



# THE EUROPEAN FILES

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# REVOLUTION EUROPE'S QUEST FOR HEALTH SOVEREIGNTY

BUILDING EUROPE'S CAPACITY  
TO INNOVATE, PRODUCE  
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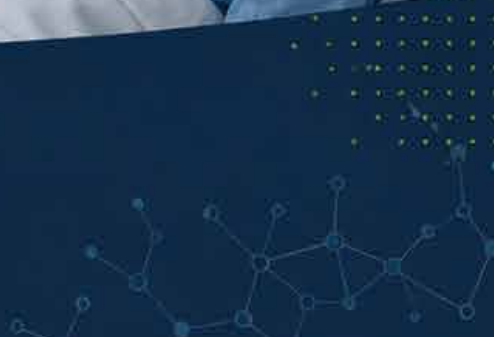
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# EDITORIAL

## EUROPE'S QUEST FOR HEALTH SOVEREIGNTY: BUILDING THE NEXT GENERATION OF BIOTECHNOLOGY

Europe is entering a decisive decade. Health has become far more than a public policy: it is now a strategic asset at the crossroads of competitiveness, industrial resilience, technological leadership and geopolitical security.

The race for biotechnology is no longer simply a race for medical innovation. It is increasingly a race for industrial leadership, economic sovereignty and global influence. The countries that succeed in mastering biotechnology will not only shape the future of healthcare but also secure leadership in advanced manufacturing, artificial intelligence, data-driven medicine and the wider bioeconomy.

As global competition accelerates, the United States and China are investing massively across the entire biotechnology value chain—from fundamental research and clinical development to industrial manufacturing and commercial deployment. Europe, meanwhile, continues to produce world-class science, yet too often fails to transform scientific excellence into industrial leadership. Bridging this gap has become one of the European Union's defining economic and strategic challenges.

This new reality is reshaping the European agenda.

Across the European institutions, a broad consensus is emerging that biotechnology will become one of the key drivers of Europe's future prosperity. It will not only determine the evolution of healthcare but will also strengthen Europe's competitiveness across strategic sectors, reinforce supply-chain resilience and contribute to Europe's long-term technological sovereignty.

It is within this context that the forthcoming Biotech Act II takes on its full significance.

More than another legislative initiative, it offers a unique opportunity to rethink Europe's entire biotechnology ecosystem. Its ambition must go beyond supporting research and innovation. It must create the conditions for innovative companies to grow, manufacture, scale and remain in Europe. Too often, discoveries made in European laboratories generate investment, production and high-value jobs elsewhere. Reversing this trend will be essential if Europe is to compete successfully in the decades ahead.

The contributions gathered in this special edition illustrate both the scale of this opportunity and the complexity of the challenge. They demonstrate that Europe already possesses exceptional scientific talent, leading universities, innovative companies and world-class healthcare systems. What remains fragmented are the connections between research, investment, regulation, manufacturing and market deployment.

Building these bridges will require more than a single legislative proposal.

Alongside the Critical Medicines Act, the Pharmaceutical Package and the European Life Sciences Strategy, the Biotech Act II should become one of the foundations of a genuine European biotechnology strategy—one capable of accelerating clinical research, mobilising investment, simplifying regulatory pathways, strengthening manufacturing capacity and enabling European companies to scale successfully within the Single Market.

Competitiveness, however, cannot become an objective in itself. Europe's strength has always been its ability to combine innovation with solidarity, scientific excellence with public trust, and industrial ambition with equitable access to healthcare. Strengthening Europe's biotechnology sector must therefore go hand in hand with faster patient access to innovation, resilient supply chains and sustainable healthcare systems.

The challenge facing Europe is therefore not whether it can innovate. It already does.

The real question is whether Europe can become the world's most attractive place to discover, develop, manufacture and deploy biotechnology—and whether it can transform its scientific leadership into lasting industrial leadership.

The decisions taken during this legislative cycle may well determine Europe's position in the global biotechnology landscape for decades to come. This is a window of opportunity that Europe cannot afford to miss.

This special edition of *The European Files* brings together European Commissioners, Members of the European Parliament, ministers, researchers, healthcare professionals, industry leaders and innovators to contribute to this essential debate. Together, they explore how Europe can seize the momentum created by the Biotech Act II to strengthen not only its health sovereignty, but also its competitiveness, strategic autonomy and global leadership.

Europe has the knowledge. Europe has the talent. Europe has the scientific excellence.

The next biotechnology revolution will not wait for Europe. The challenge now is to create the conditions for biotechnology to flourish—and remain—in Europe.

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OLIVÉR VÁRHEGYI

*European Commissioner for Health and Animal Welfare*

# Building the future of health in Europe

Europe's healthcare systems are among our greatest achievements. They are built on a simple promise: that people should receive the care they need, when they need it, wherever they live. But that promise is under increasing pressure.

Our populations are ageing. Chronic diseases are rising. Global supply chains are becoming more fragile. At the same time, scientific and technological progress is opening unprecedented opportunities to prevent, diagnose and treat disease. At the same time, scientific and technological advances are creating opportunities that were unimaginable only a decade ago when it comes to prevention, diagnosis and disease treatment. The question facing Europe is therefore not whether change is necessary. It is whether we can act quickly enough to shape that change ourselves.

This is why Europe's priority must be to translate scientific excellence into innovation that reaches patients.

## Turning Scientific Excellence into Innovation

Europe has no shortage of scientific talent. European researchers contribute around 21% of the world's leading biotechnology publications. Our universities, hospitals and research institutes are among the best in the world. We have strong pharmaceutical manufacturing capabilities and a highly skilled workforce.

Yet we continue to face a fundamental challenge. Too often, scientific discoveries made in Europe are developed, financed, scaled and commercialised elsewhere. Over the last decade, biotechnology start-ups in the United States have attracted many times more venture capital than their European counterparts. Europe remains strong in discovery, but weaker in turning discoveries into globally competitive companies and products.

This is precisely why the **Biotech Act** is so important. The Biotech Act is designed to make



Europe a better place to develop, finance and scale biotechnology. It addresses barriers that innovators repeatedly identify: access to risk-tolerant capital, complex regulatory procedures, fragmented markets and difficulties in conducting clinical trials across multiple countries. The Act seeks to simplify the environment for innovators, accelerate clinical trials, support the responsible use of artificial intelligence and strengthen Europe's biotechnology ecosystem.

Alongside the legislative proposal, we are already working with the European Investment Bank Group through the **BioTechEU** initiative to help unlock private and public investment in Europe's biotechnology sector. Together, we aim to mobilise €10 billion over the coming years to support innovative companies as they scale up, expand manufacturing capacity and bring breakthrough technologies from the laboratory to the market.

The objective is clear: Europe should not only be a continent of scientific discovery. It should also be a continent where innovation grows, where companies scale, where manufacturing takes place and where patients benefit first from the breakthroughs that European science

helps create. Europe has all the ingredients to lead this transformation.

## (A Modern Regulatory Framework for a New Era)

But innovation requires more than scientific excellence and investment. It also needs a regulatory environment that gives companies confidence to develop, test and launch new treatments in Europe. That means rules that are predictable, proportionate and fit for purpose, while fully safeguarding patient safety. Our **reform of the EU pharmaceutical** legislation is designed to create exactly those conditions.

The reform aims to make Europe's regulatory framework faster, simpler and more efficient while maintaining the highest standards of quality, safety and efficacy. It supports timely access to medicines, strengthens incentives for innovation in areas of unmet medical need and embraces the opportunities offered by digital technologies and artificial intelligence.

Similarly, we are modernising the **medical devices** framework. Medical devices and diagnostics are no longer peripheral to healthcare. They are central to how we prevent, detect and treat disease. From early diagnosis and

personalised medicine to remote monitoring and AI-supported clinical decision-making, they are transforming care pathways and helping health systems intervene earlier, more precisely and more effectively.

Europe must remain a global leader in this field. Our objective is therefore to simplify procedures where possible, improve predictability for innovators and ensure that AI-based solutions, including medical devices, are supported by a coherent regulatory framework - accelerating access to breakthrough technologies while keeping patient safety at the heart of the system.

### (The European Health Data Space: unlocking the power of data)

Data is becoming one of the defining assets of modern healthcare. The future of medical research, personalised medicine and artificial intelligence will depend increasingly on secure access to high-quality health data. This is why the **European Health Data Space** is such a transformative project.

For citizens, it will mean greater control over their own health information and easier access to their data across borders. For healthcare professionals, it will support better continuity of care and more efficient health systems. For researchers and innovators, it will open new opportunities to develop treatments, improve diagnostics and accelerate scientific progress.

It will also provide the trusted foundation Europe needs for the secondary use of electronic health data, including the development of artificial intelligence solutions in healthcare. By enabling secure and ethical access to high-quality datasets, we can support research and AI-based solutions that improve prevention, diagnosis and treatment, while maintaining citizens' trust. That balance - between innovation and trust - is essential if Europe is to lead the next generation of healthcare technologies and make better, evidence-based policy decisions.

But technology must serve a wider purpose: helping people stay healthy, not only treating them once they become ill.

The same tools that can accelerate research and innovation can also help us detect risks earlier, personalise care and prevent disease before it advances.

### (Prevention: the next frontier of health policy)

The real measure of innovation is not the technology itself, but the difference it makes to people's lives. This is where Europe's health agenda must now go further: using innovation not only to treat disease, but increasingly to prevent it and help Europeans live healthier lives for longer.

This shift is urgent. Europe cannot build sustainable healthcare systems simply by treating more disease. We must prevent more disease in the first place. Chronic conditions are already placing heavy pressure on citizens, healthcare professionals and public budgets. Cardiovascular diseases alone cause 1.7 million deaths every year in Europe and cost our economies more than €280 billion annually. Yet much of this burden can be avoided. Almost 80% of cardiovascular diseases are preventable.

This reality inspired the **Safe Hearts Plan**. The Plan seeks to transform cardiovascular health through prevention, earlier detection, screening, better use of data and more personalised approaches to risk prediction. It aims to transform cardiovascular health by strengthening prevention, improving early detection and screening, making better use of data, and supporting more personalised approaches to risk prediction and care.

It also reflects a wider shift in healthcare: from reacting to illness towards anticipating risk and intervening earlier. Digital tools, artificial intelligence, innovative diagnostics and better health data can all help drive this transformation. If we succeed, we will save lives. We will reduce pressure on healthcare systems. And we will create more space for continued investment in innovation.

Reducing preventable risk factors, including tobacco use, is also part of this shift - especially when it comes to protecting young people and lowering the future burden of cancer, cardiovascular disease and other chronic conditions.

Prevention and innovation must advance together. A Europe that prevents more disease

will be stronger, more resilient and better able to invest in the next generation of care. It is our strategic vision for Europe's future: a continent where scientific excellence becomes innovation, where innovation attracts investment, and where investment delivers real benefits for patients.

It is about ensuring that medicines remain available, that health systems remain resilient, that innovators choose Europe as a place to invest and grow, and that citizens continue to have access to the highest standards of care.

Europe has the science. Europe has the talent. Europe has the industrial base. Today, we are putting in place the regulatory, financial and policy tools needed to further improve their synergies.

The challenge now is implementation.

If we maintain our ambition, work together across institutions and Member States, and continue to place patients at the centre of our efforts, Europe can remain not only a global leader in healthcare, but also a global model for how resilience, innovation and solidarity can work together.

Europe's health agenda has entered a decisive phase. The Cyprus Presidency has demonstrated that ambitious progress is possible, delivering agreement on the Critical Medicines Act and advancing the Biotech Act at record speed. I am confident that the Irish Presidency, followed by the Lithuanian Presidency, will maintain this momentum. Together, we have a unique opportunity to complete the key building blocks of the European Health Union and create the conditions for Europe to remain a global leader in health innovation, resilience and patient care.





**NEOPHYTOS CHARALAMBIDES**

*Minister of Health of Cyprus*

# Strengthening Health Innovation and Biotechnology in the EU

**B** iotechnology has become one of the European Union's most strategic sectors, driving innovation, economic growth, high-skilled employment, and global competitiveness. More importantly, it is transforming healthcare by enabling the development of advanced therapies, innovative diagnostics, personalised medicine, and new approaches to disease prevention and treatment. As Europe faces demographic change, rising healthcare needs, and increasing global competitiveness, biotechnology is emerging as a key pillar of both public health and economic resilience.

The strategic importance of biotechnology has been reinforced by recent geopolitical developments, including the COVID-19 pandemic, disruptions to global supply chains and growing competition in critical technologies. These challenges have highlighted the need for Europe to strengthen its capacity to develop, manufacture and deploy health technologies within the Union. Biotechnology is therefore increasingly recognised not only as an innovation sector but also as a critical component of Europe's strategic autonomy and health security.

This ambition is closely aligned with the vision set out in the Letta and Draghi reports. Both reports emphasise the need

to strengthen Europe's competitiveness by deepening the Single Market, reducing fragmentation, fostering innovation and creating conditions for strategic industries to scale up within Europe. They stress that Europe must better convert its scientific excellence into industrial leadership and societal benefit, particularly in sectors such as biotechnology which are essential for future prosperity, resilience and technological sovereignty.

Despite Europe's strong scientific base and high regulatory standards, the biotechnology sector continues to face significant challenges. One of the most persistent obstacles is the fragmented implementation of EU legislation across Member States. Variations in regulatory interpretation and administrative procedures often create delays, increase compliance costs and reduce predictability for innovators.

These difficulties are particularly evident in the health sector. Many innovative products combine medicinal products, medical devices and diagnostic technologies, requiring developers to navigate multiple regulatory frameworks and approval pathways. Such complexity can slow clinical development, delay patient access to innovative treatments and reduce Europe's attractiveness as a destination for clinical research and investment.

Recognising these challenges, the European Commission adopted the European Biotech Act in December 2025 as a strategic initiative to modernise and streamline the biotechnology regulatory framework. This Act seeks to strengthen Europe's biotechnology and biomanufacturing ecosystem by improving access to funding, supporting innovation and creating a more coherent and predictable regulatory environment.

A core objective of the Act is the simplification and harmonisation of clinical trial procedures. Proposed measures include faster approval of timelines, harmonised assessment and submission requirements, improved cooperation among regulatory authorities and the introduction of a single core dossier to reduce duplication and administrative burden. These reforms are expected to accelerate the development of innovative therapies while maintaining the EU's high standards of safety, ethics and patient protection.

The health dimension of the Biotech Act is particularly significant. Advanced therapies, including gene therapies, cell therapies, RNA-based medicines, and other cutting-edge technologies, offer unprecedented opportunities for patients suffering from serious, rare, or currently untreatable diseases. To facilitate their development and market entry, the



Act promotes earlier and more continuous dialogue between developers, regulators, and health technology assessment bodies. This approach aims to reduce regulatory uncertainty, support the generation of evidence, and ultimately accelerate patient access to breakthrough innovations.

Beyond healthcare, the Act introduces a more science-based and risk-proportionate regulatory approach across biotechnology applications. This is particularly relevant for genetically modified micro-organisms, where requirements are increasingly tailored to the level of risk involved. By distinguishing between low-risk and higher-risk activities, the EU seeks to ensure efficient and proportionate oversight while maintaining strong safeguards for public health, environmental protection, and biosecurity.

The Act also seeks to support innovation in the food and bioeconomy sectors through improved regulatory guidance and more efficient authorisation procedures. While these measures can help bring innovative products to market more quickly, public trust, ethical considerations and societal acceptance will remain essential factors in ensuring the successful uptake of new technologies.

