaceutical legislation as part of the 2020 Pharmaceutical Strategy for Europe<sup>18</sup> – the major reform over the last two decades. It is to revise and replace the existing general pharmaceutical legislation. With the proposed revision, the 20-year-old regulatory framework for medicines in the EU is expected to result in solid legislative changes.

The objective is to enhance the availability, accessibility, and affordability of medicines while bolstering the competitiveness and sustainability of the EU pharmaceutical industry, focusing on higher environmental standards. The package comprises proposals for a new directive and regulation, intended to replace existing pharmaceutical legislation, including provisions for medicines targeting children and rare diseases.

The proposal consists of two legislative elements:

- \* A new Regulation replacing and amending current Regulation (EC) No 726/2004
- \* A new Directive replacing and amending current Regulation 2001/83/EC

Furthermore, there is also a Council Recommendation on antimicrobial resistance.

Developing multilayered and comprehensive documents is definitely a challenging endeavour. There is a range of improvement areas covered by the legislation, the revision has triggered intense debate and concern, given its implications and potential impact on the pharmaceutical industry.

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<sup>18</sup> [https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation\\_en#:~:text=26%20April%202023&text=The%20proposal%20adopted%20by%20the,2000%2FEC%20%2C%20respectively](https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en#:~:text=26%20April%202023&text=The%20proposal%20adopted%20by%20the,2000%2FEC%20%2C%20respectively)

## Objectives and principles

Experts believe that finally, Europe has gained lessons learned from what happened during the pandemic when supply chains were disrupted. It also realizes that future crises can't be ruled out. The healthcare system should be prepared for new shocks and upheavals.

The EU pharmaceutical legislation regulates the authorisation, manufacture, and distribution of medicines in the EU. It also provides a legal framework for the pharmaceutical sector with a patient-centered approach. The legislation aims to ensure that all patients across the EU have timely and equitable access to safe, effective, and affordable medicines.

Amid the global health challenges, including COVID-19, and to achieve pharmaceutical independence, Europe needs to invest in research, foster innovation, and strengthen cooperation among Member States. In line with the plan, the focus should be on addressing unmet medical needs while ensuring faster access to affordable medicines. One of the reform core elements relates to the intention to shorten the data protection period for pharmaceutical products from seven to five years. Companies can regain two years by launching drugs simultaneously in all 27 member states or conducting comparative clinical trials. This is the aspect that interests and concerns the pharmaceutical sector most in terms of its potential to hinder investment.

A recent study by the European Federation of Pharmaceutical Industries and Associations (EFPIA) indicates that proposed changes in pharmaceutical legislation within the EU may lead to a significant decline in Europe's share of global research and development (R&D) investment. The report forecasts a reduction of one-third in Europe's R&D investment by 2040, resulting in an annual loss of €2 billion (\$2.1 billion).<sup>19</sup>

However, the goals that the revision pursues are presented as follows:

- \* Make sure all patients across the EU have timely and equitable access to safe, effective, and affordable medicines
- \* Enhance the security of supply and ensure medicines are available to patients, regardless of where they live in the EU
- \* Continue to offer an attractive and innovation-friendly environment for research, development, and production of medicines in Europe
- \* Make medicines more environmentally sustainable
- \* Address antimicrobial resistance (AMR) and the presence of pharmaceuticals in the environment through a One Health approach.

## State of play

The main bodies involved in the realisation of the EU pharmaceutical legislation include the European Commission, the European Medicines Agency, and national competent authorities.

<sup>19</sup> <https://www.clinicaltrialsarena.com/news/eu-pharma-legislation-reform/>



With time ticking away, parliament's goal is to reach an agreement and vote on the text in the final plenary of this term in April. MEP Tomislav Sokol, serving as the EPP's shadow rapporteur for the file, stated that while the mandate for future negotiations will be established, the actual commencement of these negotiations is not expected until at least October 2024 due to the upcoming elections.<sup>20</sup>

