CONFRONTATIONS EUROPE

HEALTH: CAN EUROPE STILL GUARANTEE ITS SOVEREIGNTY ?

CONFRONTATIONS EUROPE HEALTH GROUP

Established in September 2025, the Health Group of the think tank Confrontations Europe aims to stimulate reflection on the European dimension of health policies. Through quarterly working meetings and expert hearings on a wide range of strategic issues, all related to health sovereignty, it seeks to contribute to public debate by publishing articles setting out its recommendations. Ahead of these recommendations, this Issue Paper defines the scope of the Working Group's research by taking stock of the health challenges Europeans face today.

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INTRODUCTION

The concept of health sovereignty is evolving and has multiple meanings. Historically, sovereignty has been associated with a state's ability to make autonomous decisions for its population. Today, the concept is used in a broader context: health sovereignty encompasses both a conception linked to national security, particularly control over health-product value chains, and one more closely focused on economic issues, such as maintaining investment and employment within a territory, as well as protecting the European social model. The latter is distinguished by universal access to healthcare, ambitious social protection and a commitment to collective solidarity, which underpin a unique approach to public health.

In a context marked by globalised value chains, strategic dependencies and shared health challenges, health sovereignty can no longer be understood as the pursuit of complete national autonomy. Rather, it rests on the ability to manage critical dependencies, guarantee access to essential health products, medical devices and therapeutic innovations, and ensure the viability of healthcare systems. From this perspective, the European Union (EU) provides a relevant level of action for pooling resources, coordinating crisis responses and securing supply chains.

An in-depth analysis of the implications of vulnerabilities for the healthcare system as a whole and its viability shows that the central challenge is to build a genuine ecosystem capable of guaranteeing access to healthcare, the quality of care and crisis-management capacity.

European health sovereignty thus takes shape around three complementary imperatives: **securing value chains and reducing critical dependencies; guaranteeing patients access to innovation ; and adapting healthcare systems in order to preserve the European social model over the long term.**

1. Controlling value chains and critical dependencies

The concept of health sovereignty came strongly to the fore during the COVID-19 crisis. The crisis played a fundamental role in making European governments aware of the fragility of their healthcare systems, their interdependence in the face of health crises, and their reliance on the rest of the world for supplies of medical products. Since this unprecedented crisis, the European discussion has shifted from supplies in emergencies to the structural problem of shortages of health products, which affects all Member States and an increasing number of segments of the medicines market. The causes are multifactorial and include substantial dependence on third countries. Although the figures are difficult to establish, according to the European Parliament, the EU imports around 40% of its medicines, mainly generics whose production has gradually been relocated to low-production-cost countries, and 80% of active pharmaceutical ingredients, mainly from China and India. The principal production-cost differences stem not only from labour costs and environmental costs (carbon, water quality and atmospheric emissions), but also from subsidies provided by India and China to their producers. Both import volumes and the geographical concentration in these two countries are perceived as EU vulnerabilities.

Consideration of strategic dependencies must also encompass medical devices, which, like medicines, are essential to the day-to-day functioning of European healthcare systems. Whether devices are used to treat chronicité diseases, compensate for disabilities, or provide implants and diagnostic tools, healthcare facilities and patients remain exposed to risks of supply disruptions arising from the geographical concentration of certain production activities and dependence on critical raw materials.

The vulnerabilities of medical devices and medicines have their own specific characteristics, but both involve a wide variety of components and suppliers, internationally fragmented production stages and a concentration of certain industrial expertise. This complexity makes mapping and managing dependencies particularly difficult.

To increase its resilience, the EU has placed these issues at the heart of its European health strategy. In the aftermath of the COVID-19 crisis, new cooperation mechanisms were introduced to strengthen preparedness for and prevention of health crises.