Recognising the strategic importance of biotechnology for Europe's future, the Cyprus Presidency has placed health innovation and biotechnology high on its agenda. In line with its priorities of competitiveness, resilience, innovation and strategic autonomy, the Presidency has advanced discussions on the Biotech Act package and promoted measures to strengthen Europe's biotechnology and bio-manufacturing sectors. Through its work in the Council and within the EPSCO configuration, the Presidency is contributing to the development of a modern regulatory framework capable of supporting innovation while safeguarding public health. This complements broader efforts to reinforce resilience of healthcare systems and pharmaceutical supply chains, including the provisional agreement reached by the Cyprus Presidency with the European Parliament on Critical Medicines Act. Together, these initiatives support the Union's objectives of strengthening health security, reducing strategic dependencies and ensuring access to innovative and essential medicines.

Strengthening health innovation and biotechnology is essential for Europe's competitiveness, resilience and technological leadership. By reducing regulatory fragmentation, supporting clinical research and accelerating the development of advanced health technologies, the European Biotech Act can translate scientific excellence into

tangible benefits for patients and healthcare systems. In doing so, it advances the vision set out in the Letta and Draghi reports for a more competitive, innovative and strategically autonomous Health Union.





FRANK VANDENBROUCKE

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# Towards a Sovereign Health Union

With a provisional agreement on the Critical Medicines Act reached on 12 May 2026<sup>1</sup>, Europe has taken a step forward towards a strong European health union. And yet pressures on Europe's health system have never been so high and threaten the very core of its existence. These challenges to the foundational logic of the solidarity-based European welfare state coincide with other major challenges of our time such as aging populations, innovation challenges, (cross-border) health threats, climate change and bioterrorism, socio-economic disparities, migration and medicine shortages.

## Pressures on Europe's health systems

Since long, the United States has had a fundamentally different conception of health, the state and the social contract compared to Europe. By recently signing his Executive Order 14297 on Most Favoured Nation pricing on medicines, President Trump has however started framing the European model with its negotiated prices as a form of trade cheating, thereby urging European governments to increase medicine prices.<sup>2</sup> In Europe and contrary to the United States, medicine pricing is not a discretionary policy of the executive, but rather is embedded in the logic of social insurance. Governments use pre-defined, transparent criteria to determine what society will pay for a medicine and what concrete health outcomes it will deliver. Through this process, Europe achieves good health outcomes with near-universal

health care coverage.<sup>3</sup> By only comparing the prices of medicines across the Atlantic without taking the solidarity the European HTA model provides into account – and which the American system so desperately lacks – President Trump essentially delegitimizes the European healthcare system. And yet Europe is too complacent in defending its system against such unfounded claims.

President Trump's challenge to our health system also raises a challenge from within Europe. For too long, Europe has treated the supply of basic medicines as dispensable, allowing production of medicines to migrate to where it could be done most cheaply, thereby leading to major dependencies on active substances and critical medicines from Asian countries. Medicine dependency is a security dependence and it's essential that Europe invests more in strategic independence for its medicines. The Critical Medicines Act is a first step in the right direction, but the Act should now deliver in practice. To be successful, the Act should be backed with the appropriate resources, industrial strategy and political will to make it work. This also ties into the current bone of contention in relation to the next Multi-annual Financial Framework whether public health will be funded through the broader European Competitiveness Fund as a subset of industrial policy, or rather, as it deserves, retain a standalone budget.<sup>4</sup>

Europe has also been facing competitiveness issues, making biotech firms conduct their clinical trials in China or the United States.<sup>5</sup> They do so as trials and regulatory

approval processes are faster, the capital is deeper and the scaling infrastructure is more developed compared to Europe. The proposed Biotech Act is an opportunity to change this. It aims to enable building an industrial fabric for advanced biomanufacturing on European soil and create a capital architecture that allows to raise serious money. Equally important to compete with the United States and China, the Biotech Act should enable more coordination and integration among member states on conducting research and development. To name a few, the design of multi-country trials should be facilitated through standard contracting practices, ethics review processes should be harmonized, and site start-up procedures facilitated. A structured commitment to more integration, be it through standardized contract templates, better quality ethics review, trial-ready site networks with shared quality standards and serious investment in the clinical research workforce is therefore essential to fix the competitiveness issue.

## The path forward

The pressures to Europe's health system are not independent but rather reinforce each other. They demand from Europe a clear and confident articulation of what solidarity-based public health systems mean. Europe needs to work on its competitiveness model, without thereby losing its foundational logic that health is a precondition for the well-functioning of its society and economy and wellbeing of its citizens. The 27 European welfare states represent together a market of 450 million insured citizens. Still, today the 'European layer' which would allow the health systems to function together and pool evidence, coordinate health technology assessments and coordinate supply and data, is lacking.

Where Europe is integrated, such as in the single market for goods, it is strong. Where Europe remains fragmented and acts like 27

1 <https://www.consilium.europa.eu/en/press/press-releases/2026/05/12/critical-medicines-act-council-and-parliament-reach-provisional-deal/>.

2 The justification for MFN being that Europeans "forcing American patients to pay for a disproportionate amount of global pharmaceutical research and development" by «suppressing the price of pharmaceutical products below fair market value.»

3 In Belgium, 99.4% of the population has access to reimbursed medicines under the compulsory health insurance.

4 [https://commission.europa.eu/strategy-and-policy/eu-budget/long-term-eu-budget/eu-budget-2028-2034\\_en](https://commission.europa.eu/strategy-and-policy/eu-budget/long-term-eu-budget/eu-budget-2028-2034_en).

5 The Draghi report: A competitiveness Strategy for Europe, 9 September 2024.

small markets, such as in clinical trials, market access or procurement of essential medicines, it loses its attractiveness. Europe's attractiveness to investment is not built on high prices or fast approval rates, but rather on its welfare states with universal access, strong public institutions and a social contract that gives the market its stability and its depth.

The path forward is consequently not to choose between solidarity and competitiveness, as if they were rival claims on the same euro, but to complete the European integration project. Europe should build a European health Union that is sovereign in the full sense of the word: capable of defending its own model, securing its own supply, growing its own industry and demonstrating that universal, solidarity-based healthcare is the foundation of a stable, investable and human twenty-first century society. With the Critical Medicines Act, which concerns the medicines on which Europe is already dependent today, and the Biotech Act, which aims to ensure that the medicines of the future are also produced in Europe, there's real momentum to do so<sup>6</sup>.



<sup>6</sup> Implementation of these legal frameworks should be coupled with a consistent implementation across the EU of the EU Health Technology Assessment Regulation (EU 2021/2282) which established a harmonized framework for evaluating new medicines across member states and the EU Pharmaceutical Legislation, which aims to ensure equitable, affordable and timely access to safe medicines for all patients across Europe.





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# Regional biotech ecosystems as engines of Europe's health sovereignty: from clusters to global competitiveness

As health innovation becomes a strategic arena shaped by geopolitics, Europe's quest for health sovereignty is unfolding in a far more competitive global context. The United States increasingly consider biotechnology as a national security matter, while China's bioeconomy strategy is rapidly expanding capabilities across research, clinical trials, manufacturing and industrial policy. In this increasingly competitive environment, Europe's long-standing fragmentation across research, clinical development and industrial scale-up is becoming harder to sustain. Encouragingly, Europe is beginning to respond more coherently through an emerging life sciences policy agenda, including initiatives such as the proposed Biotech Act, aimed at strengthening translation, industrial capacity and resilience.<sup>1,2,3,4</sup>

Europe's ambition for health sovereignty will rise or fall with the strength of its innovation ecosystems. Scientific excellence is undisputed, but translating discovery into scalable products, industrial capacity and patient access remains a structural weakness. Regional innovation ecosystems must therefore become strategic assets, environments capable of connecting research, clinical development, manufacturing,

regulation and investment in a coordinated way.<sup>5</sup> Europe has historically lost time, industrial capacity and value at the scale-up phase — a loss that is not abstract, but visible in fragile supply chains, uneven patient access, repeated valleys of death and the relocation of companies seeking global scale.<sup>6,7</sup>

The structural challenges highlighted in competitiveness discussions, combined with a shifting global order, require new strategies to secure Europe's leadership in biopharma as a toptier geopolitical and economic industry. In

practice, Europe has begun to change the narrative. The growing debate on European competitiveness — visible across consultations, parliamentary discussions and industry forums — reflects a broader consensus: scientific leadership alone is insufficient without industrial capacity and systemlevel delivery. Innovation ecosystems are increasingly recognised as the execution architecture through which the EU's emerging policy compass can be deployed in practice.

This shift is reflected in the Commission's current policy agenda. The "Life Sciences Strategy" places biotech at the heart of competitiveness. The proposed Biotech Act targets simplification, scaleup and industrial deployment. The Critical Medicines Act focuses on resilience, availability and strategic production. The Pharmaceutical Package seeks to rebalance access, affordability and innovation attractiveness. Funding instruments under Horizon Europe, the EIC and the future

<sup>5</sup> [https://single-market-economy.ec.europa.eu/publications/industrial-accelerator-act\\_en](https://single-market-economy.ec.europa.eu/publications/industrial-accelerator-act_en)

<sup>6</sup> <https://www.bmj.com/content/390/bmj.r1965>

<sup>7</sup> <https://www.eib.org/en/publications/20250217-drivers-of-relocation-by-innovative-eu-startups-and-scaleups>

<sup>1</sup> <https://www.lazard.com/research-insights/the-geopolitics-of-biotech/>

<sup>2</sup> <https://www.bcg.com/publications/2026/reimagining-business-models-biopharma-trends>

<sup>3</sup> <https://www.deloitte.com/us/en/insights/industry/health-care/life-sciences-and-health-care-industry-outlooks/2026-life-sciences-executive-outlook.html>

<sup>4</sup> [https://www.biotech.senate.gov/final-report/chapters/?utm\\_source=chatgpt.com](https://www.biotech.senate.gov/final-report/chapters/?utm_source=chatgpt.com)





Multiannual Financial Framework aim to close the scaleup gap. Single Market tools, including the proposed "28th regime" and a clearer "Made in Europe" logic, aim to reduce fragmentation for innovative companies while preserving Europe's standards in patient protection, public oversight and social cohesion.<sup>8,9</sup>

This is not a single policy intervention. It is an ecosystem of policies. To succeed, it must support the full biomedical innovation continuum, from fundamental science and translational research to clinical validation, manufacturing and market deployment. Competitiveness depends not only on industrial scaleup, but also on strong R&I institutions, innovative hospitals and longterm talent retention. With initiatives such as the proposed 28th regime, Europe is consolidating its own model for R&I-intensive sectors: regulated, trusted, and offering greater predictability through strong public-private coordination.

Innovation ecosystems matter because Europe's competitiveness is often decided at the interfaces between research, hospitals, manufacturing, regulation and investment. When these interfaces are fragmented, delays and inefficiencies accumulate. When they are coordinated, ecosystems become platforms for execution, resilience and industrial capacity. Recent EU-level work on cluster and innovation ecosystem policy

8 [https://ec.europa.eu/commission/presscorner/detail/da/ip\\_25\\_3077](https://ec.europa.eu/commission/presscorner/detail/da/ip_25_3077)

9 [https://commission.europa.eu/eu-inc-new-harmonised-corporate-legal-regime\\_en](https://commission.europa.eu/eu-inc-new-harmonised-corporate-legal-regime_en)

makes this transition explicit, signaling a move from cluster-based coordination towards stronger regional ecosystem strategies; from project-based support towards structured feedback loops to surface Single Market barriers; and towards shared infrastructures, earlier mobilisation of private capital, and a more strategic use of regulatory sandboxes.<sup>10,11</sup> This marks a qualitative shift: from supporting innovation to organising execution at global scale.

Advanced therapies and complex biomanufacturing illustrate why this shift matters. They act as a stress test for Europe's clinical research system, while the underlying constraints affect innovative clinical trials more broadly. Europe's weakness in this field has not been science or clinical expertise, but the industrialisation and clinical translation wall. Limited access to pilot capacity, manufacturing bottlenecks, uneven site readiness and late regulatory engagement continue to slow down early clinical development.<sup>12</sup>

Robust and resilient ecosystems can change this trajectory. They provide shared validation environments where processes and data can be reused, enable earlier and more structured

10 <http://www.clustercollaboration.eu/knowledge-sharing/publications/document-library/european-cluster-panorama-report-2024>

11 <https://data.europa.eu/doi/10.2777/9535645>

12 <https://pubmed.ncbi.nlm.nih.gov/35186986/>

interaction with regulators, and reduce risk before major investment decisions are taken. These are precisely the conditions Europe is seeking to strengthen.<sup>13</sup>

Beyond ATMPs, Europe must also become more attractive for early-stage clinical development. Europe already hosts some of the world's leading clinical research regions and hospitals, with strong scientific capabilities, experienced investigators and access to patients. The Clinical Trials Regulation was an important step towards harmonisation, but implementation still varies across Member States. This matters most in early-phase and highly innovative trials, where approval timelines, contracting and site activation conditions shape location decisions. More consistent and better coordinated procedures, specialised early-phase units, and stronger integration between hospitals, research centres and manufacturing infrastructures are therefore essential to reinforce Europe's position as a leading destination for innovative clinical research.

With instruments now defined and being deployed, health sovereignty will be built through regional ecosystems capable of transforming European science into accessible innovation and resilient industrial capacity — where delivery, scale and impact are decided.

13 Daban, M: «10 Elements of success to support place-based innovation»



**VYTENIS ANDRIUKAITIS**

*MEP (S&D, Lithuania), Rapporteur in the SANT Committee on the European Biotech Act, member of the Committee on Public Health, and former European Commissioner for Health and Food Safety*

# The Biotech Act: A blueprint for a strong, resilient, and fair Health Union

**H**ow many more patients must we fail before we admit that Europe's health innovation system is broken? How many more families, searching desperately for a treatment, must we send on an impossible journey of roadblocks and closed doors?

The reality today is that the one specialist who understands their rare condition may practise in another country. The clinical trial that offers a flicker of hope may be in another. And their medical history may sit in a system that doctors elsewhere just cannot access.

This is not a failure of science. Europe has pioneering research, deep clinical expertise, and brilliant digital health initiatives. It is a failure of political will: we have allowed these assets to remain fragmented across a labyrinth of national rules and procedures. So far, this has been holding back progress and, ultimately, costing lives.

The European Biotech Act is an opportunity to start fixing this. As the Parliament's rapporteur for this file in the Public Health committee, my goal is to shape it into a blueprint for a Europe that connects its strengths and delivers for its people. It must be a health-driven blueprint. With health applications accounting for over 75% of the biotech sector's value and jobs, I am convinced the Act can be a cornerstone of a stronger European Health Union, with patients at its centre.

## From building blocks to an ecosystem that delivers

World-class assets in research and data are not enough. To deliver for citizens, we must build a thriving, interconnected health-innovation ecosystem. The Biotech Act has greater potential than its name indicates. Instead of betting on a single technology, it must help bridge the gap between Europe's

scientific excellence and its implementation in our healthcare systems.

## We must finally translate innovation from bench to bedside.

This means unleashing the power of the assets we already have. We can leverage a responsible, AI-driven approach to dramatically speed up the discovery of new therapies, connecting our European Health Data Space and the 1+ Million Genomes initiative to find answers faster than ever before.