When discussing the current stance on the regulation, it is important to highlight that the Belgian presidency has one of the core elements of the EU pharmaceutical legislation, medical shortage issues, on its priority list – here continued coordinated action is required to address supply challenges and to make Europe's medicine supply chains more resilient in the long run. In this context, Belgian Health Minister Frank Vandenbroucke told the EPSCO Council on 30 November that one of the key tasks for Belgium is to address medicine shortages – through the proposed EU pharmaceutical legislation – as soon as possible. He wants to do this by cracking open the negotiations with Chapter 10 of the revision's proposed regulation. Though Belgium is leading the first substantial discussions on the package, it is not realistic to expect any done deal by the end of its presidency.<sup>21</sup>

## **Role of the Polish Presidency**

The Polish Presidency will start in January 2025, after Hungary. It's difficult to assess whether the consensus will be reached by then in terms of making the pharma revision a reality. Nevertheless, Poland, in the interest of all EU Member states, during its presidency of the EU Council, can take several steps to enhance the EU pharmaceutical legislation implementation, among others, advocating for improved access to medicines, especially in countries with longer wait times for new drugs. This could involve advocating for policies that incentivize pharmaceutical companies to launch their products in all EU markets, reducing disparities in access across member states. It is key to mention that Central and Eastern European EU member countries experience significant delays in accessing newly approved medicines compared to their Western counterparts. Patients in Western and larger Member States typically have access to 90% of recently approved medicines, whereas in Eastern and smaller Member States, this number is as low as 10%. Additionally, EU citizens, regardless of their location, face wait times ranging from 4 months to over 2 years to access these medicines. This highlights a notable disparity in timely access to new medications within the EU.

Furthermore, Poland can work towards strengthening the regulatory framework for pharmaceuticals. This includes the implementation of the European Falsified Medicines Directive (FMD) by promoting investment in the development and implementation of a medicinal product authorization system and ensuring compliance with EU-wide regulations.

The drug shortages topic will also be on the agenda, hence pharmaceutical companies can be required to prepare backup plans in cases of supply disruption. This could help mitigate the impact of drug shortages on public health systems.

<sup>20</sup> <https://sciencebusiness.net/news/life-sciences/mep-involved-file-confirms-pharma-reforms-will-be-delayed-until-after-next-years>

<sup>21</sup> <https://www.euractiv.com/section/health-consumers/news/belgium-looks-to-get-a-head-start-on-potential-medicine-shortages/>

Poland can support initiatives to encourage top-quality clinical trials and comparative studies for pharmaceutical products. Finally, as a country leading the unified efforts in the EU Council, Poland can promote closer cooperation and coordination among EU member states, regulatory authorities, and pharmaceutical industry stakeholders to ensure efficient implementation of pharmaceutical legislation and directives. By actively engaging during its presidency of the EU Council, Poland can contribute to the ongoing reform and enhancement of EU pharmaceutical legislation, ultimately benefiting public health and access to medicines across the European Union.

## Critical Medicines

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### Context

In recent decades, the production of medicinal products in Europe has declined significantly. This trend has daily consequences in the form of market disruptions and supply bottlenecks when manufacturers cease production within the EU.

These problems are part of a wider trend in which Europe's share of global production of active substances has fallen from 53% in 2000 to 25% in 2020, with the majority of production shifting to Asia, particularly China. Trade data shows that China accounted for 40% of global trade in active substances in 2019. The same is true for the other ingredients needed to produce the medicines Europe relies on – 74% is imported from Asia, 70% of which comes from China. This shift goes hand in hand with the increasing monopolisation of the entire value chain, where one or two manufacturers control the global market and different active substances or ingredients are produced in one and the same plant.

### Objectives and principles

In order to be able to respond effectively to future problems in the production and thus the availability of medicinal products and active pharmaceutical ingredients, Belgium, together with 21 other countries – including Poland – has proposed the introduction of the Critical Medicines Act (CMA).<sup>22</sup> The premises of this legal act are currently being worked out by the European Commission and the Council, and the Commission's draft legislation is expected to be published in 2025.

What we do know is that the objectives of the proposed regulation will be as follows:

- \* to reverse the general trend of declining production of medicinal products after their patent expiry in Europe,
- \* to diversify pharmaceutical supply chains;
- \* to ensure a “strategic autonomy” for key medicines.