The Health Emergency Preparedness and Response Authority, HERA, established in 2020, for example, strengthens Europe's ability to anticipate cross-border health threats, coordinate the acquisition of medical countermeasures, organise joint procurement and support the creation of strategic stockpiles. These tools make it possible to move beyond the competition between Member States observed at the beginning of the crisis by building European capacity for pooling resources, planning and responding rapidly. In particular, HERA created EU FAB, a network designed to maintain vaccine production capacity that can be mobilised in a health emergency. This type of infrastructure constitutes a first building block of operational health sovereignty.

In line with these ambitions, the negotiations on the Critical Medicines Act, which are nearing completion, mark a change in approach by making supply-chain resilience a public-policy objective in its own right. In particular, the Act provides for better identification of critical medicines, stronger European production capacity, diversification of supply sources, the establishment of strategic stockpiles and the inclusion of security-of-supply criteria in public procurement procedures alongside cost considerations.

Finally, the European pharmaceutical package, negotiations on which concluded in December 2025, modernises the Union's pharmaceutical legislation for the first time in more than twenty years. In particular, it provides for stronger obligations to monitor and prevent shortages, simplified and faster marketing-authorisation procedures, and an overhaul of regulatory incentives (data protection and market exclusivity). The objective is to encourage the marketing of innovative medicines, particularly those addressing unmet medical needs, and to incentivise their marketing across all Member States. The reform therefore seeks to reconcile security of supply, the competitiveness of the European pharmaceutical industry and faster, more equitable access to treatments.

2. Medical innovation and the digital transition

The health industries have now become a strategic economic priority for the EU. As Mario Draghi emphasised in his report on European competitiveness, health must be placed on the same footing as sectors such as aerospace, energy and defence, given its importance for the continent's capacity for innovation, the sustainability of its social model and the intrinsic dimension of sovereignty.

European countries, long drivers of global pharmaceutical innovation alongside the United States, are now facing an unprecedented strategic shift. The United States remains more attractive thanks to faster market access and more readily available financing. Its ecosystem is therefore considerably more favourable to biotechnology investment, while allowing higher returns on innovation through non-negotiated prices that are significantly higher than European prices. Indeed, the United States currently invests approximately twice as much as the EU in public and clinical R&D. Since 2015, China has undertaken reforms favourable to innovation, notably by accelerating its regulatory assessment procedures. In 2024, Chinese companies developed 28 new molecular entities, overtaking the United States (25) and Europe (18) for the first time. Between 2022 and 2024, Chinese biotechnology companies generated more than 600 first-in-class candidates, representing growth of 260%, twice the growth observed in the United States, Europe or Japan. More recently, US policy has intensified competitive pressures by promoting the Most-Favoured-Nation clause, which could lead to higher medicine prices in the EU, imposing tariffs that penalise European exports, and negotiating with pharmaceutical companies to relocate production to the United States. The gradual shift of R&D and production activities towards Asia, together with these new US measures, weakens European health value chains, which are now exposed to lasting strategic dependence.

The medical-device sector is also experiencing a marked loss of ground relative to the United States and China, the latter having become a major player with attractive prices and innovative technologies. One reason is that access to the European market is longer, more costly and less predictable than across the Atlantic. Multiple national requirements, including country-by-country assessments, the lack of harmonisation among ethics committees and differential pricing, add substantial regulatory complexity.

Like the pharmaceutical sector, the European medical-device industry faces intensifying international competition amid accelerating technological innovation, particularly in digital health, artificial intelligence, robotics and connected devices. Historically a global leader in several medical-technology segments, Europe is now seeing its position weakened by environments more conducive to innovation and investment in the United States and certain Asian economies.

The implementation of the European Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR) has strengthened patient safety and clinical-evidence requirements. However, these regulatory developments have also created significant constraints for manufacturers, particularly the small and medium-sized enterprises that make up most of the European industrial base in this sector. Assessment times, the limited capacity of notified bodies and significantly increased compliance costs can slow patients' access to innovations and undermine the European Union's attractiveness for the development of new medical technologies.