It also means to keep building on excellence. Our 24 European Reference Networks (ERNs), which connect over 1,600 specialist centres across more than 350 hospitals, are a prime example of how European collaboration saves lives. The Act must now recognise them for what they are: the strategic infrastructure of our European health ecosystem. When that

happens, ERNs will then be empowered with stable, ringfenced funding and a stronger, formal role across the entire research lifecycle. This is our opportunity to establish clear cross-border pathways so that expertise can travel to the patient, and the patient to the expertise.

And then, let's make bold choices. Let's use regulatory sandboxes to bring novel therapies forward, in a controlled but agile way. Let's build high-speed, multi-country clinical trials designed not just for bureaucratic convenience, but to help patients that have run out of options.

## Forging a resilient Health Union

Europe's resilience must begin at home. For too long, internal fragmentation has weakened our health security and deepened the very dependencies we now seek to escape.





Strengthening our strategic autonomy in health is a necessity, and the Biotech Act can serve this by fostering a predictable environment that encourages investment in cutting-edge biomanufacturing.

But resilience also comes from shared capacity. Rather than duplicating efforts in every country, we should aim for a smart, connected, hub-and-spoke network of manufacturing infrastructure that serves the needs of cross-border patients. By leveraging the strength of European collaboration, we can ensure that a patient in a smaller Member State has access to the most advanced therapies on the same terms as one in a larger one.

But this must not concentrate innovation in a few traditional hubs. Solidarity is a founding principle of our Union, and true resilience comes from shared capacity. The Act must incentivise research and manufacturing

capabilities across all Member States, so that patients in smaller countries have access to innovation on the same terms as those in larger ones.

Each single Member States is small next to the US or China. But together, they are a continent with scale to drive innovation.

#### **Innovation that serves patients**

As we build this ecosystem, our European values must be our guide. Speed can never come at the expense of our standards. Patient safety, equity, and fundamental rights are the bedrock of our approach, and they are not for sale.

Our vision is of an innovation ecosystem that delivers fair and equitable access for all. I will be working to build a balanced framework that rewards real breakthroughs, attracts capitals, and de-risks investments – especially in areas like rare and ultra-rare diseases, where

markets haven't been able to cater to patients who need it the most. I believe that affordable treatments can reach patients in good time, while also easing the pressure on our health systems, and safeguarding the sustainability of our social model.

The task before us is to turn a patchwork of excellence into a world-leading ecosystem. By adopting a health-driven blueprint that connects our assets, empowers our shared infrastructure, and embeds solidarity at its core, the Biotech Act can deliver a stronger, more resilient, and fairer European Health Union.

The European Parliament is ready to build an ambitious position, and I stand ready to work hand in hand with the Commission and the Council to deliver a transformative act.



**WOUTER BEKE**

*Member of the European Parliament (EPP/  
cd&v - Belgium)*

# Scaling Europe's biotech industry: from research excellence to industrial leadership



For the past decades, Europe has been treating biotechnology primarily as a health policy issue. That was a mistake. Biotech has become deeply geopolitical. This new reality is now more tangible than ever. Across almost every stage of the biotech lifecycle — from venture capital and clinical trials to manufacturing, commercialisation and thus access to patients — Europe is losing market share to global competitors. If the EU wants to keep up its ambitions on strategic autonomy and resilience, it will have to embrace its strengths while acknowledging its issues and act accordingly.

In that light, Europe's biotech problem is not a lack of talent, knowledge or scientific quality. European universities, hospitals and research institutes remain among the best in the world. The paradox is that Europe excels at discovery but struggles at scale.

Too many European biotech companies still relocate abroad once they need significant growth capital. Too many promising start-ups are acquired before they become European industrial champions. Too often, Europe exports innovation while importing dependency.

The contrast with our global competitors is striking. The US has built an ecosystem where innovation can rapidly scale into global industrial leadership due to massive investments. China is aggressively integrating research, industrial policy and manufacturing capacity into one long-term strategy. Europe, meanwhile, remains fragmented — financially, regulatorily and industrially. Scientific excellence alone is no longer enough if Europe cannot transform innovation into industrial strength.

Enter: the Biotech Act I. One of the few cornerstones of the EU's competitiveness agenda as it sits at the intersection of industrial and health policy with a growing geopolitical angle to it. This regulation goes directly to the core of who we are and should be: a deeply anchored

social welfare state driven by innovation as the one of the motors for our economy and public health. Europe cannot become a continent that invents technologies for others to industrialise while risking later or no access at all for our own patients.

For too long, innovation in this field has been approached with excessive caution or even suspicion. Of course, ethical and safety standards remain essential and national budgets are scarce. But there is a difference between responsible regulation and creating an environment that systematically discourages investment and scale. If Europe becomes known primarily for its fragmentation, complexity and regulatory uncertainty, companies and investors will simply continue to look elsewhere. We should therefore value innovation and excellence because without them, Europe would gradually lose not only competitiveness, but entire industries. Industrial leadership cannot exist without scientific leadership, and scientific leadership cannot survive if innovation is pushed outside Europe. That means rewarding research, protecting intellectual property, accelerating approval procedures where possible and ensuring that Europe remains attractive for talent, investment and entrepreneurship.

At the same time, we should be honest: scaling Europe's biotech industry will require much more than the Biotech Act alone. It's only a piece of the puzzle, not the sole magic bullet. Due to fragmentation in investing and financing mechanisms, European companies often struggle to access late-stage venture capital precisely when they need to scale internationally. In the last decade, for example, 66 out of the 67 IPO's of European companies were launched outside the EU. This is why deeper harmonisation of European capital markets is essential. Europe researches like a continent, but still finances innovation like 27 separate economies. Without significantly more venture capital and stronger capital

markets integration, Europe will continue to lose promising biotech firms to the US.

Scaling also requires industrial capacity. Europe needs stronger biomanufacturing infrastructure, resilient pharmaceutical supply chains, affordable energy and access to highly skilled labour if it wants to expand its innovation capacity into broad commercialisation. If we are serious about building globally competitive biotech champions, Europe must finally think in terms of scale.

Therefore, we need to protect without being protectionist. In an interconnected world, Europe should remain open, internationally connected and deeply engaged in global innovation networks. But openness without industrial capacity creates dependency — and dependency weakens resilience.

The Covid pandemic exposed the vulnerabilities of relying excessively on external supply chains in critical sectors such as medicines and pharmaceutical ingredients. The geopolitical tensions of recent years have only reinforced that lesson. Strategic autonomy therefore means ensuring that Europe retains the capacity to research, manufacture and deliver critical health technologies itself. Not by closing itself off from the world, but by building sufficient scale and industrial strength at home. In biotech, resilience and competitiveness increasingly go hand in hand.

Europe still has lots of ingredients to succeed. The question is, however, no longer whether Europe can innovate. The question is whether those innovations will still be developed, manufactured and commercialised in Europe ten years from now.

The Biotech Act I should mark the moment Europe chooses ambition over fragmentation. Because in a sector as strategic as biotechnology, Europe cannot afford to remain merely a place where innovation starts. It must also become the place where innovation grows, scales and leads globally, for the sake of our patients and our industry.



Interview with

**CLAIRE SKENTELBERY**

*Director General, EuropaBio*

**Does Europe still have a realistic chance of remaining competitive with the United States and China in biotechnology—and under what political conditions?**

Europe is not short of scientific prowess nor of intellectual openness. Yet these assets are blunted by structural shortcomings. The absence of a truly integrated Single Market—most notably an incomplete Capital Markets Union—limits access to the scale of financing routinely available in the United States and, increasingly, China. Regulatory fragmentation compounds the problem: divergent national rules and slower approval timelines impose costs, delay innovation and deter investment. In health biotech, the need to navigate up to 27 distinct pricing and reimbursement regimes further slows patient access and undermines Europe's appeal as a launch market. Without tackling these systemic frictions, Europe's competitive position will continue to erode.

**Will the upcoming Biotech Act be a true industrial turning point, or just another regulatory adjustment?**

It could yet mark a turning point. The promise lies in streamlining clinical trials and accelerating development pathways—areas where Europe has lagged. Faster, more predictable processes would enhance the continent's attractiveness as a research hub. Investment incentives, including instruments such as supplementary protection certificates, could also help anchor R&D and manufacturing within the EU. Much, however, hinges on execution: the ambition, coherence and financial depth of the final framework—particularly regarding strategic projects and access to capital—will determine whether the Act reshapes the landscape or simply tidies its edges.

# Building a competitive and sustainable biotech ecosystem in Europe



**Why does Europe continue to lose its biotech companies at the scale-up stage, and what must the EU change immediately?**

The fault lies chiefly in financing. European firms with global ambitions often look across the Atlantic—frequently to Nasdaq—to access deeper pools of specialised capital. This reflects a broader incapacity to mobilise risk capital at scale within Europe itself. Advancing the Savings and Investment Union is therefore not a technocratic aspiration but an economic necessity. Without it, Europe will remain a nursery for innovation rather than a home for global biotech leaders.

**Is health sovereignty compatible with a globally open and competitive biotech industry?**

Yes—provided it is interpreted pragmatically. Sovereignty need not imply protectionism. Rather, it should denote the capacity to reinforce domestic capabilities while remaining embedded in global networks of research, supply and distribution. A resilient biotech ecosystem depends as much on international integration as on local strength.

**Should Europe be willing to take greater regulatory risks to accelerate innovation?**

Not in the sense of lowering standards. Europe's regulatory credibility rests on its commitment to safety and environmental protection. The lesson of the pandemic, however, is that speed and rigour are not mutually exclusive. More agile, risk-based processes can shorten timelines without diluting safeguards. The task is to eliminate procedural inertia, not to weaken oversight—a principle the Biotech Act could usefully enshrine.

**Is Europe too cautious—perhaps even too distrustful—of biotechnology to remain a global leader?**

The issue is less cultural distrust than institutional complexity. Decision-making in the EU requires alignment across 27 member states, alongside democratic scrutiny and stakeholder consultation. This inevitably slows progress compared with more centralised systems. The challenge is not to abandon this model, but to render it more nimble: better coordination, quicker decision-making and a firmer grip on collective priorities. Without this, national sensitivities and political caution will continue to dilute and delay Europe's ambitions in biotechnology.



NATHALIE MOLL

Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA)

# The Biotech Act can help Europe compete again in life sciences but on its own cannot deliver the change that Europe urgently requires

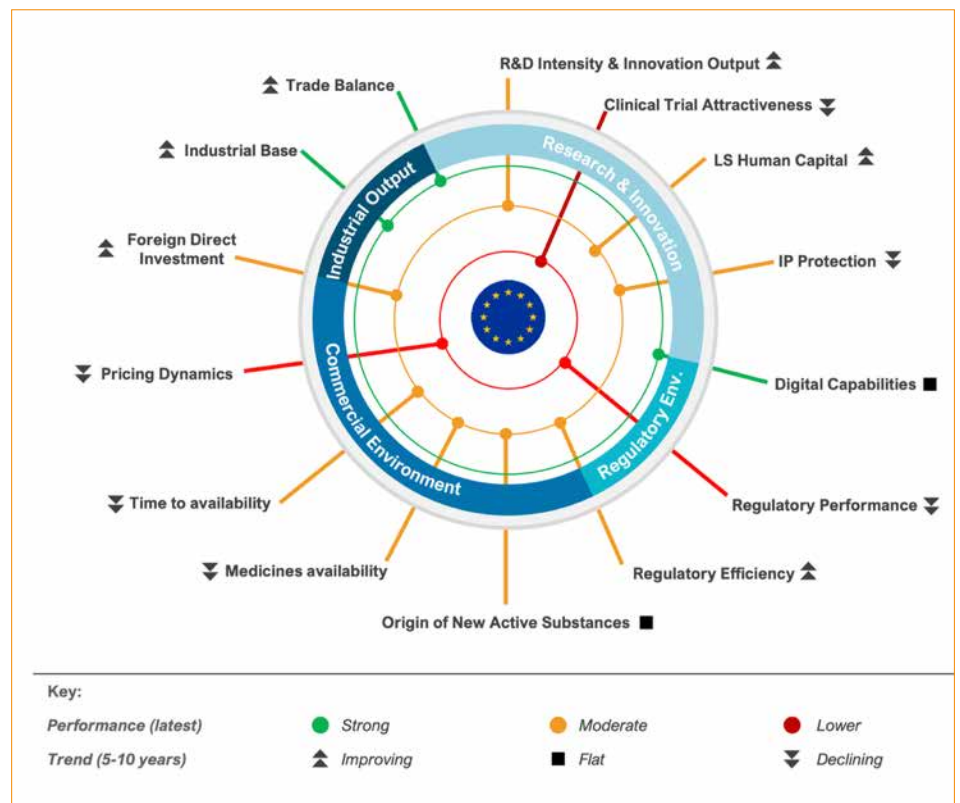
Europe has enormous strengths in science, manufacturing and its industrial base, but struggles to translate this into investment, clinical trials and new medicines. Faced with rising global competition, a more ambitious approach is needed.

The rationale for strengthening Europe's position in the global life sciences ecosystem is clear. If Europe can match or exceed the pace and scale of other regions, it will mean stronger growth, more high-value jobs, and better health for our populations.

There is much to be proud of<sup>1</sup>: our industrial base; Europe's world-leading scientific excellence, reflected in the EU's continued leadership in producing highly cited medical sciences publications; and the fact that without the pharmaceutical industry, the EU's goods trade balance would shift from a €133 billion surplus to a €93 billion deficit.

In other areas, the picture is less encouraging. In 2025, out of a total of 104 new molecules, 46 originated from Chinese headquartered companies, whilst 28 and 16 originated from US and European headquartered companies respectively. Europe lost its position as the world leader in discovering new molecules in 2000. By 2025, it ranked third globally, behind China and the United States.

Over the last decade, European pharmaceutical R&D investment has grown steadily, but at a pace that has not kept up with global



## Growth rate (CAGR) of R&D investment by national and foreign pharma companies, 2023

Rank	Country	Growth Rate (CAGR)
1st	China	12.1%
2nd	USA	6.4%
3rd	Switzerland	6.1%
4th	EU	5.4% <sup>^</sup>
5th	UK	3.9%

<sup>^</sup>EFPIA countries aggregate (excluding Switzerland and the UK)

trends. EU growth rates are lower than the US and less than half China's rate of growth.




a year (356 days), compared with 430 days in Europe.

Despite some progress, EU approval timelines remain longer than that of China and the US. China's approval times stand at 390 days, and the US is approving medicines within

Even for products that navigate European's regulatory system, there is no guarantee of reaching patients. The median time to [access new treatments](#) in Europe is 532 days, ranging

1 Charles River Associates (2026), *Assessing Europe's Competitiveness as a Location for the Life Sciences Industry*, prepared for EFPIA. Available at: <https://www.efpia.eu/media/5mrvbnamw/assessing-europe-s-competitiveness-as-a-location-for-the-life-sciences-industry.pdf>

### Number of global clinical trial starts, 2023

1st	2nd	3rd	4th	5th
				
6,392	3,747	1,978	1,025	101

*\*This represents the number of commercial clinical trial starts only  
US data represent the North America region. EU data represent the EEA region*

from 56 days in Germany to 1,201 days in Romania. Only half of approved innovative medicines are available to European patients<sup>2</sup>.

Access issues have persisted for more than a decade and with today's geopolitical pressures, they risk getting worse. Data shows a downward trend of FDA approved medicines being approved in Europe, with a particularly steeply drop since October 2025. Should this trend continue, China will overtake Europe for the first time in approving and launching new medicines.