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<sup>22</sup> <https://www.politico.eu/wp-content/uploads/2023/05/02/Non-paper-security-of-medicines-supply-02.05.23.pdf>



This act is intended to be a specific set of instruments comprising a package of general instruments – reversing the general decline in European production and introducing diversification of supply – and specific instruments – ensuring adequate capacity for Europe to produce essential medicines on a large scale in order to minimise the risks associated with access to them.

## **State of play**

There is no doubt that the debate on the shortage of medicines and the EU's strategic autonomy in the field of health will be high on the EU's agenda – as evidenced both by the above-mentioned document initiated by Belgium, the statements of the EU Health Commissioner and the legislative acts recently adopted by the EU institutions – including the European Parliament's resolution on the COVID-19 pandemic: lessons learned and recommendations for the future. In its opinion on the development of the Critical Medicines Act, the European Economic and Social Committee (EESC) called for, among other things, the inclusion of appropriate EU guidelines for the pricing of finished medicinal products on the European market and for reimbursements in order to ensure the competitiveness of active pharmaceutical ingredients (APIs) and finished medicinal products manufactured in Europe.<sup>23</sup>

As a next step, the European Medicines Agency published the first EU Critical Medicines List in December 2023 to create an appropriate legal framework for the preparation of concrete measures and possible solutions to address shortages of critical medicines.<sup>24</sup> The list contains medicines for which a continuous supply is necessary, i.e. when the interruption of their use can lead to serious health consequences. Two criteria were taken into account when compiling the list: the severity of the disease and the availability of alternative medicines.

On 16 January this year, the Commission launched the Critical Medicines Alliance<sup>25</sup> to coordinate public procurement at the EU level, increase European production capacity, diversify supply, develop a common strategic approach to stockpiling medicines in the EU, and help leverage EU and national resources for these tasks.

The Alliance, the European Commission notes, will become “the industrial arm of a strong European Health Union”. The Critical Medicines Alliance is open to all companies and organisations, Member States, local and regional authorities and their agencies, social partners, civil society, health professionals, patients, consumers as well as other stakeholder groups, EU bodies, and agencies.

According to the Commission's assumptions, the Alliance should start its work in April 2024 and the first recommendations for measures to improve the availability of critical medicines should be published in autumn at the latest. The Alliance itself is expected to operate for five years and actively participate in the adoption of the above-mentioned legislation in this area.

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<sup>23</sup> <https://www.eesc.europa.eu/en/news-media/news/critical-medicines-act-secure-europes-pharmaceutical-independence>

<sup>24</sup> [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_23\\_6377](https://ec.europa.eu/commission/presscorner/detail/en/ip_23_6377)

<sup>25</sup> [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_24\\_182](https://ec.europa.eu/commission/presscorner/detail/en/ip_24_182)

## **Role of the Polish Presidency**

Regardless of the political mood and the outcome of the parliamentary elections, the role of the Polish Presidency trio in the work on the Critical Medicines Initiative appears to be crucial. The noticeable decline in the production of pharmaceuticals in Europe, especially of active ingredients, is a significant problem related to market disruptions and supply shortages, especially when production is relocated outside the EU, particularly to Asia.

As mentioned above, a draft of the Critical Medicines Regulation is expected to be published in 2025. Therefore, Poland's role in this context may include active participation in the process of creating and implementing the Critical Medicines Act. As an originator of this initiative, Poland can make a significant contribution to shaping regulations aimed at securing the production of medicinal products in the European Union.

In addition, Poland has the opportunity to work to achieve strategic autonomy by supporting pharmaceutical production in Europe, reversing the trend of declining production, and diversifying pharmaceutical supply chains. Participation in the Critical Medicines Alliance, initiated by the European Commission, is another aspect of Polish activities. The Alliance aims to coordinate public procurement, increase European pharmaceutical manufacturing capacity, diversify supply, and develop a common strategic approach to stockpiling medicines in the EU.

It should also be emphasised that during its EU Council Presidency, Poland will have the opportunity to take a leading role in the debates on pharmaceutical shortages and strategic autonomy in the field of healthcare. We will be able to act as a conciliator and moderator and reach an agreement between the often conflicting interests of Member States in this important area.

