

# Public Policy Review

Periodic review of the European public  
policy landscape

July 2024 – January 2025

*The current edition covers legislative initiatives of the second half of 2024.  
It is designed to provide the readers with a retrospective overview. All initiatives will be further  
monitored by the EHC.*

# Table of Contents

|   |   |
|---|---|
| <i>Reflecting on the previous EU legislative term (2019-2024)</i> | 4 |
| <i>Future EU Health Priorities: A Look Ahead</i>                  | 5 |
| <i>European elections 2024</i>                                    | 5 |
| <i>European Health Union</i>                                      | 6 |
| Pharmaceutical legislation  | 6 |
| European Health Data Space (EHDS)                                 | 6 |
| <i>Health Technology Assessment (HTA)</i>                         | 7 |
| <i>EU Critical Medicines Act</i>                                  | 7 |
| EHC joins Critical Medicines Alliance                             | 7 |
| EU List of Critical Medicines                                     | 8 |
| <i>Social care</i>  | 8 |
| <i>Looking forward</i>  | 9 |
| Polish Presidency of the Council of the European Union            | 9 |

## Reflecting on the previous EU legislative term (2019-2024)

The health policy landscape during the European Union (EU) legislative term from 2019 to 2024 was notably shaped by the response to the COVID-19 pandemic. This period not only brought health issues to the forefront of the EU's political agenda but also provided a rare opportunity for significant reforms and initiatives aimed at strengthening the European Health Union. These efforts are expected to leave a lasting impact on public health across Europe for decades, particularly in areas such as health security, access to medicines, and cross-border healthcare.

The COVID-19 pandemic accelerated the EU's efforts to create a more unified and resilient health framework, pushing forward initiatives that might otherwise have taken longer to implement. The pandemic highlighted the need for greater coordination in health policy, improved preparedness for future health crises, and greater solidarity in managing cross-border health risks. This laid the groundwork for broader reforms that will shape EU health policy in the coming years.

One of the most ambitious initiatives introduced by the European Commission was the reform of the EU's pharmaceutical legislation, the most significant overhaul in the last 20 years. This reform seeks to improve the accessibility, affordability, and environmental sustainability of medicines while fostering innovation and maintaining the EU's global competitiveness in the pharmaceutical industry. The aim is to create a more sustainable and patient-centered pharmaceutical system that can better respond to the needs of European citizens, especially in times of health crises.

During its legislative term, the European Parliament formalized its position on this reform. Key points of contention included the duration of market exclusivity, regulatory data protection, the definition of unmet medical needs, and the incentives for developing new medicines. The newly elected EU institutions will likely finalize negotiations and adopt the revised legislation in the upcoming term.

Another significant initiative was the establishment of the European Health Data Space (EHDS). The aim of this initiative is to facilitate cross-border access to patients' electronic health records, which would enable healthcare professionals across the EU to seamlessly access patient data. Practically, this means integrating key medical information—such as medical images, laboratory results, and health summaries—into a European portal known as MyHealth@EU, accessible to both healthcare professionals and patients.

One point of controversy surrounding the EHDS is the provision for 'secondary use' of data. This would allow anonymized or pseudonymized medical records to be transferred to a centralized national data space for research purposes. This aspect of the legislation has raised concerns about privacy and data security, which will likely require further clarification in the negotiations ahead. Nevertheless, the EHDS represents a major step toward ensuring that the EU's digital health infrastructure can support not only patient care but also medical research and public health efforts on a European level.

In addition to these health-focused initiatives, the EU also made progress on social policies, including the introduction of the EU Disability Card. As the legislative term drew to a close, the European Parliament reached a provisional agreement on the card, which is designed to improve mobility for individuals with disabilities across the EU. The new rules, already agreed upon by both the Parliament and the Council, will provide an EU-wide disability card granting preferential access, such as reduced entry fees, priority access, and reserved parking, among other benefits. The legislation also includes provisions for participants in mobility programs like Erasmus+ and for third-country nationals.

## Future EU Health Priorities: A Look Ahead

Looking to the future, several key health priorities are likely to shape the EU's policy agenda. The European Commission's health agenda for 2024-2029 will likely aim to strengthen healthcare systems across the EU, ensuring they are resilient, accessible, and capable of addressing future health crises. Key priorities include enhancing crisis preparedness and management, particularly in response to pandemics and cross-border health threats, while improving access to affordable medicines, vaccines, and medical equipment. A focus will also be placed on the development of innovative health products and technologies, alongside investing in digital health infrastructure, including the European Health Data Space, to improve data sharing and interoperability among healthcare systems.