#### An opportunity to improve the clinical trials landscape in Europe

The Biotech Act can provide a timely boost for research, clinical development and advanced manufacturing, ultimately accelerating access to new therapies for patients.

The Act has the potential to tackle one of the most enduring and concerning trends in the life sciences: Europe's relative decline in clinical trials. Trials attract investment and talent, while helping to bring the latest treatments to patients. Over the past decade, despite the total number of global clinical trials increasing by 38%, Europe has lost 60,000 trial places.

At the same time, the United States and China have invested heavily in becoming more attractive for research and innovation. That has clear implications for Europe's global competitiveness and should ring alarm bells not only in the life sciences sector, but for policymakers and society.

There are several reasons for this worrying trend. Fragmentation in the administration of clinical trials in the EU has presented a long-standing challenge for pharmaceutical companies. Faster, more predictable, harmonised approvals processes are sorely needed. This means accelerating timelines for trial start-up and assessment, while ensuring that multi-country trials can operate through a single,

streamlined process without additional national requirements.

The Biotech Act's ambition to reduce clinical trial approval timelines to 75 days would make Europe more attractive for innovative or time-critical trials. These timelines would also be among the fastest globally, particularly as they include ethics committee approval, unlike in some other jurisdictions where this is handled separately.

At the same time, Europe must invest in the future of clinical research by strengthening infrastructure, supporting trial sites, developing expert talent, and advancing digital tools. Underpinning all of this is the need to ensure that the EU Clinical Trials Information System (CTIS) is simple, reliable, flexible, and genuinely user-friendly.

#### SPC extension: an effective incentive for R&D investment

Clinical trials are an important piece of the puzzle – intellectual property (IP) is another. Recent research shows that compared with global peers, the EU currently falls behind the US, UK and Switzerland for its intellectual property offering. Strengthening IP protection, through a targeted extension of the Supplementary Protection Certificate (SPC) regime, will be an important lever to enhance Europe's attractiveness for pharmaceutical R&D.

SPCs were introduced to address a structural imbalance: medicines typically take 12 to 15 years to develop, yet the 20-year patent term begins at the time of filing. By the time a product reaches the market, a substantial portion of this limited patent protection period has already elapsed. SPCs restore some of this lost time.

In its current form, the Commission's proposal is unlikely to move the needle in terms of company investment decision. A new report by [Copenhagen Economics](https://www.efpia.eu/media/dtichwbw/ce_the-value-and-cost-of-spc-extension-05june2026.pdf)<sup>3</sup> shows that Europe faces a strategic choice. If the objective is to strengthen competitiveness, attract R&D

investment and support the development of innovative medicines, the SPC extension must be designed as a meaningful innovation incentive, with a sufficiently broad scope and flexible, workable and non-cumulative eligibility criteria.

#### Strategic enablers for a competitive European biotech ecosystem

A robust Strategic Projects framework can accelerate innovation, support scale-up, reduce fragmentation, and foster high-density innovation clusters that attract investment and talent. At the same time, enhanced and more accessible funding instruments are essential to provide biotechnology companies with the long-term capital needed to develop and commercialise innovations in Europe, preventing the relocation of promising projects outside the EU. Finally, a coherent and innovation-friendly approach to AI governance and data access, aligned with existing regulatory frameworks and supported by secure, interoperable data infrastructures, will enable the responsible integration of AI across the biotechnology value chain.

#### The choices made today will shape Europe's long-term strength

Europe has a choice to make. The global life science landscape is shifting, demanding a rapid, bold response.

The [Biotech Act](#) is an important signal of the kind of innovation ecosystem Europe wants to create, but it is not a standalone solution. When access to innovative medicines is slow and unpredictable, innovation goes elsewhere. It is unrealistic to expect greater investment and faster access to new treatments for Europeans if Member States also demand the lowest possible prices and highest government clawback rates. Reversing Europe's decline in research and development investment would require sustained structural reform, stronger action at the Member-State level, and a rethink of how healthcare systems invest in innovation.

Europe has the science. It has the talent. Now it must create the right conditions for companies to choose Europe as a place to research, develop and deliver new medicines to patients. If we get it right, the reward is higher growth, greater resilience, and better health. The choice is ours.

<sup>2</sup> <https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/patients-in-europe-waiting-longer-for-new-medicines-as-inequality-grows-between-member-states/>

<sup>3</sup> Copenhagen Economics (2026), *The Value and Cost of a Supplementary Protection Certificate Extension*, prepared for EFPIA. Available at: [https://www.efpia.eu/media/dtichwbw/ce\\_the-value-and-cost-of-spc-extension-05june2026.pdf](https://www.efpia.eu/media/dtichwbw/ce_the-value-and-cost-of-spc-extension-05june2026.pdf)



JEANNETTE BALJEU

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Renew Europe - Netherlands

# From breakthrough to manufacturing: Europe's biotech sector must build what it invents

The future of European biotech may be taking shape in a former factory in Delft. A familiar building to me. The site was once a production site of DSM and Gist-Brocades, industrial giants that played a major role in the Dutch economy. Its history is well-known in The Netherlands and especially in Delft, near my hometown Rotterdam. Businesses go through lifecycles and so did both mentioned companies. Their factories may be gone, but the innovation never left, I realize when I visited this now startup-site of DSM-firmenich. Today, this site is home to biotech start-ups developing everything from innovative proteins and biochemicals to next-generation medicines.

These technologies, shaping the coming decades, are being developed in European laboratories and incubators today. Europe has the scientists, the talent and the research institutions. The challenge lies elsewhere. I have experienced too often that promising European biotech companies reach the point where they need larger investments, faster approvals and industrial scale, only to discover that the grass is greener in China or the United States. And so they move on, a step forward for them but a loss for Europe. And not only a loss for businesses, but also a loss of public money, as most of the inventions are facilitated in the beginning by research institutions partly financed by public money.

The numbers are difficult to ignore. Access to finance for scale-up funding in the EU remains more limited than in other regions. US biopharma start-ups secured approximately nine times more late-stage funding than their EU counterparts. Between 2015 and 2025, around 219 billion euros in venture capital was invested in health biotech in the US, compared to only 25 billion euros in the EU. Europe's share of global clinical trials fell from 22 percent in 2013 to 12 percent in 2023, while

China's share more than tripled over the same period. The problem is not a lack of innovation. The problem is that Europe still makes scaling up harder than it should be.

Part of the challenge is regulatory. Today, companies conducting multinational clinical trials often face a fragmented system with different procedures, timelines and requirements across Europe. A process that takes around 60 days in the United States and China takes an average of 113 days in Europe. In practice, every additional delay creates uncertainty for investors and founders deciding where to place the next factory, investment round or research facility. These are barriers Europe built itself.

Ecosystems like in the Netherlands and Denmark work, because knowledge, capital and entrepreneurship reinforce one another. At the same time, even strong national ecosystems eventually run into European limitations when scaling up. This is precisely why the European Commission's proposed Biotech Act matters. It acknowledges where the real problem lies: Europe needs to be able to turn innovation into companies that can grow, attract investment and manufacture at scale.

The first proposal, focused primarily on health biotech, begins to address these barriers directly. Faster and more streamlined approval pathways for multinational clinical trials can cut unnecessary delays. Regulatory sandboxes can help innovative technologies reach the market sooner. Strategic biotech projects can benefit from accelerated permitting. Importantly, the proposed Health Biotechnology Investment Pilot with the European Investment Bank recognises another long-standing European weakness: access to late-stage financing, precisely the phase where many promising companies struggle most.

But Europe should not stop at health biotech. The next phase, the forthcoming Biotech Act II, will be just as important. Industrial biotech, advanced fermentation, biological crop protection, bio-based materials can strengthen Europe's competitiveness as well as reduce dependence on fossil feedstocks or foreign supply chains. Yet the challenge remains strikingly familiar. A European company developing sustainable biological solutions should not still have to navigate 27 different systems before reaching the European market. Innovation does not stop at borders. Europe's Single Market should truly behave as one and stop goldplating in national regulations.

In our discussions within the European Parliament I am looking for a more pragmatic approach. Legislation should ultimately be judged by outcomes, not ambition alone. The question is not whether Europe can produce excellent science. We already know that it can. The real question is whether a biotech entrepreneur in Leiden, Leuven or Munich will face fewer barriers three years from now than they do today. Because we cannot afford to take these matters to a new political mandate, we must deal with it now. The task is making sure Europe becomes the place where those ideas scale up into industries, the likes of the old DSM and Gist-Brocades plants. This means that the European Parliament should embrace new technologies that will improve our lives and livelihoods. And we should encourage Member States to look at the bigger picture of a strong Europe with a true single market.

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[https://ec.europa.eu/commission/presscorner/detail/en/qanda\\_25\\_3079](https://ec.europa.eu/commission/presscorner/detail/en/qanda_25_3079)


**FLORIKA FINK-HOOIJER**

*Director-General - DG HERA - Directorate-General for Health Emergency Preparedness and Response Authority, European Commission*

# Biotechnology, medical countermeasures and preparedness: DG HERA's role in Europe's health sovereignty

Six years after the COVID-19 pandemic fundamentally changed our perception of health security, one lesson remains undeniable: preparedness is not a luxury. It is a necessity – for our citizens, for our society, for our economy.

Recent public health emergencies, including the Ebola Bundibugyo outbreak in the Democratic Republic of Congo and a Hanta-/Andesvirus outbreak on a cruise ship, remind us that such health threats are not episodic. They cross borders, sometimes before they are properly detected, and do not wait for political alignment or regulatory readiness. Viruses and other health threats do not sleep. Preparedness cannot either.

Europe is operating in an increasingly complex and volatile geopolitical environment. Growing instability, supply chain disruptions and competition for critical technologies are reshaping resilience and security. For this reason, preparedness is also a strategic imperative and an essential component for Europe's sovereignty.

The European Commission's Health Emergency Preparedness and Response Authority (DG HERA) was established to ensure that Europe can anticipate health threats and respond rapidly with the medical countermeasures needed to protect citizens. Our work spans the entire preparedness cycle, from surveillance to research, development, manufacturing readiness, supply chain security, procurement, stockpiling and deployment.

At the heart of Europe's preparedness lies biotechnology. It has become the backbone of modern health security, enabling diagnostics, therapeutics and vaccines that can be rapidly adapted to emerging threats, while advances in mRNA technologies, synthetic biology and genomics are transforming how we detect and respond to them. For DG HERA, the value of biotechnology lies in its ability to generate medical countermeasures that can be deployed rapidly when lives are at stake. The rapid development

of mRNA vaccines shows what biotechnology can achieve. Yet, innovation on its own is not sufficient. Strengthening surveillance systems, including wastewater monitoring, pathogen genomics and epidemic intelligence, improves early detection. Breakthroughs will only protect populations if they can be produced at scale and delivered where needed.

Preparedness also means strengthening the pipeline of medical countermeasures development. Through HERA Invest, the EU's first dedicated health investment instrument, DG HERA helps innovative European SMEs advance high-potential medical countermeasures by addressing financing gaps in critical stages of development. This brought us the world's first approved antidote to ricin poisoning.

But preparedness extends beyond Europe's borders. In an interconnected world, global cooperation and preparedness contribute to Europe's security. Through the EU Global Health Resilience Initiative, we are strengthening cooperation on surveillance, medical countermeasures and manufacturing resilience. This commitment is reflected, for example, in the EU's €360 million pledge to Gavi, the Vaccine Alliance, helping to strengthen immunisation and outbreak preparedness where it is needed most.

As Europe is strengthening global preparedness, at the same time, it is also taking measures to enhance its own resilience through health sovereignty. This means retaining the expertise, technologies and manufacturing capacity needed to protect European citizens. Manufacturing readiness is a critical component of this approach, as dependence on global supply chains for medical products remains a major vulnerability during crises. Europe cannot rely entirely on production decisions taken elsewhere when citizens' health is at stake.

Against this backdrop, and in order to strengthen Europe's industrial preparedness, DG HERA has invested in EU FAB, a network of

manufacturing facilities with reserved vaccine production capacity that can be activated rapidly during health emergencies. Complementing this effort, DG HERA is launching RAMP UP, a network of manufacturers, innovators and suppliers designed to strengthen industrial readiness and help overcome production bottlenecks when demand surges. Additionally, DG HERA is actively supporting the "100 Days Mission" to produce a safe and effective vaccine within 100 days of identifying a pandemic threat. Through support for organisations such as the Coalition for Epidemic Preparedness Innovations (CEPI), as well as the establishment of the European Vaccines Hub (EVH), we are accelerating vaccine research and improving preparedness. Together, these initiatives help ensure that Europe can rapidly scale up the production of critical medical countermeasures when needed.

Whether facing emerging infectious diseases, vector-borne or climate-related threats, antimicrobial resistance, chemical, biological, radiological and nuclear threats, armed conflicts or a future "Disease X" – our ability to protect citizens depends on how quickly vaccines, therapeutics and diagnostics can be developed and deployed. These medical countermeasures are essential tools of response. Recognising their importance, the European Commission adopted its Medical Countermeasures Strategy in 2025, providing a comprehensive framework to accelerate innovation, strengthen manufacturing and ensure critical health tools when emergencies strike.

Looking ahead, as the European Union is currently deciding on its budget for the next seven years, preparedness and the ability to respond, when necessary, must remain a priority. Ultimately, the investments we make today will determine how effectively Europe can protect its citizens tomorrow. DG HERA will continue to play its part in ensuring that Europe is ready for what lies ahead.



**NICOLÁS GONZÁLEZ CASARES**

*Member of the SANT and ITRE Committees*

# Innovation and Access to Medicines in Europe's Biotech Framework

The European Biotech Act represents one of the most significant attempts in recent years to strengthen Europe's position in biotechnology and biomanufacturing. It reflects a growing recognition that Europe must enhance its scientific, industrial and manufacturing capabilities if it wants to remain competitive in a rapidly changing global environment.

This objective deserves broad support.

Europe needs stronger biotechnology ecosystems, more investment, greater manufacturing capacity and a regulatory environment capable of attracting research and innovation. The challenge, however, is not simply to generate more innovation. It is to ensure that innovation ultimately benefits patients and healthcare systems.

Too often, the debate is framed as a choice between competitiveness and access. This is a false dichotomy. In healthcare, innovation and access are inseparable. Scientific breakthroughs only generate value when they reach the people who need them.

A biotechnology strategy that succeeds in attracting investment but fails to improve access to medicines cannot be considered a complete success. Likewise, a healthcare system that prioritises affordability but fails to foster innovation will struggle to respond to future health challenges.

The real question is therefore not whether Europe should prioritise innovation or access. The question is how to design a biotechnology framework that delivers both.

## Beyond Exclusivities: The Debate on SPC Extension

One of the most debated provisions of the proposed Biotech Act is the extension of Supplementary Protection Certificates (SPCs)

for biotechnology products and Advanced Therapy Medicinal Products (ATMPs).

The objective is clear: to encourage investment and development activities within the European Union. Yet there are legitimate reasons to question whether extending exclusivity periods at the end of a product's lifecycle is the most effective way to achieve this goal.

Additional exclusivity inevitably delays competition. In the case of biological medicines, it postpones the entry of biosimilars that have consistently demonstrated their ability to

expand patient access and reduce costs for healthcare systems.

Competition should not be viewed as the enemy of innovation. On the contrary, the transition from monopoly to competitive markets is one of the most important drivers of continuous technological progress. Delaying that transition risks increasing costs while reducing incentives for further innovation.