## **Europe's Beating Cancer Plan**

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### **Context**

Europe's Beating Cancer Plan is a European Commission initiative that aims to prevent, detect, treat, and improve the quality of life of cancer patients in Europe. The Plan is structured around four key action areas where the EU can add the most value, namely prevention, early detection, diagnosis and treatment, and quality of life of cancer patients and survivors. The Plan includes ten flagship initiatives and sixty supporting actions. The Plan is implemented in cooperation with the Member States, the European Parliament, the Council, the European Economic and Social Committee, the Committee of the Regions, civil society organisations, the private sector, and other stakeholders. The plan has a founding budget of EUR 4 billion, including EUR 1.25 billion from the future EU4Health programme.

The plan fits into the wider context of EU health policy, which also includes the European Health Union, the EU4Health Strategy, the European Green Deal, the European Pillar of Social



Rights,<sup>26</sup> the European Strategy for Equality between Women and Men, the European Strategy for the Rights of Persons with Disabilities and the European Data Strategy.<sup>27</sup> The plan also capitalises on the potential of Horizon Europe, including the EU Mission: Cancer, which aims to reduce the burden of cancer in Europe through the development and implementation of ambitious and concrete targets and actions. The plan also takes into account the recommendations and opinions of the European Economic and Social Committee and the Committee of the Regions, which emphasise the importance of cancer prevention, improved cancer care, cross-sectoral and interdisciplinary cooperation, and the involvement of citizens and stakeholders. The plan builds on existing and planned EU legislation and regulations that affect cancer prevention and treatment, such as the Council Recommendation on vaccine-preventable cancers, the Cancer Prevention Package — Revision of the Council Recommendation on smoke-free environments, and the Council Recommendation on Strengthening prevention through early detection: A new approach on cancer screening replacing Council Recommendation 2003/878/EC.

## **State of play**

The European Commission has published a roadmap with progress indicators for the Plan,<sup>28</sup> which will be regularly updated and evaluated. The European Commission has set up an implementation group and a stakeholder contact group to monitor and coordinate progress. The Implementation Group is composed of representatives of the European Commission, the Member States, the European Parliament, the Council, the European Economic and Social Committee, the Committee of the Regions, and the EU Mission: Cancer. The Stakeholder Contact Group consists of representatives from civil society organisations, the private sector, academia, and other interest groups. The Implementation Group has held three meetings so far to discuss the implementation plan for the EU Mission: Cancer and the roadmap for the Plan. The Stakeholder Contact Group has held one meeting so far to present the general structure and objectives of the plan. The European Commission has invited all members of the Stakeholder Contact Group to complete a survey to identify their interests and expectations of the Plan. The Commission will also launch a call for applications for the thematic groups that will address the pillars and cross-cutting themes of the plan. The European Commission also plans to hold regular stakeholder information meetings and workshops to ensure dialogue and cooperation on the plan.

## **Role of the Polish Presidency**

According to the above-mentioned roadmap, which sets out the different phases of the Plan's implementation, many activities and initiatives related to the Plan will be underway or in the final stages during the Polish Presidency. While the European Parliament elections may cause the schedule to shift, our focus during the presidency will likely be on the following legislative proposals concerning the battle against cancer:

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26 <https://eur-lex.europa.eu/PL/legal-content/glossary/european-pillar-of-social-rights.html>

27 <https://www.gov.pl/web/ia/europejska-strategia-w-zakresie-danych>

28 [https://health.ec.europa.eu/system/files/2022-01/2021-2025\\_cancer-roadmap1\\_en\\_0.pdf](https://health.ec.europa.eu/system/files/2022-01/2021-2025_cancer-roadmap1_en_0.pdf)

