Public Policy Review

Periodic review of the European public policy landscape

2025

The current edition covers legislative initiatives of 2025.
It is designed to provide the readers with a retrospective overview. All initiatives will be further monitored by the EHC.

Table of Contents

Navigating EU Health Policy Implementation in 2025: What It Means for the Bleeding Disorders Community

The year 2025 marked a transition in European Union (EU) health policy from design to delivery. Following the 2024 European elections and the formation of new EU institutions, policymakers shifted their focus from crisis management to system-building. For the European Haemophilia Consortium (EHC) community, this change is particularly important: EU decisions increasingly shape how innovation reaches patients, how health data are governed, and how the security of supply for essential medicines is ensured.

Unlike previous years dominated by pandemic recovery, 2025 concentrated on implementation. Flagship initiatives such as the European Health Data Space (EHDS) and the Health Technology Assessment (HTA) Regulation entered their operational phase, while negotiations on pharmaceutical reform and the Critical Medicines Act intensified. Together, these files shape the environment in which rare disease treatments, including those for haemophilia and other bleeding disorders, will be developed, assessed, reimbursed and delivered across Europe.

For people living with rare and chronic conditions, EU legislation is no longer abstract. Joint clinical assessments, cross-border digital health records, disability mobility rights and strategic planning for critical medicines directly influence access, affordability and continuity of care. The challenge for policymakers is to ensure that competitiveness and efficiency do not override equity, and that innovation translates into real-world benefit for all patients, regardless of geography and socioeconomic situation.

European Health Union

Pharmaceutical legislation

In 2025, the EU continued negotiations on the largest reform of pharmaceutical legislation in over twenty years. Building on the Commission's 2023 proposal, institutions worked to modernise the rules governing the development, authorisation, and availability of medicines across Europe.

Key debates focused on balancing innovation incentives with public health goals, including regulatory data protection, market exclusivity, incentives for unmet medical needs, environmental requirements, and measures to prevent shortages. A central objective is to improve access to medicines in all Member States by encouraging faster and more equitable market launch.

Discussions also addressed how the new framework should support advanced therapies and rare disease treatments, ensuring innovation reaches patients efficiently while maintaining high safety standards. For the bleeding disorders community, the reform will influence long-term access and sustainability of treatment options once negotiations are finalised and implemented.

Read more here.

In 2025, the EHC actively contributed to the revision of the EU pharmaceutical legislation by joining stakeholder coalitions to advocate for patient-centred and innovation-friendly reforms. Through the European Patients' Forum (EPF), it supported calls to safeguard meaningful patient involvement in regulatory decision-making, and via the TRANSFORM Alliance it endorsed a joint position on the Pharmaceutical Package to promote equitable and sustainable access to medicines across Europe.

European Health Data Space (EHDS)

In 2025, the European Health Data Space moved from legislation to implementation. Following the adoption of the Regulation, Member States began preparing the national infrastructures needed to connect to MyHealth@EU, enabling cross-border access to electronic health records for patients and healthcare professionals. This marked the start of the practical delivery of EU-wide digital health integration.

EHDS is built on two core functions. Primary use allows patients and clinicians to securely access health data across borders, supporting continuity of care when travelling or receiving treatment in another Member State. Secondary use enables anonymised or pseudonymised data to be used for research, public health, policymaking, and innovation under a common EU governance framework. During 2025, work focused on technical standards, governance structures and guidance on consent, data protection and interoperability. Stakeholder engagement also increased, including discussions on how patient input and real-world evidence can be integrated responsibly.

For people with bleeding disorders, EHDS offers opportunities to improve cross-border care and strengthen evidence generation, while also raising important issues around privacy, patient control, and equitable access to digital health systems. Overall, 2025 confirmed EHDS as a structural pillar of Europe's digital health transformation.

Read the Regulation here.

In 2025 the EHC followed developments around the European Health Data Space (EHDS) regulation by engaging with wider patient community efforts to raise awareness and ensure patient rights and needs are reflected in implementation discussions.

Health Technology Assessment (HTA)

The year 2025 marked the operational start of the EU Health Technology Assessment Regulation, transforming long-standing voluntary cooperation into a permanent EU framework for joint clinical

assessment of health technologies. This milestone shifted HTA from coordination to implementation, with direct relevance for how innovative medicines are evaluated across Member States.