The question policymakers should ask is not whether innovators deserve incentives. They do. The question is whether extending



monopolies after decades of protection is the most efficient and proportionate incentive available.

### Better Pull Incentives for European Biotechnology

If Europe wants to strengthen its biotechnology sector, it should consider a broader toolbox.

Market certainty can be as important as intellectual property protection. Joint procurement mechanisms, early access programmes, innovative purchasing models and coordinated European demand signals can provide companies with greater visibility while ensuring that patients benefit from faster access to valuable technologies.

For many innovators, the prospect of predictable uptake within large public healthcare systems may be a stronger incentive than a distant extension of exclusivity whose value remains uncertain at the moment investment decisions are made.

A biotechnology policy focused exclusively on supply-side incentives risks overlooking the importance of demand-side measures that can simultaneously support innovation and access.

### Attracting Clinical Development Through Better Framework Conditions

The same logic applies to clinical research.

Europe has rightly identified the need to attract earlier-stage clinical trials and development programmes. However, the factors that influence where companies conduct research are largely immediate rather than distant.

Efficient clinical trial authorisation processes, high-quality research infrastructures, regulatory predictability, rapid patient recruitment and clear pathways to adoption are likely to matter far more than an additional period of exclusivity that may only materialise many years later.

If Europe wants to compete globally for clinical research investment, improving the clinical and regulatory environment is likely to produce greater results than relying primarily on intellectual property incentives.

### Biosimilars as a Competitiveness Strategy

One of the paradoxes of the current debate is that biosimilars are often discussed primarily as a cost-containment tool when they should also be recognised as an industrial policy asset.

A strong European biosimilar sector strengthens manufacturing capacity, supports strategic autonomy, creates highly skilled jobs and improves resilience of supply chains.

Most importantly, biosimilars expand access.

Every euro saved through biosimilar competition creates opportunities to finance new innovations and broaden patient access to advanced therapies. Competitiveness and affordability are not opposing objectives in this context; they reinforce one another.

Supporting European biofabrication and biosimilar production should therefore be seen as an essential pillar of the Union's biotechnology strategy.

### Hospital Exemption: Innovation for Forgotten Patients

Perhaps the most important access issue within the biotechnology debate concerns Advanced Therapy Medicinal Products developed under hospital exemption frameworks.

These pathways exist for a reason. Not all patients represent commercially attractive markets.

While therapies targeting large patient populations will often attract private investment and industrial development, many patients with rare, highly specialised or ultra-small conditions depend on public institutions, hospitals and academic centres to develop innovative treatments.

The discussion should not focus exclusively on how rapidly these products can be pushed towards commercial marketing authorisation. The primary objective should remain addressing unmet medical needs.

Supporting hospital exemption means supporting innovation for forgotten patients.

Where therapies developed under hospital exemption have broader commercial potential, developers should receive regulatory guidance, business support and appropriate pathways towards commercialisation. But Europe should also preserve space for non-profit and public-interest innovation aimed at patient populations that the market alone cannot adequately serve.

A truly successful biotechnology strategy must create incentives not only for blockbuster products, but also for therapies that address the needs of those who would otherwise have no options.

### Europe Must Build Its Own Model

The debate surrounding the Biotech Act ultimately reflects a broader choice about the future of European healthcare innovation.

Some argue that stronger exclusivities and longer monopoly periods are the primary path to competitiveness. Yet the international evidence suggests caution.

The United States has produced remarkable biomedical innovation, but it also combines the highest healthcare spending in the OECD with persistent access barriers and health outcomes that frequently underperform those of many European countries.

Europe should not seek to replicate that model.

Europe's strength has always been its ability to combine scientific excellence, industrial leadership and social solidarity. The Biotech Act provides an opportunity to reinforce that distinctive approach.

The success of European biotechnology should not be measured solely by investment flows, patent portfolios or manufacturing capacity. It should also be measured by whether patients can access the innovations that Europe's scientific and industrial ecosystem produces.

In healthcare, innovation achieves its purpose only when it reaches people.

That should remain the guiding principle of Europe's biotechnology framework.





STEFAN WOXSTRÖM

*SVP Europe and Canada at AstraZeneca.*

# Securing Europe's Health Sovereignty: From Innovation to Outcomes

**H**ealth sovereignty today is not defined by physical control alone: stockpiles, warehouses or emergency reserves. Those still matter, but the real test for Europe is whether it can be the place that discovers and develops the next generation of life-changing medicines, or the place that waits and hopes for them to come from elsewhere.

Now, more than ever, health sovereignty, industrial competitiveness and economic growth are not separate agendas. They are the mutually reinforcing building blocks of a more secure health future for European citizens. If innovation, manufacturing and access shift elsewhere, Europe's sovereignty is constrained.

## Europe is losing ground - fast.

In a world where capital, talent and scientific leadership are increasingly mobile, Europe risks falling behind faster-moving competitors. The United States and China are not just investing more, they are moving faster, scaling quicker and evolving policies in line with scientific advancement. In life sciences, speed is strategy.

The numbers tell a stark story. Over the past two decades, Europe's share of global pharmaceutical R&D has fallen from around 41% to just over 30%. In 2024, the United States produced 25 new medicines, China - 28. Europe delivered just 18 - and fewer than ten originated in the EU27. China, meanwhile, has grown its pharmaceutical R&D five times faster than Europe and overtook it in new medicine launches in 2023.

Because Europe's world-class science base - its researchers, hospitals and universities - is no longer enough on its own. Innovation follows ecosystems, not just excellence. It flows to places that combine scientific strength with speed, scale and predictability across regulation, clinical trials, intellectual property and market realities. Too

often, Europe offers the science, but not the ecosystem.

If nothing changes, Europe risks becoming what policymakers quietly fear but rarely say out loud - a third-wave consumer market for breakthrough medicines, where innovation arrives late, at higher cost, or not at all.

The consequences are already visible. Over 40% of medicines launched in the United States in the past five years are still not available in Europe. And when they do arrive, it takes 597 days on average to access them. Too often, access is defined by national evaluation and pricing policies that prioritise cost containment well-above clinical outcomes or their wider economic and social potential.

For patients, this is not abstract. It means waiting longer, getting treated later, or missing out entirely. For economies, it means higher downstream healthcare costs, more hospitalisations, lower workforce participation and weaker long-term growth. Put simply - when patients fall behind, economies do, too.

This trajectory is not inevitable. It is the result of policy choices - and it can be reversed.

We are living through a golden age of medical innovation. From genomics and precision medicine to AI-enabled diagnostics and data-driven care, the science is advancing at unprecedented speed. The question is whether Europe will lead—or follow.

Answering that question requires a fundamental reset in how Europe thinks about health.

Health is not a drain on public finances. It is a driver of economic strength, resilience and security.

The pharmaceutical sector alone invests over €55 billion annually in R&D in Europe and supports more than 2.5 million jobs. More broadly, a healthy population underpins productivity and fiscal stability. Underinvest in health today, and you pay for it - many times over - tomorrow.

This is why spending on innovative medicines and modern health systems should be recognised for what they are - growth-enhancing investment. Embedding this principle in the EU's New Economic Governance Framework and the European Semester would be a decisive step toward aligning fiscal policy with long-term competitiveness.

Europe must also modernise how care is delivered.

Europe is ageing fast. With it comes a surge in chronic disease just as the healthcare workforce is shrinking. Demand for healthcare is rising sharply while capacity is falling - and demographics mean we will not simply grow our way out of the gap. Fewer workers will be supporting more patients, putting unprecedented strain on health systems.

Shifting from acute, hospital-centred care to prevention, early diagnosis, precision medicine and integrated care is not just a clinical imperative - it is an economic one. Healthier populations are more productive, more resilient and less costly to support. Investing in prevention and better care is, ultimately, an investment in Europe's competitiveness and growth.

Here is the paradox at the heart of Europe's health debate: we often treat innovation as a cost pressure, when, in reality, it is one of a very limited number of policy options available to secure Europe's future.

Medicines that prevent disease progression, avoid hospitalisation and keep people in the workforce are not expenses to be minimised.

Still, no single reform will be enough. Europe's challenge is systemic - and so must be its response.

## The Biotech Act is a strong start

At EU level, the proposed Biotech Act is an opportunity to move from rhetoric to reality. It acknowledges that Europe needs an ecosystem that works end-to-end: from

laboratory to factory to patient. The task now is execution - fast, coordinated and ambitious.

Done right, the Biotech Act can cut through fragmentation and outpace others on clinical trials and incentives to invest and manufacture in Europe. And make no mistake: clinical trials are not just a scientific question; they are a competitiveness issue. Companies go where systems move fastest. Today, Europe is losing that race.

Equally critical is a globally competitive framework for intellectual property and innovation rewards. If Europe wants to attract and keep high-value R&D, it must send a clear signal - medical research will be recognised, protected and rewarded.

Herein lies the key test of EU ambition. The Act is a strong start - but it must close a real and widening gap. Today, commercial trials in the US launch in roughly half the time it takes in the EU. At best, the Act now would reduce that difference to a few months. The proposed SPC reward, meanwhile, would apply to only a small fraction of new medicines.

Policymakers should not question if it goes too far - but if it goes far enough to keep Europe in the global race.

#### **Brussels cannot do this alone.**

Health sovereignty is ultimately decided in national capitals and local health systems. It is Member States that determine how quickly transformative therapies reach patients.

Faster regulatory approvals mean little if medicines are then rejected at national level for "immature" data or endpoints accepted everywhere else. Reform at EU level cannot be offset by hesitation on the ground.

The same is true for clinical trials. The Biotech Act's reforms will not recover Europe's lost share in clinical trials if medicines are not launched here. Or if national bottlenecks on ethics assessment, trial site contracts and patient consent erase any speed gains agreed in Brussels.

And in a world of tariffs on medicines, incentives to manufacture in Europe must be matched by an uptake of the medicines produced. Otherwise, the cost of exporting to markets that move faster and buy more remains way too high.

Member States must meet EU reform with national policy. They must ensure their systems are ready for innovation. Slow, fragmented reimbursement and market access processes mean that European patients still wait longer than those elsewhere. Even when made available, few countries truly realise the value of innovation. Without the right diagnostics, workforce skills, care pathways and data infrastructure, the most advanced medicines won't treat the right patient at the right time.

This is where coordination matters most. Without aligned action between EU institutions and national governments, Europe risks having

world-leading science and second-rate patient outcomes.

There are tools available. Innovative funding models, public-private partnerships and EU-level investment instruments can help crowd in private capital and anchor key capabilities in Europe. But they must be deployed at scale and with urgency.

Because this is the bottom line - a competitive investment environment is not a gift to industry, it is a condition for sovereignty.

#### **The choice is still ours. But the window is closing.**

Europe can continue on its current path: managing decline, importing medical breakthroughs and accepting a second or third-tier role in medicines that will tackle the health challenges of the century.

Or it can act decisively to reset its approach.

That means treating health as a strategic investment, not a sunk cost. It means implementing the Biotech Act with speed and ambition. It means fixing access so that innovation reaches every European patient, not just some.

In healthcare sovereignty, leadership belongs to those who move first.

Europe must decide if it wants to set the pace or follow it.





**TILLY METZ**

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# Europe's Quest for Health Sovereignty

**H**ealth sovereignty has emerged as one of the defining political challenges facing the European Union. The COVID-19 pandemic exposed the extent of Europe's vulnerability to medicine shortages, disrupted supply chains, external manufacturing dependencies, and fragmented national responses in times of crisis. These weaknesses have become ever more glaring amid rising geopolitical tensions and intensifying global competition in biotechnology.

Establishing health sovereignty in Europe must therefore go beyond the capacity to respond to crises and encompass the European Union's ability to guarantee access to high-quality healthcare, secure reliable supplies and production of essential medicines and technologies, and sustain global competitiveness in health innovation.

Achieving this objective requires a broader vision of health policy, one that recognises healthcare not simply as a social expenditure, but as a strategic investment in Europe's long-term stability, productivity, and security. This is particularly important at a time when many healthcare systems across the EU are facing mounting pressures from poor public health investment, workforce shortages, widening inequalities in access to care, and growing dependence on fragile global supply chains. Strengthening the resilience of these systems has therefore become central to Europe's capacity to withstand future crises and maintain its strategic autonomy.

## **Securing medicines and strategic resilience**

Access to affordable medicines is a fundamental healthcare right and a central component of European health sovereignty. Yet medicine shortages in Europe increased twentyfold between 2000 and 2018, while prices simultaneously continued to rise

sharply. In Italy the cost of some essential cancer treatments has increased by as much as 1,500% in recent years.

Europe also remains heavily dependent on external suppliers for active pharmaceutical ingredients, leaving Member States vulnerable to geopolitical tensions, export restrictions, and global supply chain disruptions. Between 60% and 80% of active pharmaceutical ingredients are now manufactured outside the EU. At the same time, extensive intellectual property protections often delay access to medicines and limit the development of affordable biosimilar and generics.

Strengthening health sovereignty therefore will require a more coordinated industrial and pharmaceutical strategy at EU level. Europe must invest in resilient manufacturing capacity, diversify supply chains, and support the production of essential medicines within the Union while maintaining open and cooperative global partnerships.

Strategic resilience must go hand in hand with affordability and equitable access. Public investment in research and innovation should contribute to ensuring that medicines developed with public funded research remain accessible and affordable to patients across all Member States. Coordinated procurement, stronger cooperation on shortages, and support for generic and biosimilar production can all help reinforce both Europe's resilience and access to care.

## **From crisis response to permanent preparedness**

The Covid-19 pandemic clearly showed that no Member State can effectively manage large-scale cross-border health threats alone. European coordination proved essential during moments of extreme pressure. Joint procurement mechanisms, cross-border



cooperation, vaccine development partnerships, and the creation of the Health Emergency Preparedness and Response Authority (HERA) marked substantial steps towards a more coordinated European health response.

Yet preparedness cannot remain limited to emergency instruments activated only during crises. We need to move from reactive crisis management to permanent preparedness capacity. This means strengthening European coordination on stockpiling, surveillance and emergency manufacturing capabilities. It also means improving interoperability between national systems and reducing fragmentation that weakens Europe's ability to act collectively and rapidly.

The lessons learned from the COVID-19 pandemic are already informing cooperation across multiple areas, reflecting a growing level of trust between EU institutions, Member States, and international health organisations. Maintaining and strengthening this progress will be essential to ensuring future health sovereignty.

**Investing in the healthcare workforce**

The EU already faces a shortage of an estimated two million healthcare workers, a gap expected to widen as the workforce ages and retirement rates increase. Low

pay, excessive workloads, burnout, and poor working conditions, all pressures that were intensified by the COVID-19 pandemic, have made healthcare careers less attractive. This is driving professionals out of the sector or towards countries offering better salaries and conditions. The result has been growing inequalities between Member States and the increasing desertification of healthcare services in rural and underserved regions.

Addressing these shortages will require coordinated European action on training, retention, mobility, and working conditions. Investments in health innovation and biotechnology must be matched by investments in the workforce capable of delivering care and supporting medical innovation across the Union.

**Prevention and the One Health approach**

Achieving health sovereignty must also include stronger investment in prevention and preparedness against long-term health threats. Climate change, antimicrobial resistance, biodiversity loss, and environmental degradation are increasingly shaping public health outcomes across Europe and globally.