- \* **Improving the quality and availability of screening — Poland** can contribute to the revision of **the Council Recommendation on Strengthening prevention through early detection: A new approach to cancer screening replacing Council Recommendation 2003/878/EC**,<sup>29</sup> and to the implementation of the **European Reference Network on Cancer Screening**.<sup>30</sup> Poland can also share its experience and best practices in organising and monitoring cancer screening, particularly with regard to cervical and colorectal cancer. To this end, Poland can participate in consultations and negotiations on the new Council Recommendation, cooperate with other Member States and the European Commission within the European Reference Network, and develop and implement national cancer screening programmes in line with European guidelines and standards.
- \* **Vaccine-preventable cancer prevention — Council Recommendation on vaccine-preventable cancers will also be reviewed shortly**<sup>31</sup> — it aims to help Member States prevent cancers linked to human papillomavirus (HPV) and hepatitis B virus (HBV) infections. The Recommendation aims to increase the number of vaccinations against HPV and HBV, especially in girls and boys, and to improve the monitoring and evaluation of vaccination programmes.
- \* The fight against tobacco smoke — the subject of the Polish Presidency's work will most likely be the **Cancer Prevention Package — Revision of the Council Recommendation on smoke-free environments**.<sup>32</sup> As announced by the European Commission, this initiative aims to update and extend the scope and quality of protection from exposure to tobacco smoke, including through the inclusion of new products such as disposable e-cigarettes and heated tobacco products and the extension of the smoking ban to certain outdoor areas.
- \* **Supporting healthy lifestyles — Poland**, with its experience in the field of disease prevention, will be able to effectively promote the **HealthyLifestyle4All initiative**, which aims to raise awareness and promote healthy eating, physical activity, and the reduction of tobacco and alcohol consumption. Poland can also support **the implementation of the European Action Plan to Reduce the Harmful Use of Alcohol**<sup>33</sup> and a **European action plan against the use of tobacco**.<sup>34</sup>

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29 [https://www.europarl.europa.eu/thinktank/pl/document/EPRS\\_BRI%282021%29690526](https://www.europarl.europa.eu/thinktank/pl/document/EPRS_BRI%282021%29690526)

30 [https://health.ec.europa.eu/publications/europes-beating-cancer-plan\\_en](https://health.ec.europa.eu/publications/europes-beating-cancer-plan_en)

31 <https://www.europarl.europa.eu/legislative-train/theme-environment-public-health-and-food-safety-envi/file-council-recommendation-on-vaccine-preventable-cancers>

32 <https://www.eesc.europa.eu/en/our-work/opinions-information-reports/opinions/train-de-mesures-sur-la-prevention-du-cancer-revision-de-la-recommandation-du-conseil-relative-aux-environnements-sans>

33 [https://health.ec.europa.eu/system/files/2022-02/eu\\_cancer-plan\\_en\\_0.pdf](https://health.ec.europa.eu/system/files/2022-02/eu_cancer-plan_en_0.pdf)

34 [https://health.ec.europa.eu/system/files/2022-02/eu\\_cancer-plan\\_en\\_0.pdf](https://health.ec.europa.eu/system/files/2022-02/eu_cancer-plan_en_0.pdf)

## Events dedicated to the Polish Presidency in the Council of the European Union

The Pathway to the Presidency conference is a continuation of previous initiatives of the Institute for Social Policy Development dedicated to the Polish Presidency of the Council of the EU – the special event in September as part of the 32nd Karpacz Economic Forum and the October Healthcare Policy Summit: Health Priorities of the Polish Presidency of the EU Council 2025.

**The Conference Health Priorities of the Polish Presidency of the Council of the European Union 2025 – a special event as part of the 32nd Karpacz Economic Forum – 6 September 2023.**



Last year, a unique roundtable debate entitled Health Priorities of the Polish Presidency of the Council of the European Union 2025, which we organised in cooperation with the Institute of Eastern Studies, took place as part of the 32nd Karpacz Economic Forum. It was a great opportunity to discuss key issues related to the health priorities of the Presidency of the Council of the European Union, which Poland will take over on 1 January 2025 and will hold for the next six months. We invited more than 30 representatives of public institutions, system experts, professionals from various fields of medicine, representatives of industry organisations, and patient organisations to take part in the discussion.

Speakers at the event included clinicians from the fields of rare diseases, diabetes, endocrinology, clinical genetics, cardiology, neurology, oncology, and psychiatry.