Additionally, the Commission will promote preventive health initiatives, including health promotion campaigns targeting diseases like cancer and mental health challenges. The EU will continue to encourage healthier lifestyles and disease prevention strategies, ensuring equitable access to care and fostering a more integrated and innovative approach to public health across member states. This comprehensive vision seeks to enhance public health outcomes, address current healthcare challenges, and prepare for future global health threats.

## European elections 2024

The European elections in June 2024 resulted in the center-right European People's Party (EPP) remaining the largest group in the European Parliament. Meanwhile, the liberal Renew group and the Greens experienced significant losses in seats. This shift to the right is expected to lead to stronger support for industries and a renewed focus on enhancing European competitiveness. With this shift, there may be increased emphasis on ensuring that the EU's economic policies continue to foster growth while maintaining high social standards.

Regarding the European Commission, Olivér Várhelyi has been designated as the new Commissioner for Health and Animal Welfare. A lawyer by training, Mr. Várhelyi is currently serving as the European Commissioner for Neighbourhood and Enlargement. His extensive background includes serving as Hungary's Permanent Representative to the EU and leading the unit responsible for Industrial Property Rights within the Directorate-General for Internal Market and Services at the European Commission. As Commissioner for Health, Mr. Várhelyi will play a crucial role in overseeing the

ongoing reforms to the pharmaceutical sector, the health data space, and other initiatives designed to strengthen Europe's health resilience in the years to come.

## European Health Union

### Pharmaceutical legislation

As readers may recall, in 2023, the European Commission proposed a comprehensive reform of the EU's pharmaceutical legislation, the largest in over 20 years, with the aim of making medicines more accessible, affordable, and environmentally sustainable while fostering innovation and competitiveness in the EU pharmaceutical industry.

The revision focuses on improving the availability of medicines, addressing shortages, enhancing the approval process for new treatments, and ensuring better access to life-saving drugs for all EU citizens.

Key aspects of the revision include:

- Streamlining regulatory processes to speed up the approval of medicines, especially for rare or complex diseases.
- Strengthening the European Medicines Agency (EMA) and improving cooperation among EU member states to better manage shortages.
- Encouraging innovation, particularly in areas like pediatric and antibiotic treatments.
- Ensuring fair pricing and access to medicines across the EU.

As of now, the European Commission's proposal for the revised legislation is under negotiation between the European Parliament and the Council of the EU, with discussions ongoing regarding key provisions such as intellectual property rules, pricing policies, and incentives for pharmaceutical research. The revision aims to be concluded by 2025.

### European Health Data Space (EHDS)

As readers may recall, in May 2022, the European Commission launched the [\*European Health Data Space\*](#) (EHDS) as part of the European Health Union to allow cross-border access to patients' electronic records so that general practitioners (GPs), hospitals, and medical practitioners can see a patient's medical data throughout the EU. On 21<sup>st</sup> January, the EU adopted this new Regulation.

For patients, the EHDS would make it possible, for example, for a Lithuanian tourist to pick up a prescription in a French pharmacy, or for doctors to access the health information of an Italian patient undergoing treatment in Belgium. This so-called 'primary use' of data will mean a patient's data such as medical images, lab results or health summaries added to a European portal called MyHealth@EU. Medical professionals and the patients themselves will be able to access the data (in the relevant European language) through this platform.

Platforms for data secondary use such as research, public policy or medical innovation, will also be set up to improve research collaboration across the EU through the vast amount of data collected.

The regulation will come into force in mid-March, with a conference on the implementation of the European Health Data Space will be organised on 18 March by the Polish Presidency of the Council of the EU.

Read Regulation [here](#).

## Health Technology Assessment (HTA)

The European Health Technology Assessment (HTA) Regulation 2021/2282 represents a fundamental shift in how medical technologies are evaluated across the European Union. Implemented in January 2025, this groundbreaking legislation establishes a permanent framework for joint assessments, marking a significant advancement in European healthcare policy harmonization.

The regulation introduces a progressive implementation timeline: beginning with cancer treatments and advanced therapy medicinal products in 2025, extending to orphan medicines in 2027, and encompassing other new medicines by 2028. This phased approach allows for systematic adaptation while maintaining high-quality standards. For rare diseases like hemophilia, where evidence generation can be challenging, this coordinated approach is particularly significant.

The regulation's core objective is to streamline evaluation processes while preserving member states' authority over pricing and reimbursement decisions. This balance ensures national healthcare systems retain control over resource allocation while benefiting from shared expertise and standardized clinical evidence assessment.