In recent decades, 60% of newly emerging epidemic diseases have been zoonotic in origin, including HIV, Ebola, SARS, MERS, and

COVID-19. The pattern is clear. Ecosystem destruction, the overuse of antibiotics in agriculture and medicine, and the release of pharmaceutical pollutants into water and soil are not isolated environmental issues; they are growing public health threats. Antimicrobial resistance alone already causes around 35,000 deaths every year in the EU, a burden comparable to influenza, tuberculosis, and HIV/AIDS combined.

The One Health approach therefore needs to become more systematically integrated into European policymaking, because reducing future vulnerabilities requires policies capable of addressing the structural drivers of health crises before they escalate into emergencies.

**Conclusion**

European health sovereignty cannot be reduced to preparedness for the next crisis alone. It requires a long-term commitment to strong public healthcare systems, affordable medicines, secure supply chains, investment in healthcare workers, and one health approach. Meeting these challenges successfully would strengthen not only Europe's capacity to protect public health, but also its social cohesion, economic resilience, and strategic autonomy in an increasingly uncertain world.





LYNELLE HOCH

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# Scaling Cell Therapy in Europe: Why the Biotech Act Must Keep Pace with Innovation

Some medical advances treat a disease. A rare few can end it. CAR T-cell therapy belongs to the second kind. Some patients who received a single CAR T-cell infusion for blood cancers ten years ago now have no evidence of disease — no ongoing treatment, no relapse. That is a different category of medicine, and Europe helped build it.

## Pioneering treatments, powerful returns

The science of CAR T-cell therapy has advanced rapidly. The field is now moving into earlier treatment settings and beyond blood cancers entirely — into autoimmune disease. Patients living with conditions such as lupus and multiple sclerosis face a lifetime of treatment with no end in sight. CAR T-cell therapy has the potential to change that with a single infusion. This is a fundamental shift in what healthcare can deliver.

When one treatment can do the work of a lifetime of interventions, the economics of

care are transformed. A therapy that returns a patient to their family, their work, their life is a return on investment, paid back in reduced welfare costs, workforce productivity released, hospital capacity freed, and years of life enjoyed.

## The science is ready. The systems are not.

I lead the Cell Therapy Organization at Bristol Myers Squibb. We are the only company with two approved CAR T-cell therapies against two distinct targets, and more than 19,000 patients globally have been treated with a BMS cell therapy product. We are building toward providing treatment for five times more patients by 2030.

Whether Europe will be at the centre of this transformation comes down to choices: about how these medicines are assessed, manufactured, regulated, and delivered. Those choices are exactly what the Biotech Act gives co-legislators the opportunity to get right.

Three interconnected shifts are needed to allow health systems in Europe to deliver this next wave of treatment to patients.

**First, recognising the true value of these medicines is recognized by payers.** A one-time, potentially curative therapy cannot be judged by a single year's budget impact — yet that is precisely what most national reimbursement frameworks do. For many CAR T-cell therapies, randomised controlled trials are neither feasible nor ethical. The EMA has accepted this, granting authorisation on single-arm data. Most national Health Technology Assessment (HTA) bodies have not followed, and the result is a therapy that clears the regulatory bar and then stalls at the reimbursement door.

Closing that gap requires two things: HTA frameworks that assess Advanced Therapy Medicinal Product (ATMP) on the long-term value they create — for patients, for workforce participation, for healthcare systems — and the real-world evidence to support those assessments. Today, that evidence sits trapped in fragmented national registries that cannot communicate with each other, meaning each country relearns the same lessons independently. Interoperable registries, built on common standards and the European Health Data Space, can be the foundation of every reimbursement decision that follows. The Biotech Act is the right vehicle to incentivize common registry standards and anchor EU-level guidance on what constitutes robust ATMP evidence.

**Second, the way regulators handle manufacturing enhancements for these therapies needs to reflect how they actually work.** An ATMP is not a conventional pill. It is an individualized therapy shaped by the process that takes patient cells from apheresis, through manufacturing and supply chain, to infusion. That process is integral to the ultimate therapy, and it will continue to evolve and improve. Yet today, even a routine process



change can trigger a lengthy regulatory submission, regardless of how minor that change may be.

Other regulatory systems, have addressed this. Submissions are tiered to match the significance of the change, where minor updates are filed quickly, and intensive review is reserved for changes that genuinely warrant it.

The EU needs more flexibility. That means a framework proportionate to risk: faster handling of routine manufacturing variations, adaptive GMO-related exemptions, and early and agile EMA scientific guidance so manufacturers are not navigating uncertainty alone. The Biotech Act should establish that framework explicitly, tailored to ATMPs rather than borrowed from conventional biologics.

**Third, the places and people that deliver them must be strengthened to ensure access at scale.** Delivering these therapies at scale will require a broader network of treatment-ready hospitals, and enough trained staff to administer them beyond oncology and haematology.

Targeted investment to qualify more treatment centres and expand fast-track professional training would allow more patients to receive treatment closer to home. The Biotech Act can enable this funding of strategic infrastructure and co-legislators should ensure it does.

### Now it falls to co-legislators

The Biotech Act is the first time Europe has treated biotechnology as what it is: strategic infrastructure, no less than energy or defence. But the real opportunity now lies with the European Parliament and the Council. As co-legislators, they have the mandate and the tools to go further and to ensure the Act funds ATMP-ready infrastructure across Member States, incentivizes the interoperable data architecture the science demands, and tailors its regulatory provisions to how CAR T-cell therapies are made and delivered.

I have seen what happens when policy and science move together — and I have seen what CAR T-cell therapy does for patients. Europe has every reason to lead in this next era of medicine — and the Biotech Act is the opportunity to make sure patients will benefit.





**TOMISLAV SOKOL**

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# Strengthening Europe's pharmaceutical sovereignty

Across the European Union, 2023 and 2024 saw record levels of medicine shortages reported, with 136 medicines running critically short across Member States. From antibiotics and cancer therapies to cardiovascular medicines and basic hospital treatments, shortages have increasingly become a direct threat to patients, healthcare systems, and public trust. The COVID-19 pandemic exposed the fragility of global supply chains, but the challenges did not disappear when the pandemic ended. Instead, they evolved into a structural vulnerability for Europe.

At the same time, the European Union has become dangerously overdependent on imports of active pharmaceutical ingredients (APIs) and key medicinal components from third countries, especially India and China. Today, a significant share of the medicines used by European citizens relies on supply chains located far outside Europe. This dependency creates serious risks for the Union's strategic autonomy, particularly in a world shaped by growing geopolitical instability, trade tensions, and increasing global competition.

The new geopolitical reality makes it clear that Europe must strengthen its competitiveness and resilience in the pharmaceutical sector, which is undeniably a strategic sector for the Union. This has also been strongly underlined in the Draghi Report, which emphasized the urgent need for Europe to invest in industrial capacity, innovation, and strategic sectors capable of safeguarding European security and competitiveness. Pharmaceutical production and medicine security must therefore become central pillars of Europe's industrial and health policy.

This is precisely why the Critical Medicines Act represents a historic step forward.

After we concluded political work on the broader pharmaceutical legislation at the end of last year, we were also able to deliver on the Critical Medicines Act. A historic agreement was reached after 13 hours of intense negotiations, just minutes before 6 a.m. on Tuesday, 12 May. The agreement demonstrates that when Europe faces strategic challenges, it can act decisively and with unity.

As Rapporteur of the European Parliament, I worked to ensure that the Critical Medicines Act becomes much more than a symbolic response to shortages. It is a concrete and ambitious instrument designed to address shortages, ensure the availability and accessibility of medicinal products, strengthen Europe's production capacities, and boost the competitiveness of the EU pharmaceutical sector.

The Critical Medicines Act introduces a new strategic approach to pharmaceutical manufacturing in Europe. According to the new rules, building pharmaceutical factories and modernising existing capacities will be treated as strategic projects. This is a major shift in European industrial policy. Strategic projects will benefit from streamlined procedures, including faster permitting and licensing procedures, easier access to EU financing, and enhanced administrative and technical support.

For too long, pharmaceutical investment in Europe has been slowed by excessive bureaucracy and fragmented national procedures. Meanwhile, competing global economies have been investing aggressively in domestic pharmaceutical production. Europe cannot afford to lose further ground in such a critical sector.

That is why the Act creates the conditions for more investment in European

pharmaceutical manufacturing. More EU funding will be available for projects that contribute to strengthening Europe's security of supply and reducing strategic dependencies.

However, strengthening Europe's pharmaceutical sovereignty is not only about production capacity. It is also about how public authorities purchase medicines.

One of the most important achievements of the Critical Medicines Act is the reform of public procurement rules for critical medicinal products and their active substances. Until now, procurement procedures were often driven almost exclusively by the lowest price. This approach may have reduced costs in the short term, but it also contributed to the relocation of production outside Europe and increased dependency on third countries.

The new rules change this fundamentally.

For medicinal products where Europe is highly dependent on third countries, preference should be given to production based in the European Union. Price will no longer be the sole or dominant criterion in public procurement. Instead, contracting authorities will be able to favour suppliers of critical medicinal products and their active substances manufactured in the Union by applying a scoring system that proportionately rewards the share of manufacturing taking place within the EU.

In this context, contracting authorities may allocate additional points to manufacturers that offer 50% or more of the medicinal products and their active substances manufactured in the Union. This creates a powerful incentive for companies to invest in European production capacities and supply chains.



This is not about protectionism. It is about resilience, reliability, and security of supply. Europe cannot continue outsourcing the production of critical medicines while expecting guaranteed access during crises. Strategic autonomy in healthcare is no longer optional but a necessity.

The same principles will also apply to collaborative procurement conducted by the European Commission on behalf of Member States. By coordinating procurement at the European level and prioritising secure and diversified supply chains, the Union can better protect patients and healthcare systems across all Member States.

Europe has recognised that medicine security is inseparable from strategic sovereignty. We cannot allow shortages of critical medicines to become the new normal. We

cannot remain dependent on fragile external supply chains for products that are essential for the health and safety of our citizens.

The Critical Medicines Act provides Europe with the tools to change this reality. It strengthens resilience, supports European production, modernises procurement rules, and reinforces Europe's competitiveness in one of the world's most important strategic industries.

Our objective is simple but ambitious: to build a resilient, competitive, and self-sufficient European Union when it comes to medicines. European patients deserve secure access to the medicines they need, produced through supply chains that Europe can rely on even in times of crisis.

This is what pharmaceutical sovereignty means. And this is what the Critical Medicines Act is designed to achieve.



SIBILIA QUILICI

Executive Director Vaccines Europe

# The role of vaccines innovation in Europe's biotech strategy

## A sector already delivering for Europe

Europe remains one of the world's leading vaccine development and manufacturing ecosystems and a global supplier of vaccines. Leading Vaccines Europe, I see this strength up close every day. It is factories running, pipelines advancing, and scientists working to solve problems that did not exist a decade ago, while continuing to refine the vaccines already protecting millions.

The [trade figures](#) speak for themselves. In 2024, the EU exported approximately \$24.5 billion worth of vaccines worldwide, representing 7.9% of total EU pharmaceutical exports, while importing \$3.4 billion, generating a trade surplus of \$21.1 billion. This is equivalent to 10.9% of the total EU pharmaceutical trade surplus.

Europe's leadership was also evident during the COVID-19 pandemic. By January 2022, the EU had produced [approximately 40%](#) of the world's COVID-19 vaccine exports showing what a strong domestic vaccine industry can deliver when it matters most. This was only possible because the underlying research platforms, manufacturing infrastructure and regulatory expertise already existed in Europe.

What makes this sector distinctive is not just its scale, but its complexity. Developing a vaccine requires exceptional scientific and technical expertise, long-term investment and highly specialised manufacturing capabilities. From discovery to approval, timelines can extend over a decade. The sector depends on strong disease surveillance networks, generations of accumulated know-how, and an ecosystem that is difficult to rebuild once lost.

The vaccines industry is also one of the most research-intensive sectors in Europe, and that pipeline of innovation remains strong. Vaccines Europe's latest [pipeline review](#) shows member

companies are currently developing 91 vaccine and monoclonal antibody candidates targeting infectious diseases, emerging health threats and AMR. This is an industry not simply responding to today's challenges but actively preparing for tomorrows.

Immunisation has come a long way from relying on a narrow set of technologies. Today's vaccine platforms span a much broader range, enabling protection against a wider array of pathogens and allowing approaches tailored to age, socioeconomic status, geography and other population needs. This diversity is a strategic asset: the more vaccine technologies available, the better placed the world is to respond quickly when new health threats emerge. It is exciting to see this level of innovation on our doorstep. It is now up to Europe to ensure it continues to grow.

Yet, the vaccine sector is not spared from the decline affecting Europe's innovative research-based pharmaceutical industry, whose share of global clinical trials has [halved](#) over the past decade.

This trend is reflected in immunisation research. Vaccine trials [increased globally](#) during the COVID-19 pandemic, however the EEA's global share of immunisation trials has since fallen from 17% in 2018 to 8% in 2023. This decline has been sharpest in Phase 3 and Phase 4 trials, as activity shifts increasingly toward Asia and Oceania. Disparities across EEA countries add a further layer of fragmentation to Europe's vaccine innovation ecosystem.

I have watched this trend deepen. Increasingly, Europe risks being treated as the cautious choice rather than the obvious one.



### Getting the policy environment right

The EU has a real opportunity to keep growing vaccine capacity in Europe, and the proposed [Biotech Act I](#) is a step in the right direction, signalling that Europe's health sector is a strategic industrial and scientific asset. While vaccines are covered by default under the Act as biotechnologies and medicines, the initiative is an opportunity to ensure that the vaccine sector is considered on its own terms, accounting for the specificities of its unique ecosystem.

Having engaged closely following the publication of the Biotech Act I, I believe it is important that a sector with distinct needs is not overlooked by being treated as identical to other biotechnologies.

The vaccine lifecycle depends on strong surveillance systems, preparedness planning, sustainable manufacturing capacity, and long-term public health strategies. If Europe wants to maintain its global leadership, it needs policy that actively safeguards the competitiveness of its vaccine industry. Targeted policy refinements would help ensure that the specificities of the vaccine ecosystem are fully reflected in the implementation of the EU Biotech Act I.

Good decisions depend on good data. Yet, gaps and delays in epidemiological and vaccine-effectiveness data continue to slow public health decision-making, resilience of the supply chain, and hold back innovation. The Act should ensure that high-quality data is independently and promptly available.

The regulatory framework needs the same scrutiny. The Act currently exempts certain advanced GMO-based therapies from environmental assessment requirements - but vaccines are left out. Closing this gap, for example through a clear exemption for eligible vaccines in the EU's Clinical Trials Regulation, would cut red tape for next-generation vaccines and the further development of existing vaccines while continuing to maintain strong environmental or public health protections.

Finally, there's the question of strategic recognition. The Act creates a new category of "Strategic Health Biotechnology Projects" to support Europe's most competitive, resilient and technologically advanced health initiatives. Vaccines are a natural fit. They prevent disease, depend on advanced manufacturing, and deliver outsized public health and economic returns. The same logic applies to the Act's biodefence-focused strategic projects. Explicitly recognising prevention in both categories would enhance Europe's

ability to spot and respond to biological threats, including through tools like the EU Biothreat Radar.

### Unlocking investment in prevention

The Global Health Resilience Initiative similarly recognises Europe's role as a global health leader. Delivering on that ambition requires a strong and competitive European vaccine ecosystem. Safeguarding Europe's vaccine industry is essential not only for health security, but also for economic resilience, technological leadership, and strategic autonomy. To ensure that the EU can lead on shaping the future of global health, sustained investment in vaccine innovation, manufacturing capacity, and enabling policy frameworks must remain central to that ambition.