## Healthcare Policy Summit: Health Priorities of the Polish Presidency of the EU Council 2025 – 4 October 2023.



In October last year, we once again had the opportunity to discuss what the Polish Presidency will look like in just over a year's time among outstanding experts, decision-makers, doctors, stakeholders and industry representatives, i.e. people who know the problems of the Polish and European healthcare system best. During the debate, a call was made to create a common vision of the presidency in the area of healthcare priorities across all sectors. Experts pointed out that Poland should endeavour to gain the full trust of the European community, which it will receive if it pursues a policy based on facts and figures. All participants unanimously acknowledged the importance of this expert summit and noted that the organisation of similar events should be a model for the preparation of health priorities, also during future Polish presidencies.

We were able to learn about the needs and urgent priorities of health policy from a very diverse perspective, as the speakers were specialists in the fields of allergology, surgery, diabetes, rare diseases, endocrinology, immunology, cardiology, neurology, oncology, paediatrics, psychiatry and rheumatology, among others.

## Experts on the Polish Presidency in the Council of the European Union

Determining the key focuses of the presidency of the Council of the European Union is not just a crucial matter, but also one that requires careful consideration. We believe that “The Pathway to the Presidency conference and the accompanying report will only be the beginning of an in-depth reflection on this issue and will create the conditions for Poland to take a leading role in the EU in the field of healthcare and health policymaking. To this end, it is worth listening to the voices of healthcare experts. Many of them have already shared their observations as part of the new “Talk about the Presidency” podcast series.

Join us in watching and listening to Talk about the Presidency. With your interests in mind, we have compiled the most noteworthy remarks from the noteworthy guests who took part in this exceptional project.



### **Prof. Bolesław Samoliński:**

*“The contribution of experts played a major role in the success of the first Polish Presidency of the Council of the European Union. At that time, Deputy Minister of Health Adam Frąnczak commissioned experts to develop the main directions of health policy, which significantly influenced its design during the presidency”.*

*“Under the Presidency, issues of national health systems will be replaced by a broader health policy. We focus on creating and promoting a health-promoting attitude and on activities aimed at preventing and limiting diseases of civilisation”.*



### **Prof. Adam Fronczak:**

*“The current health priorities are wide-ranging and cover many important health issues affecting Europe and its population. As the forthcoming Polish Presidency develops, it is important that they are further refined, as was the case during the first Polish Presidency. The European Commission and other European institutions are key players in shaping health policy, with a direct impact on the refinement of the priorities”.*

*“Healthy ageing is a fixed item on the presidency’s health agenda. With Europe’s ageing population, it is important to focus on how older people can stay active and how to effectively address their health problems. It is our responsibility to work together at a European level to address the challenge of caring for the well-being of seniors and helping them remain active in society”.*



### **Igor Radziewicz-Winnicki MD PhD:**

*“Drug safety and epidemiological safety are extremely important. The significance of the modern pharmaceutical industry in maintaining this safety has been highlighted by the COVID-19 pandemic. The swift and efficient response of the pharmaceutical industry to evolving health conditions and needs is a crucial contribution to global health security”.*

*“A crucial hurdle is the reality that the manufacturing of pharmaceuticals heavily relies on low-cost labor from countries outside of the European Union. It is important for Poland, and other EU members, to not exclusively rely on this production model. It is crucial to invest in the development of our own pharmaceutical industry, which is becoming essential to ensure the drug safety”.*



### **Irena Rej:**

*“Many times, ideas originating from ministerial offices face obstacles that prevent their implementation, such as technical issues, organizational complexities, or Poland's geographical setting. The realities and limitations of the pharmaceutical industry should be taken into account by health policy makers”.*

*“An approach based on trust and co-operation with the business, rather than imposing solutions, is crucial both in Poland and internationally. Such interactions between the public and private sectors are essential for the effective functioning of the healthcare system”.*



### **Jarek Oleszczuk MD PhD:**

*“As Poland assumes the role of EU Council Presidency, it is crucial to assess the country's healthcare strengths and the healthcare gaps and needs of other member states in the European Union. Priority should be given to identifying and utilizing Polish capabilities to reinforce health protection at the European level”.*