## EU Critical Medicines Act

As the one of the top priorities for EU health policy, European Commission is expected to propose the EU Critical Medicines Act is a legislative initiative aimed at addressing the European Union's vulnerability to disruptions in the supply of critical medicines. The act focuses on ensuring the availability of essential drugs, particularly in situations of shortages or emergencies, by strengthening the resilience of supply chains. Key measures include enhancing the stockpiling of critical medicines, improving transparency and information-sharing among stakeholders, and promoting the development of more diversified supply sources. The goal is to safeguard public health by ensuring that life-saving medicines are consistently accessible, especially during crises like pandemics or geopolitical tensions.

## EHC joins Critical Medicines Alliance

The EHC joined the Critical Medicines Alliance – European Commission’s Initiative initiative aimed at ensuring the availability and accessibility of essential medicines across the European Union. It brings together stakeholders from the public and private sectors, including healthcare providers, pharmaceutical companies, policymakers, and patient organizations, to address and prevent critical medicine shortages. The alliance focuses on enhancing the resilience of medicine supply chains, improving transparency, and promoting strategic stockpiling of key drugs. Its goal is to ensure that life-saving medications are consistently available, particularly during emergencies or disruptions, thereby safeguarding public health and the well-being of EU citizens.

## EU List of Critical Medicines

On 16<sup>th</sup> December 2024, the European Commission, the Heads of Medicines Agencies (HMA) and EMA published the first version of the Union list of critical medicines. It contains more than 200 active substances of medicines for human use considered critical for healthcare systems across the EU/EEA, for which continuity of supply is a priority and shortages should be avoided. The European medicines regulatory network will prioritise critical medicines for EU-wide actions to strengthen their supply chain.

The publication of the Union list will not impact existing or to-be-established national lists of critical medicines. However, it will support the network’s efforts in drawing up national lists where these do not yet exist. In addition, it will support and expedite the EC’s analysis of the supply chain of critical medicines to determine potential vulnerabilities. A medicine is considered critical if it is used in serious diseases and cannot be easily replaced by other medicines, for example, in case of a shortage. It is included in the Union list of critical medicines if it meets certain criteria, including being critical in more than one-third of EU/EEA countries.

The medicines, critical for the EHC community can be found in the section ‘B - Blood and blood forming organs’.

The noticeable omission in the list is Von Willebrand factor. The EHC is engaging with relevant stakeholders to ensure that the next edition would feature all critical medicines for bleeding disorders.

*The list is available [here](#).*

## Social care

On 14 October 2024, the Council of the European Union has formally adopted the agreement on the European Disability Card, which aims to enhance mobility for people with disabilities across the EU. This is a positive development for Europeans living with a rare disease, many of whom are affected by a related disability. The European Disability Card will act as proof of disability status, granting equal access to special conditions and preferential treatments in various settings like public transport, cultural events, museums, leisure and sports centres, and more. These benefits may



include free entry, reduced tariffs, priority access, personal assistance, and mobility aids. The card will complement national disability cards already issued by individual countries.

Additionally, the enhanced European Parking Card will ensure access to designated parking spaces and facilities for persons with disabilities throughout EU countries, replacing existing national parking cards. The proposal was put forth in September 2023, and negotiations between the EU Council and European Parliament are underway. Once a legal act is passed, EU governments will have 2.5 years to implement these cards for their nationals. This initiative aligns with the EU's Strategy for the Rights of Persons with Disabilities 2021-2030, building upon the EU disability card pilot project and Council Recommendation 98/376.

Read more [here](#).

## Looking forward

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

On 1 January 2025, Poland took over the Presidency of the Council of the European Union. Till June 30, it will ensure the continuity of the EU agenda, legislative processes, and cooperation among member states. In the field of health, Polish Presidency of the Council of the European Union will focus on:

- **Strengthening Europe's Health Security:** This will involve improving preparedness for health crises, such as pandemics, by enhancing cooperation between EU Member States, ensuring better access to critical medicines and medical supplies, and reinforcing the role of the European Health Emergency Preparedness and Response Authority (HERA).
- **Tackling Health Inequalities:** The presidency will work to address disparities in health access and outcomes across the EU. This could involve promoting equitable healthcare systems, improving access to treatment for vulnerable populations, and addressing social determinants of health.
- **Digital Health Transformation:** Poland will prioritize advancing digital health tools and the use of data in healthcare. This includes developing a European health data space and enhancing digital services to improve health outcomes and efficiency in healthcare delivery.
- **Sustainable and Resilient Health Systems:** The presidency will focus on strengthening EU health systems, making them more resilient and sustainable in the face of aging populations, increasing disease burdens, and other long-term challenges. This may include discussions on health workforce issues, financing, and improving the quality of care.
- **Antimicrobial Resistance (AMR):** Poland will continue to push for EU-wide efforts to combat AMR, focusing on promoting the responsible use of antibiotics and other antimicrobials, along with advancing research into new treatments.

Find the full programme [here](#).