Overall, a strong manufacturing and supply side is necessary but not sufficient. Preparedness and resilience also depend on demand. Part of this comes down to manufacturers' ability to engage with the bodies that set vaccination recommendations, but it is just as much a matter of Member States clearly signaling their future vaccine needs.

Europeans are facing converging challenges that will shape Europe's future resilience and prosperity. The population is ageing: it is projected that by 2050, there will be nearly [130 million Europeans aged 65+](#). As Europe's population ages, healthcare systems face a [double pressure](#) in rising demand for healthcare services while the working-age population financing those systems continues to shrink.

With a demographic winter looming, the case for preventive care has never been stronger. Keeping people healthy for longer is a social and fiscal imperative. Adult immunisation programmes alone can generate returns of up to [19 times](#) the initial investment. Yet in most EU Member States, [less than 0.5%](#) of healthcare budgets are allocated to immunisation. This is difficult to reconcile with the scale of benefits it delivers.

As highlighted in [a recent DG ECFIN Economic Brief](#), the New Economic Governance Framework (NEGF) offers a real opportunity to help address this imbalance. The framework aims to support Member States in implementing targeted structural reforms that improve the cost-effectiveness and fiscal sustainability of healthcare systems. Under this framework, Member States can commit to reforms which increase growth, resilience, and long-term fiscal sustainability, in exchange for longer adjustment periods to rebalance public finances.

In Belgium, the government doubled expenditure on prevention in Wallonia. Italy offers another example, treating prevention as fundamental to tackling the healthcare costs of an ageing population. Its 2026 budget law allocates €238 million a year over three years for prevention and early diagnosis, with a further €247 million earmarked for 2026 alone. These are the examples I point to when I am asked whether change is possible. Not investing in preventive care today will simply shift the burden into the future, where costs resurface as more expensive and far less predictable.

In this context, preventive measures with the highest return on investment, particularly immunisation and screening, should be recognised not simply as healthcare expenditure, but as strategic investments that can significantly reduce avoidable disease burden and long-term costs, while strengthening Europe's preparedness, resilience, and competitiveness.

### A policy moment Europe cannot afford to miss

Together, the EU Biotech Act I and the NEGF provide a unique opportunity to position vaccine innovation and preventive care as strategic assets for Europe's future. By better aligning industrial policy, public health, and long-term fiscal sustainability, Europe can reinforce its preparedness, resilience, competitiveness, and global leadership.

The vaccine industry stands ready to contribute. The opportunity is there to translate this ambition into action.



AVRIL DALY

President, EURORDIS — Rare Diseases Europe

# Rare diseases as a strategic driver of Europe's biotech leadership

For decades, Europe has been losing ground in the global competition for life sciences investment, research, and development. The Biotech Act I proposal is an important part of an effort to reverse this trend, which is why it has been welcomed by Europe's rare disease community with enthusiasm.

The case for boosting Europe's biotech sector is both moral and strategic. The unmet needs are enormous. While more than 30 million people in Europe live with a rare disease, approved treatments exist for approximately 5% of known rare diseases<sup>1</sup>. Many rare diseases remain poorly understood, with limited knowledge of their mechanisms, few validated biomarkers, and no established therapeutic approaches – representing an enormous area of unmet medical need.

At the same time, rare diseases are also an area of strategic importance for Europe. Over 70% of rare diseases are genetic in origin and research in this area has been at the forefront of biotechnology innovation. Rare disease research has played a key role in the early validation of therapeutic platforms, including adeno-associated virus (AAV) gene therapies, whose success has since opened up new possibilities across medicine more broadly. And as small and heterogeneous patient populations with rare conditions make conventional clinical trial designs poorly suited to generating the evidence required, researchers and regulators have had to embrace and refine alternative approaches. Adaptive trial designs, real-world evidence, platform technologies, are some of the tools refined in rare disease research

because conventional methods could not work at very small scale. Europe's advantage in biotechnology has, and will continue to be built, in significant part, on rare disease science.

Europe is building up distinct advantages in this field. Its 24 European Reference Networks connect specialist clinical centres across all Member States, sharing expertise and patient data at a scale that has no equivalent elsewhere. Its orphan medicines framework, has generated a quarter-century of regulatory experience and institutional knowledge in bringing complex therapies to small patient populations. And the European Rare Diseases Research Alliance (ERDERA) has built a collaborative research infrastructure – spanning registries, data networks, and patient

partnerships – that is genuinely world-leading. These are the foundations on which a globally competitive rare disease biotech strategy can be built.

The proposed Biotech Act responds to several of these challenges. Facilitating clinical trials in Europe, especially those multi-national, while keeping the high-level quality of trials in Europe<sup>2</sup> – is a meaningful

<sup>2</sup> European Commission (2025) Proposal for a Regulation of the European Parliament and of the Council establishing a framework of measures for strengthening the Union's biotechnology and biomanufacturing sectors, particularly in the area of health (COM(2025) 1022 final). Brussels: European Commission. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2025:1022:FIN>

<sup>1</sup> Nguengang Wakap, S. et al. (2020) 'Estimating cumulative point prevalence of rare diseases: analysis of the Orphanet database', *European Journal of Human Genetics*, 28(2), pp. 165–173. <https://doi.org/10.1038/s41431-019-0508-0>



step for rare disease patients. The shortening of authorisation timelines and streamlining of procedures are welcome steps; however, they will require adequate resources for authorities to meet these standards without relaxing safeguards or bypassing key steps, including patients' involvement.

Through a dedicated investment pilot and associated initiatives, the Biotech Act I also takes concrete steps to mobilise public and private capital across the biotech lifecycle. It will be crucial that these measures that matter directly for the smaller companies, are also extended to academic institutions, and non-profit organisations on whom rare disease development often depends<sup>3</sup>.

There is also a real opportunity to go further. Formally empowering ERNs as platforms for cross-border clinical trial recruitment would transform an underutilised asset into an

active engine of rare disease research. EU-funded shared infrastructure for platform technologies – modular, reusable scientific tools that developers can access and adapt across rare disease applications – would also be transformative. COVID-19 demonstrated what becomes possible when foundational scientific platforms already exist. Building equivalent infrastructure for rare disease gene therapies, cell therapies, and RNA-based medicines would have lasting effects on Europe's capacity.

Underpinning all of this is a principle the Biotech Act must embed more firmly: patient involvement is not only a matter of governance. This is a scientific and regulatory necessity. In ATMP development in particular, where therapies are often first-in-class and patient populations extremely small, the ability to define meaningful outcomes and relevant endpoints depends critically on patient knowledge and experience. What constitutes meaningful benefit for patients living with degenerative conditions may

differ substantially from conventional clinical assumptions, and that difference matters for trial design, regulatory assessment, and for whether a therapy reaches the patients who need it. Embedding patients as genuine scientific partners – with the training, resources, and structural access to contribute at every stage of the development pathway – is therefore not a peripheral concern for the Biotech Act. It is central to whether the evidence it helps generate is fit for purpose.

The Draghi and Letta reports were unambiguous: Europe must invest in sectors where it has distinctive advantages and convert them into economic strength.

The Biotech Act I's measure of success will be whether it accelerates the development of therapies for patients most in need, including those in the most underserved areas, while building the industrial and scientific capacity Europe needs to compete. In rare disease biotechnology, those two objectives converge.

<sup>3</sup> Ibid.





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# Clinical Trials at the Heart of EU's Competitiveness: Delivering on the Promise of the EU Biotech Act

EU's life sciences sector is at a turning point. While the region continues to generate world-class science, it is increasingly struggling to translate that excellence into innovation, investment, and timely patient benefit. The challenge is not scientific capability, but whether the EU's systems can operate at the speed and scale required in a highly competitive global environment.

Clinical trials sit at the centre of this challenge. They are not only a key step in the development of new medicines, but also a decisive factor in where innovation happens. Over the past decade, the European Economic Area's share of global clinical trials has declined from 22% to 12%<sup>1</sup>, as activity has shifted to regions offering faster approvals,

greater predictability, and more scalable systems. In a global environment where trial placement is a competitive decision, speed matters: faster timelines enable earlier data generation, earlier investment decisions, and ultimately faster patient access.

For companies like Pfizer, having submitted nearly 230 clinical trials applications under the EU's Clinical Trials Regulation since 2022, the efficiency and predictability of the clinical trials framework directly influence where future research is conducted.

It is in this context that the EU Biotech Act comes at a moment of strategic urgency. It

reflects a growing recognition that restoring EU's competitiveness will require more than incremental improvements: it will require a system capable of acting at scale. The intention to create a more harmonised, streamlined and science-based clinical trials framework is therefore a welcome and necessary improvement.

Indeed, important challenges remain. Despite progress under the Clinical Trials Regulation, the system continues to be characterised by fragmentation, comparatively slower timelines, and operational inefficiencies. A single EU application still results

<sup>1</sup> The economic impact of industry clinical trials across Europe, EFPIA, available at: <https://www.efpia.eu/media/zdzo0bey/the-economic-impact-of-industry-clinical-trials-across-europe.pdf>



Many of Pfizer's phase 1 clinical trials take place at the Pfizer Clinical Research Unit (PCRU) in Brussels. Since it opened in 1992, the Brussels PCRU has enabled the development of many medicines, running more than 500 phase 1 clinical studies with the help of several thousand participants.

in multiple national decisions, and we often encounter misalignment between regulatory and ethical assessments, duplicative requests for information, and inconsistent interpretation across Member States. These structural issues continue to delay trial initiation and reduce EU's attractiveness as a location for clinical research.

Addressing these shortcomings is critical, as other regions continue to move faster and operate at greater scale. For example, in China, late development trial recruitment often runs 2-5 times faster than US and EU benchmarks, thanks to large and concentrated patient pools, well-resourced sites, and maturing clinical capabilities. In 2025, China launched a nationwide 30-day fast-track review process<sup>2</sup> for innovative drug clinical trials. Ultimately, without further efforts to reduce fragmentation and improve predictability, the EU risks missing out on the scientific, economic, and patient benefits that clinical research can deliver.

In this context, the EU Biotech Act is a strong step forward, not because it offers all the solutions, but because it signals what kind of clinical trials environment the EU wants to have: one which values safety, speed, efficiency and predictability.

The proposal introduces tangible measures for improving the clinical trials framework, including:

- **Shortening approval timelines for multinational trials from 106 to 75 days.** This is essential if the EU wants to regain attractiveness as a location for clinical research. Importantly, this is exactly what patients need and what Pfizer has been delivering. Pfizer has pioneered patient-centric trial designs, integrated real-world data, and embraced digital innovation to accelerate timelines without compromising safety. During the COVID-19 pandemic, we moved from concept to authorisation of an mRNA vaccine in record time.
- **Removing the additional 50-day assessment period for ATMPs.** This will accelerate access to potentially transformative therapies without compromising the rigour of the review.
- **Enabling faster processing of substantial modifications, including parallel handling.** Currently, the system prevents sponsors from submitting new changes

while a substantial modification is already under assessment, forcing sequential submissions. This improvement removes that constraint.

- **Coordinated assessment for combined studies.** The increasing need to develop in vitro diagnostic medical devices alongside new medicinal products is currently delaying trial initiation due to separate evaluations and timelines. Streamlining and combining these assessments would enable personalised treatments to reach patients more quickly.
- **Strengthened EMA support for multi-country trials.** By enabling more integrated EU-wide coordination, simplified procedures, and targeted scientific guidance, the EU Biotech Act will accelerate the setup and conduct of multi-country trials across Member States.

The commercial logic behind these reforms is already visible elsewhere. When Pfizer entered a licensing agreement with 3SBio, one of the key factors was that 3SBio had been able to advance multiple clinical trials efficiently and generate positive interim Phase II results — progress made possible by a regulatory environment that supported accelerated development. It was the quality and pace of the clinical programme, enabled by the jurisdiction, that made the asset an attractive partner. This is precisely the virtuous cycle that well-functioning clinical frameworks can create: faster development builds confidence, which draws in global partners and capital.<sup>3</sup>

The EU is not yet able to replicate that dynamic at scale. While improvements enhance coordination, the system remains structurally fragmented. Final approval decisions continue to be taken at national level, leaving scope for divergence and unpredictability. If the EU is to fully restore its competitiveness, a more ambitious step should be considered, moving toward a model where core scientific and ethical assessments are conducted once at EU level, ensuring greater consistency, speed, and scalability.

EFPIA's "One Vision"<sup>4</sup> provides a clear direction for such an evolution. A truly integrated system based on "one system, one governance" would combine a connected digital ecosystem with a more coordinated and strategically led regulatory framework. This would

enable seamless data flow, reduce duplication, and ensure more consistent decision-making across the EU while preserving Member States' roles where appropriate. Anchoring the Biotech Act in this vision would help ensure that EU builds not just a coordinated system, but a globally competitive one.

Finally, regulatory reform alone is not sufficient. Accelerating the path from research to authorization only delivers its full value if the medicines that result can reach patients — without being delayed by fragmented or under-resourced processes. This makes the access environment as strategically important as the clinical trials framework. As highlighted by EFPIA's Director General Nathalie Moll<sup>5</sup>, Europe's longstanding emphasis on cost containment has constrained its ability to attract investment and translate scientific excellence into patient benefit. Rebalancing how medicines are being valued — recognizing not just their price but their broader economic and societal contribution — is the necessary complement to everything the EU Biotech Act sets out to achieve on the clinical trials side.

The EU Biotech Act arrives at a defining moment. The EU still possesses the ingredients of a world-leading life sciences ecosystem — scientific depth, skilled talent, industrial infrastructure, and a large and diverse patient population. What it has lacked is a system capable of converting those assets into competitive speed and scale. The Biotech Act is a meaningful step toward that conversion.

But the step must not become the destination. The reforms outlined here — faster timelines, reduced fragmentation, better coordination — matter because of what they unlock: earlier patient access, stronger investment signals, and a more competitive position in the global race for clinical research. Sustaining that momentum will require the EU to go further: toward a genuine EU model of core scientific and ethical assessments, and toward an access environment that rewards innovation rather than simply containing its cost. The prize is an EU where clinical trials are not a last resort for sponsors, but a first choice — because the system is fast, predictable, and built for the science of today.

2 National Medicinal Products Administration, Policy Interpretation of the Announcement on Optimizing of the Review and Approval Process for Clinical Trials of Innovative Drugs, available at: [https://english.nmpa.gov.cn/2025-10/14/c\\_1138493.htm?utm](https://english.nmpa.gov.cn/2025-10/14/c_1138493.htm?utm)

3 Pfizer completes licensing Agreement with 3SBio, Pfizer, available at: <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-completes-licensing-agreement-3sbio>

4 EFPIA's ONE Vision: Unlocking Europe's Regulatory Innovation for Faster Patient Access, available at: [https://efpia.eu/media/riqlun1/efpia\\_one-vision.pdf](https://efpia.eu/media/riqlun1/efpia_one-vision.pdf)

5 Europe must rethink how it values medicines, says EFPIA chief, Euractiv, available at: <https://www.euractiv.com/interview/europe-must-rethink-how-it-values-medicines-says-efpia-chief/>



**PATRICK BARILLOT**

*Ceo Lovaltech*

# From Research Excellence to Industrial Scale-Up: enabling Europe's biotech competitiveness – the Lovaltech experience

Europe's ambition for health sovereignty will be judged on its ability to transform scientific excellence into industrial capacity that remains on European soil. As Lovaltech, our trajectory – from an academic discovery in Tours (France) to a first-in-human intranasal COVID19 vaccine trial and an emerging mucosal vaccine platform – illustrates both Europe's strengths and its structural bottlenecks.