These developments are all the more strategic because medical devices play a central role in transforming healthcare systems. Innovation is not limited to technological breakthroughs: it also involves continuous product improvement, digital integration and changes in the organisation of care. Advanced diagnostic technologies, remote-monitoring solutions, clinical decision-support software, connected devices and medical artificial intelligence help improve prevention, personalise care, make care pathways more efficient and support the financial sustainability of European healthcare systems. They also help streamline care pathways, strengthen coordination among professionals and improve the overall efficiency of healthcare systems.

At the same time, the United States benefits from an environment particularly favourable to technological innovation in healthcare, supported by massive investment in digital technologies, more predictable market-access procedures for certain categories of innovative devices and easier access to private financing. China is likewise pursuing an ambitious strategy to support its medical-technology industry, combining public investment, the development of industrial capabilities and the rapid development of solutions integrating artificial intelligence and large-scale health data.

Sovereignty in the development and production of innovative devices and medicines is an essential lever for addressing population ageing, the rise in chronic diseases and pressures on healthcare human resources. In this context, the European Union must ensure that it builds a framework capable of reconciling a high level of safety, innovation capacity and industrial competitiveness.

The issues extend beyond the medical-products sectors. Over the past thirty years, medicine has seen an acceleration of scientific and technological progress. The use of digital technologies, particularly artificial intelligence, is a key driver of this trend. Although the EU is relatively well positioned in the use of artificial intelligence in healthcare, especially in diagnostics and pharmaceutical research, it remains highly dependent on external suppliers in more strategic areas such as genomics and, more broadly, cloud services and cybersecurity.

In response to these vulnerabilities, the EU is acting on several fronts. The Health Technology Assessment (HTA) Regulation, adopted in 2021 and progressively applied since 2025, represents a new step in building the health internal market. It introduces joint clinical assessments at European level for innovative medicines and, eventually, certain high-risk medical devices.

Without calling into question national powers over pricing and reimbursement, this pooling of efforts aims to reduce duplication, harmonise scientific assessments and accelerate patients' access to innovations. In parallel, in 2025 the European Commission launched a targeted revision of the regulations on medical devices (MDR) and in vitro diagnostic medical devices (IVDR). Possible simplifications include adapting conformity-assessment procedures to innovative technologies, greater use of real-world evidence and new in silico methodologies, and a framework better suited to breakthrough devices, with a view to reducing the time and cost of accessing the European market.

More recently, the Irish Presidency of the Council made the finalisation of Biotech Act I one of its priorities. In particular, this legislation proposes to modernise the clinical-trials framework by reducing the time needed to set up multinational trials and introducing new incentives to anchor the development and manufacturing of biological medicines in the EU.

This movement follows on from the Critical Medicines Act, which was the subject of a political compromise in spring 2026, incorporating supply-chain resilience and European-preference criteria into the procurement of certain critical medicines. In September 2026, the Commission is pursuing this approach with the draft regulation on public procurement, which is also expected to include similar criteria for purchases of health products beyond critical medicines alone, and the European Innovation Act, which introduces European-preference criteria for public funding of projects at the research and development stage, notably to support the development of innovative start-ups in Europe. This is also the objective of the proposal to establish a legal framework for companies, EU Inc., also known as the 28th regime, presented in March 2026. It responds to the need to offer innovative start-ups a simplified regime capable of attracting the private capital necessary for their growth.

On the digital front, the ambitious EU Artificial Intelligence Act initiative and the Regulation on the European Health Data Space will enable the establishment, from 2030, of a federated data-collection model, with a single access point for data use through Health Data Access Bodies (HDABs) at national level. The value of these two pieces of legislation lies not only in creating a unified European framework for these new markets, but also in promoting an open model and standards of transparency, personal-data protection and risk management, thereby offering attractive conditions for non-European countries.

3. Protecting the European social model: the need to reform healthcare systems

National healthcare systems face growing structural challenges linked to demographic ageing, the rise in chronic diseases, shortages of healthcare personnel and the emergence of new issues such as environmental health and mental health. These pressures are amplified by increasing budgetary constraints, themselves reinforced by recent geopolitical tensions. In this context, Europe finds itself in a complex position: its healthcare model, founded on principles of solidarity and public regulation, is now being tested by international competition.