In 2025, joint clinical assessments (JCAs) began for oncology medicines and advanced therapy medicinal products. These EU-level assessments focus on clinical effectiveness and safety, providing a common scientific basis that national authorities can use in their pricing and reimbursement processes. While Member States retain competence over economic evaluation and access decisions, EU HTA reduces duplication and improves consistency in evidence review.

Throughout the year, work concentrated on establishing governance structures, assessment methodologies and stakeholder engagement processes. Member States and the European Commission also advanced guidance on evidence requirements, timelines and the integration of patient input into assessments. This was particularly important for rare and complex conditions, where traditional clinical trial data may be limited and real-world evidence plays a growing role.

Read more [here](#).

In 2025 the EHC actively engaged with the implementation of the EU Health Technology Assessment (HTA) Regulation by participating in stakeholder discussions and advocating for meaningful patient involvement in the new joint assessment processes that began under the Regulation in January 2025.

EU Critical Medicines Act

As an initiative designed to strengthen the security of supply for essential medicines across Europe, the Act responds to vulnerabilities revealed by recent shortages, global disruptions and increasing dependency on limited manufacturing locations. Its overarching objective is to ensure that patients across the EU can rely on continuous access to medicines that are vital for public health.

The Critical Medicines Act focuses on building resilience throughout the entire lifecycle of medicines, from production and procurement to distribution and monitoring. Key policy areas under development include:

- **Strategic stockpiling frameworks** to support coordinated reserves at the EU and national levels.
- **Supply chain diversification**, reducing reliance on single suppliers or regions.
- **Early-warning and shortage prevention systems**, improving real-time information sharing between authorities, manufacturers, and healthcare systems.
- **Regulatory flexibility and coordination**, allowing faster responses when disruptions occur.
- **Support for European manufacturing capacity**, helping secure the long-term sustainability of critical medicines production within the EU.

Throughout 2025, discussions also explored how the Act could better integrate public procurement, competition policy and industrial strategy with health objectives. This reflects a broader EU shift

toward strategic autonomy, ensuring that essential medicines remain available even during geopolitical tensions, pandemics or market instability.

For patients with rare and complex conditions such as bleeding disorders, the Critical Medicines Act is particularly relevant. Shortages can disproportionately affect small patient populations when alternative treatments are limited. The Act therefore has the potential to improve predictability, transparency and accountability across supply chains, supporting continuity of care in all Member States.

Read more here.

In 2025 the EHC actively engaged with the development of the EU Critical Medicines Act, issuing a formal statement welcoming the initiative to strengthen supply chains and calling for the bleeding disorders community's needs to be reflected in the final framework. It also shared suggested amendments with Members of the European Parliament and held a series of meetings with relevant policymakers to advocate for stronger patient-centred provisions and reliable access to critical therapies for people with bleeding disorders.

EU List of Critical Medicines

The Union List of Critical Medicines continued to play an increasingly strategic role throughout 2025 by identifying medicines for which continuity of supply is essential for public health across the EU. The list supports coordinated EU action to prevent and manage shortages, strengthen supply chains, and prioritise regulatory and investment efforts at the European level.

Medicines are included on the list when they are considered indispensable for treating serious or life-threatening conditions and when they cannot be easily substituted in case of disruption. Inclusion requires that a medicine is deemed critical in more than one-third of EU/EEA countries, ensuring that the list reflects shared European priorities rather than purely national concerns.

Throughout 2025, the Union list served as a practical tool for regulators and policymakers by:
- Guiding EU-wide monitoring of vulnerable supply chains.
- Supporting early-warning systems for potential shortages.
- Prioritising inspections, regulatory flexibility and coordination actions.
- Informing strategic investment and manufacturing planning at the EU level.

The list does not replace national critical medicines lists but complements them, helping Member States align their approaches and close gaps where national mechanisms may not yet exist. It also enables the European Commission, the European Medicines Agency (EMA) and national authorities to better analyse risks linked to production concentration, dependency on limited suppliers, and logistical bottlenecks.

For the bleeding disorders community, engagement with the evolution of the Union List is essential to ensure that all therapies critical for treatment and prevention of complications are adequately recognised. Future updates of the list offer an opportunity to improve visibility of treatments used in

rare and complex conditions, helping to safeguard continuity of care during market disruptions, manufacturing issues or geopolitical challenges.