*“Member States should develop mechanisms to enable the earliest possible marketing authorisation and availability of advanced therapies to patients. It is crucial for patients that therapies that are available abroad are also available in their home country. Rapid access to modern therapies is essential for improving patients' quality of life”.*



### **Marcin Rynkowski:**

*“The upcoming Polish Presidency in 2025 will be different from the previous one, mainly due to the greater number of legislative initiatives and the need for more intensive work. During our first presidency, we focused mainly on the adoption of several sets of conclusions by the Council of the European Union.”*

*“The coordination of activities in Brussels is based on personal relationships between the representatives of the Member States. The director responsible for coordination plays a key role, both because of the need to react quickly and because of the need to maintain good relations”.*



### **Małgorzata Bogusz:**

*“The forthcoming Polish EU Council Presidency is very important. As part of a trio of three Member States, including Poland from January 2025, followed by Denmark and Cyprus, we have the opportunity to show progress in healthcare since our last presidency. It is an opportunity to showcase the changes in healthcare that Poland has achieved in the last decade”.*

*“In the context of the upcoming Polish Presidency of the EU Council, it is important for Poland to effectively implement selected health priorities. We should learn from the experience of other Member States and their approach to health priorities, especially in the face of challenges such as the COVID-19 pandemic and the consequences of the war in Ukraine”.*



### **Grzegorz Rychwalski:**

*“The remaining year until the presidency should be dedicated to preparing everyone for the implementation of our priorities. The presidency itself is only a continuation of the work, the culmination of efforts undertaken earlier”.*

*“In the field of pharmaceutical policy – soon, as the leader of the EU Council, we will engage in trilogues with the European Commission and the European Parliament to adopt the final wording of regulations agreed upon within the pharmaceutical package. The second challenge awaiting us is work on the package concerning intellectual property, and the third will be the initiation of legislative actions on the medicines security act, aimed at supporting the production of active substances and basic medicinal products”.*



### **Dr. Małgorzata Gałązka-Sobotka:**

*“Health policy belongs to the areas where member states independently define rules and principles, but we are fully convinced that health capital determines the sustainable development of the entire European community, not just individual countries”.*

*“We should not propose an entirely new agenda, detached from the priorities set by our predecessors. A priority of strategic importance is undoubtedly the continuous search for solutions that will increase the resilience of healthcare systems to shocks”.*



### **Stanisław Maćkowiak:**

*“Among the priorities, there should also be the development of an action plan for rare diseases. They were included in the agenda of our predecessors, so this topic should be continued. It is still a serious problem, as it affects 6 to 8% of the European population”.*

*“Coordination of certain actions will be important. There is no point in creating separate centers in each member state dealing with the treatment of the rarest diseases affecting a few people throughout Europe. One center for the entire European Union would be sufficient to help all its citizens”.*



### **Arkadiusz Grądkowski:**

*“The announced priorities still require clarification. Setting them is just the beginning. A concrete idea for implementation is needed, and it should start as soon as possible”.*

*“The pandemic has shown how important the significance of medical equipment is. It is crucial for Poland and Europe to be completely secured in terms of medical products. Europe has imposed such challenging requirements regarding their production that it is beginning to lag behind in this innovative industry. Streamlining the granting of competencies to notified bodies – institutions certifying medical equipment should also be one of our priorities”*

You can listen to all episodes of the series on our website at <https://irss.org.pl/podcasty/>.

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  - Presidency of the Council of the European Union <https://www.consilium.europa.eu/pl/council-eu/presidency-council-eu/>
  - Proposal for a regulation concerning substances of human origin [https://health.ec.europa.eu/blood-tissues-cells-and-organs/overview/proposal-regulation-substances-human-origin\\_en](https://health.ec.europa.eu/blood-tissues-cells-and-organs/overview/proposal-regulation-substances-human-origin_en)
  - SoHo: Council and Parliament struck a deal <https://www.consilium.europa.eu/en/press/press-releases/2023/12/14/blood-tissues-and-cells-council-and-parliament-strike-deal/>
  - Spanish presidency programme <https://spanish-presidency.consilium.europa.eu/media/e4ujaagg/the-spanish-presidency-programme.pdf>
- Timeline of the Presidencies of the Council of the European Union