This dilemma is illustrated by recent data on European patients' access to innovative medicines. The average time to access approved medicines stands at 597 days, reflecting an upward trend. At the same time, almost one in two innovative medicines granted centralised authorisation in Europe was not accessible to patients in 2025.

This situation affects all therapeutic categories: oncology treatments have an average access time of 655 days and an availability rate of 51% in the EU. Patients with rare diseases also face particular obstacles, with orphan medicines achieving an availability rate of only 43% across Europe. For this population, access times are particularly important, since these therapies are often the first or only available treatment option.

Epidemiological and demographic changes are also profoundly transforming how care is delivered. A growing proportion of care is now provided over the long term, as close as possible to patients' living environments, in order to foster their autonomy and limit hospital admissions. This shift is reinforced by growing pressures on healthcare provision, notably the ageing of healthcare professionals, medical-workforce demographic challenges and the spread of areas with poor access to medical services across large parts of the territory. In this context, health products and digital-health solutions play an increasingly important role in promoting prevention, maintaining access to care, supporting patients remotely and assisting healthcare professionals in their daily practice.

This development is accompanied by increased dependence on certain health products and medical devices used every day to manage chronic diseases. Their effectiveness, however, depends on access both to the technologies themselves and to the therapeutic support needed for their proper use. In addition to medicines, continuity of care also depends on secure access to numerous medical technologies that are essential to patients' everyday lives.

The risk of healthcare systems deteriorating over time is very real. Indeed, there is an upward trend in unmet healthcare needs in the EU: the proportion of people affected rose from 1.9% in 2019 to 3.6% in 2024, with this deterioration concentrated among the most disadvantaged sections of society. In his competitiveness report, M. Draghi described this challenge as existential: if Europe failed to become more innovative, its economy would be condemned to stagnation and would no longer be able to finance its social model. Europe would then abandon its values of equity and inclusion and, by extension, what defines its very raison d'être.

There is a consensus (WHO, OECD, EU) on the measures needed to reform healthcare systems and address the unprecedented increase in demand for care under significant resource constraints. This consensus rests on prevention, the digital transition, strengthening primary-care systems and integrating care pathways. All countries have undertaken reforms in this direction to varying degrees, but the pace remains too slow to bring about radical change.

Within this dynamic, the EU has very limited competences. Its influence therefore operates through action in the following areas: health security; health research; European Reference Networks for rare diseases; action plans (cancer, cardiovascular diseases, mental health); and the attractiveness of European territories for R&D and innovative production. Broader reflection is therefore needed on the European levers that could be used to support national efforts.

CONCLUSION

In response to the ground lost over the past fifteen years, numerous legislative initiatives in progress are seeking to give shape to the complex and ambitious project of European health sovereignty :

- European awareness has accelerated since the COVID-19 crisis, leading to new instruments to strengthen supply-chain resilience and preparedness for health crises (HERA, Critical Medicines Act);
- A determination to strengthen the innovative and attractive dimension of health regulation (EHDS, Biotech Act);
- Progress towards better European coordination, while maintaining predominant national competences in health (pharmaceutical package, EU HTA);
- Growing consensus that health is a strategic issue for competitiveness, security and social cohesion in the European Union;
- Increasing recognition of health as a strategic industrial ecosystem encompassing medicines, medical devices, health data and digital technologies.

Are these policy responses commensurate with the health challenges ?

The Confrontations Europe Health Working Group intends to present its recommendations in order to deepen reflection on the most appropriate instruments to :

- Reduce strategic dependencies and strengthen European industrial capacities, particularly for critical medicines, active pharmaceutical ingredients and medical devices;
- Restore Europe's attractiveness in innovation, biotechnology and digital health in the face of US and Chinese competition, in both R&D and production;
- Identify European levers that can more effectively support the transformation of healthcare systems in a context of demographic ageing, rising chronic diseases, healthcare workforce shortages and budgetary constraints;
- Define the governance, financing and coordination instruments capable of bringing about genuine European health sovereignty that reconciles competitiveness, resilience and equitable access to care.