Read more [here](#).

In 2025, the EHC issued a [statement](#) calling for von Willebrand factor to be included on the EU List of Critical Medicines, underlining its essential role in the treatment of people with von Willebrand disease. It also reached out to the European Medicines Agency (EMA) and, together with the European Association for Haemophilia and Allied Disorders (EAHAD), contacted national competent authorities to inquire whether they consider von Willebrand factor to be a critical medicine at national level and to encourage its recognition within the EU framework.

EU Biotech Act

In 2025, the European Union continued advancing work on the EU Biotech Act, a strategic initiative designed to strengthen Europe's position in biotechnology and life sciences. The Act is part of the EU's broader effort to boost competitiveness, innovation and strategic autonomy while ensuring that cutting-edge technologies translate into societal and health benefits.

The Biotech Act aims to create a more supportive ecosystem for research, development, manufacturing and deployment of biotechnologies in Europe. It addresses long-standing barriers such as fragmented regulation, slow translation from research to market, and uneven access to financing and infrastructure across Member States.

Key objectives of the EU Biotech Act include:

- **Accelerating innovation** by improving conditions for research and development in health, pharmaceuticals, and advanced therapies.
- **Simplifying regulatory pathways**, reducing administrative burden while maintaining high safety and ethical standards.
- **Strengthening investment and scale-up**, helping European biotech companies move from laboratory to commercial production within the EU.
- **Enhancing manufacturing capacity**, supporting resilient and sustainable production of innovative health technologies in Europe.
- **Promoting public-private cooperation**, linking academia, industry, regulators, and healthcare systems more effectively.

For health policy, the Biotech Act is particularly relevant to the development of advanced therapies, personalised medicine, and rare disease treatments. By fostering a predictable and innovation-friendly framework, the Act seeks to ensure that breakthroughs reach patients faster while remaining accessible and safe.

For the bleeding disorders community, the Biotech Act supports an environment in which novel therapeutic approaches, including advanced and personalised treatments, can be developed and scaled within Europe. At the same time, patient organisations will need to engage to ensure that

innovation policies remain aligned with affordability, equitable access, and patient-centred outcomes, rather than focusing solely on industrial competitiveness.

Read more [here](#).

In 2025 the European Haemophilia Consortium (EHC) actively monitored developments around the EU Biotech Act, tracking the proposal's evolution and implications for patients and innovation as part of its broader European health policy work.

Social care

In 2025, Member States began preparing the implementation of the European Disability Card, which enables mutual recognition of disability status across the EU. The aim is to make travel and mobility easier by ensuring equal access to services and benefits for persons with disabilities in other Member States.

The card grants access to the same preferential conditions as nationals in areas such as transport, culture, leisure, and public services, while complementing existing national disability cards. Work in 2025 focused on technical standards and awareness to ensure consistent application in practice.
For people with bleeding disorders, the card supports greater mobility and social inclusion, provided implementation is effective at the national level.

Read more [here](#).

Looking forward

Cypriot Presidency of the Council of the European Union

On 1 January 2026, Cyprus assumed the rotating Presidency of the Council of the European Union, chairing meetings of the Council and guiding legislative and policy work across EU agendas until 30 June 2026. The presidency is conducted under the motto "An Autonomous Union. Open to the World", reflecting its focus on strengthening the EU's internal autonomy while maintaining engagement with global partners.

Under the Cyprus Presidency, health policy forms part of a broader social and resilience agenda, led by the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO). In the field of health, the Presidency will focus on:
- **Strengthening the European Health Union:** Reinforcing the integration and resilience of EU health systems, including improved cooperation among member states to respond to future health challenges.
- **Health System Resilience and Access:** Enhancing access to quality healthcare, medical products, and services as part of a resilient health infrastructure.

- **Health in the Context of Strategic Autonomy:** Aligning health policies with the broader goal of EU autonomy, including preparedness for health crises and ensuring the availability of essential medical supplies.
- **Mental Health and Social Well-Being:** Placing particular attention on mental health issues, notably by engaging stakeholders and emphasising youth mental health within broader social policy discussions.

Find the full programme [here](#).