We created Lovaltech in 2022 to take over an innovative intranasal protein vaccine developed by the BioMAP research team (INRAE / University of Tours), designed to induce both mucosal and systemic immunity and block SARS-CoV2 replication at the respiratory entry site. Our vaccine is built on a unique multivalent fusion protein associated with biocompatible muco-excipient, and in preclinical models it has shown the capacity to protect against disease and reduce transmission across variants, making it one of the few candidates in the world explicitly targeting sterilising immunity against current and future SARS-CoV2 strains.

Thanks to early public support (MESRI, ANRSMIE, Bpifrance DeepTech, and the 2022 iLab competition), we have financed GMP production of our vaccine antigen and mucosal excipient through European CDMOs, including GTP Bioways and Stanipharm, and we have launched the MUCOB00ST Phase I/II clinical trial in France. This first-in-human study, registered as NCT06821126, compares an intranasal booster dose of our LVT001 vaccine with a standard intramuscular mRNA COVID19 booster, and will enroll 36 participants in Phase I and 202 participants in Phase II. The trial is cosponsored by ANRSMIE and the Tours



University Hospital under the new European framework that allows shared sponsorship, which demonstrates how updated EU rules can directly support innovative clinical models.

Our journey captures Europe's core advantage: dense and excellent academic ecosystems, strong public research organizations and hospitals, and targeted innovation instruments that allow a deeptech startup to emerge rapidly around a breakthrough. It also exposes the "valley of scaleup" that the European Biotech Act must now address if Europe wants to translate such successes into enduring industrial leadership.

First, we experience every day how clinical and regulatory pathways for novel modalities remain complex and fragmented.

Our intranasal recombinant protein vaccine sits at the intersection of biologics, mucosal delivery and combination products (vaccine plus device). Navigating scientific advice, trial approval, and device-vaccine alignment across national authorities and the EMA is highly resource-intensive for a small company, even when we run a single-country trial. We believe that a more integrated European approach to innovative vaccines and mucosal products – with shared evaluation frameworks, predictable timelines, and early dialogue platforms – would reduce uncertainty, accelerate time-to-clinic, and make Europe a more attractive location for first-in-human trials.

Second, we feel directly the fragility of the financing continuum. We have been able to

fund early development through French and European public instruments and nondilutive grants, complemented by seed equity. The next step – progressing LVT001 through full Phase II, preparing pivotal development, and advancing pipeline assets such as a universal intranasal flu vaccine and a nasal malaria candidate – requires a level of capital and risk appetite that Europe is only starting to build. Without stronger latestage European biotech funds and catalytic publicprivate vehicles aligned with the Biotech Act, companies like Lovaltech will inevitably be pushed to seek strategic capital and listing venues outside the EU, with the wellknown consequences for ownership, decisionmaking and manufacturing location.

Third, we are convinced that health sovereignty must be understood in terms of platforms, not only products. Our proprietary platform combines recombinant “smart antigens” engineered for breadth of protection, a mucosal excipient system designed for stability and delivery, and scalable bioprocesses that are compatible with European GMP facilities. This combination is applicable

to multiple respiratory pathogens beyond COVID19: influenza, RSV, and other viruses where blocking transmission at the mucosal surface can prevent both disease and the emergence of new variants. By nurturing such crosspathogen platforms and linking them to European epidemiological and pandemicpreparedness strategies, the Biotech Act can turn individual startups like ours into strategic assets for longterm health security.

Finally, our story shows the power of European collaboration when it works well. A publicprivate network spanning INRAE, the University of Tours, CHU de Tours, ANRSMIE, industrial partners such as GTP Bioways, Stanipharm and Aptar Pharma, and national and European funding bodies has brought an academic mucosal vaccine from the laboratory to clinical trial in just a few years. We would welcome a European Biotech Act that systematises these success factors: incentives for cosponsorship models, simplified access to transnational clinical networks, and mechanisms to prioritise projects that both address unmet medical needs and reinforce European manufacturing capacity.

If Europe wants to lead in nextgeneration vaccines and mucosal immunology – key pillars of future pandemic preparedness and respiratoryvirus control – it must ensure that companies like Lovaltech can not only emerge, but scale and stay in Europe. That means aligning regulatory innovation with industrial policy, coupling research funding with manufacturing incentives, and mobilising growth capital to keep strategic IP, skills and production within the Union.

Our contribution to Europe's quest for health sovereignty is specific: a new generation of intranasal protein vaccines capable of inducing robust mucosal and systemic immunity, produced and developed in Europe, with the potential to reduce transmission and protect against current and future variants. The European Biotech Act can turn this type of pioneering project from an exception into a model – ensuring that European research excellence systematically leads to European industrial champions





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# Bridging the gap between advanced therapy development and patient access in Europe: regulatory, clinical and translational challenges

Europe's ambition to secure health sovereignty through global leadership in advanced therapies is now a central policy priority—both timely and achievable, and of clear strategic importance.

At the level of basic science and early clinical research, Europe is formidable. Its universities, hospitals, and research centres consistently generate high-quality data and pioneering therapeutic concepts. Many of today's transformative ATMPs originate from publicly funded European science. Yet European patients frequently access these therapies later than their counterparts in the United States. Some therapies do not reach Europe at all. This translational gap is not a single "valley of death," but a series of misalignments along the translational pathway that slows, distorts, and ultimately limit access. Unless Europe addresses the structural disconnect between discovery, development, regulation, and access, its ambitions (both economic and societal) will remain out of reach. Here are three of the most critical disconnections.

Beginning at the point of origin, there is a fundamental misalignment of incentives between early-stage developers—often academic or publicly funded—and downstream commercial actors. Academic innovators are rewarded for scientific novelty and early proof-of-concept, not for scalable development, regulatory optimisation, or evidence generation aligned with payer needs. On the other hand, industry has the knowhow to navigate the regulatory system and take the products to market. The necessary 'handover' after early development works well for chemical and biological medicines, but is not delivering for ATMPs. Their complexity and high uncertainty result in a discontinuity in development strategies, where promising therapies stall or are too expensive to be reshaped late in the process. This is especially evident in the case of some orphan therapies, where commercial returns are often limited or uncertain.

Second, fragmentation across the European system continues to undermine efficiency. Clinical trial approvals, manufacturing oversight (including Hospital Exemption), regulatory responsibilities and reimbursement decisions remain distributed across national and EU levels in ways that are not always coherent. Recent efforts to strengthen coordination and centralization in clinical trials and HTA are important and appreciated steps. However, their impact is gradual and, to date, relatively limited, while other regions continue to advance at a faster pace. Looking at the whole picture along the medicines life-cycle, variability in risk tolerance, administrative capacity, and clinical infrastructure further compound the disconnection.

Finally, European health systems cannot sustain the high prices required to generate adequate returns for industry without jeopardising their long-term financial stability. This tension sits at odds with one of Europe's defining principles: equitable and universal access to care, and results in development priorities being too often shaped by expected financial returns rather than unmet clinical need. Compounding this, much of the foundational science behind ATMPs is publicly funded, creating a legitimate concern that society pays twice: first for the research, and again for the final product at premium prices.

The proposed changes in EU legislation and the Biotech Act acknowledge many of these challenges and signals a shift towards a more strategic, innovation-friendly framework. Its emphasis on expedited pathways, regulatory flexibility, and strengthened coordination is directionally correct, and very welcomed. However, the real question is not whether the legislation is wellintentioned, but whether it is sufficiently ambitious in practice. Incremental adjustments are unlikely to close the gap, and the pace of implementation risks lagging far behind the speed at which the science—and global competitors—are moving.

The benefits that innovative therapies bring to European patients and to the economy are not in question. But legislation can do only so much, what is required is a more radical integration.

Take affordability as a case in point. While outcome-based payment models and risk-sharing agreements offer partial remedies, they do not address the underlying challenge: the distribution of value and risk across the system. Correcting this imbalance will require more assertive policy action, including fairer value-sharing mechanisms and a more strategic use of Europe's collective purchasing power to support sustainable and equitable access. Greater transparency around R&D contributions, alongside the exploration of public or not-for-profit manufacturing models, could further strengthen this approach.

A less discussed issue is the allocation of regulatory resources. The current model relies heavily on national competent authorities contributing to centralised EMA procedures, often without clear alignment of incentives or accountability. This can lead to inefficiencies and variable quality in assessments. For highly specialised products such as ATMPs, a more centralised model—prioritising scientific expertise over national representation—would improve consistency and speed.

Europe does not lack the expertise, ingenuity, or ambition to lead in advanced therapies, but it needs the coherence to deploy them effectively. The Biotech Act offers an opportunity to move beyond incremental reform towards a genuinely integrated system. This will require difficult choices: greater centralisation where it adds value, alignment of incentives from early stages, and a willingness to experiment with new regulatory and economic models. ATMPs, as the frontier of biomedical innovation, are the ideal testbed for a more flexible, responsive, and integrated regulatory ecosystem. We are choosing between relevance and decline.

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# Europe's preparedness will only be as strong as its vaccine and biotech base

Europe cannot afford to rediscover preparedness only when the next crisis arrives. COVID-19 exposed deep vulnerabilities in health security, manufacturing capacity and supply chains, but the lesson goes far beyond a single pandemic. We now live in a world of overlapping crises: geopolitical conflict, climate pressure, and resource scarcity are contributing to medicine shortages, antimicrobial resistance, and a growing risk of emerging infectious diseases. The old distinction between “here” and “elsewhere,” or between “temperate” and “tropical” diseases, is fading. As global mobility persists, outbreaks spread faster, supply chains fracture more easily, and resilience has become a defining test of European sovereignty.

Europe starts from a position of strength. It has a world-class scientific base, excellent universities, leading research institutes, and strong support mechanisms for early-stage innovation, from Horizon Europe to the European Research Council. It also has a proud heritage in vaccinology and has long been a global centre of vaccine research, development and manufacturing. Yet scientific excellence alone is not enough. Europe's enduring weakness lies in translation: too often, promising research fails to become scaled industrial capacity, advanced clinical development, or readily deployable medical countermeasures.

This gap is particularly visible in vaccines. Vaccine R&D faces a steep “valley of death”: proof of concept arrives late, manufacturing is complex, investment cycles are long, and commercial incentives are uncertain—especially for pathogens without established markets. At the same time, Europe struggles with fragmented capital markets, a limited pool of specialist growth finance, and administrative hurdles that slow clinical trials and scale-up. If Europe is serious about preparedness, it must better support the transition from laboratory promise to manufacturing reality.

The creation of HERA in 2021 was an important political signal. It recognised that preparedness cannot be a one-off reaction but must become a permanent European function. Yet HERA's mission now needs to be matched by sustained funding, stronger coordination powers and a clearer long-term industrial interface.

There has been meaningful progress. Under the Preparedness Union agenda, the Commission has advanced strategies on stockpiling and medical countermeasures, alongside instruments such as HERA Invest and EU FAB's “ever-warm” manufacturing capacity. The Global Health Resilience Initiative further underscores priorities such as resilient supply chains, local manufacturing and vaccination. These initiatives point in the right direction—but they must be fully resourced, better integrated, and anchored in long-term industrial realities.

This is why the Biotech Act matters so much. It is a once-in-a-generation opportunity to move from strategy to true industrial policy. To succeed, it must align the entire innovation chain—from research and clinical development to manufacturing, procurement and deployment. It should also address a structural mismatch in EU funding frameworks: innovative biotech companies often fall between categories, too large to qualify for SME support but too small to compete globally with established pharmaceutical players.

The Biotech Act must also deliver regulatory agility. During COVID-19, Europe demonstrated that faster, science-based pathways are possible. The priority now is to embed this flexibility in both crisis and non-crisis settings: accelerating clinical trial initiation, improving predictability, and reducing administrative burden without lowering standards. Speed is not only a crisis imperative—it is a competitiveness factor.

That competitiveness dimension is increasingly urgent. Global competition in biotech and vaccines is intensifying,

with strong public backing in the United States, China and India. Europe risks losing investment, talent and manufacturing capacity unless it responds decisively. The proposed Competitiveness Fund and initiatives such as BioTechEU are important signals, but their success will depend on delivering fresh capital, rapid deployment and user-friendly access. Critically, they must recognise the specific characteristics of vaccine innovation and enable blended financing models that support both SMEs and mid-sized innovators.

Vaccines are not simply another therapeutic category. They sit at the intersection of public health, industrial policy, resilience and global security. Their development and production require complex supply chains, long lead times and tailored procurement approaches. Their true value lies not only in responding to crises, but in preventing them. Europe should reflect this reality more explicitly in its policy choices.

Preparedness, however, cannot stop at Europe's borders. Infectious diseases spread across continents, accelerated by travel and environmental change. Europe therefore has both an interest and a responsibility to remain a reliable global partner—through cooperation with organisations such as CEPI and Gavi and through support for regional manufacturing. Strategic autonomy and global solidarity are not in tension; in health security, they reinforce one another.

The conclusion is clear: there is no European preparedness without European industry. A resilient Europe requires a strong, innovative and globally competitive vaccine and biotech base. Preparedness is not just a health policy issue—it is an industrial, economic and geopolitical priority. The task now is to translate the lessons of past crises into sustained investment, effective policy frameworks and close collaboration between public institutions and the biotech sector.

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# EU pharmaceutical policy at a crossroads: A call to EU Institutions and Member States to concretely act now

The role of the European Union (EU) in defining healthcare policy has become more prominent after the outbreak of the COVID-19 pandemic. Since 2020, both EU Institutions and Member States have recognised the importance of a stronger coordination at EU level. This has led to a significant number of new EU healthcare legislative initiatives, at a scale not seen in the previous two decades. While sending signals on the EU's prioritisation of healthcare, the outcome of such proposals has not always been as positive for the innovative pharmaceutical sector.

On the one hand, many legislations did not provide for a holistic approach that would interlink healthcare and industrial approaches, as well as other policy areas (such as environment or digitisation). This is the case of proposals solely focused on public health and affordability, without taking into account elements to boost EU competitiveness and innovation. On the other hand, innovative companies have been facing fundamental changes that require time before actual implementation of, and adjustment to, the new realities. This has proven especially burdensome to small- and mid-sized innovative biopharmaceutical companies, that EUCOPE represents, and even more for those investing in high-risk R&D areas, such as rare diseases.

Currently, innovative companies are adapting to, or preparing for the application of, several new legislations and requirements. This includes, among others, the revised General Pharmaceutical Legislation (GPL), the Critical Medicines Act (CMA), the European Health Data Space (EHDS), the EU HTA Regulation with the Joint Clinical Assessment (JCA) framework. Moreover, other proposals are currently being discussed, such as the revision

of the Medical Devices Regulation (MDR) and In-vitro Diagnostics Regulation (IVDR), as well as the proposed European Biotech Act. Some of these legislations will have a potentially positive impact on the innovative pharmaceutical sector, while others will increase administrative requirements and compliance costs, in addition to other cross-sectoral legislations, such as the Urban Wastewater Treatment Directive (UWWTD).

A landmark legislation is the revised GPL. Some provisions, such as accelerated approval timelines or the introduction of platform technology master files and regulatory sandboxes, will improve the regulatory framework. However, these developments will not offset harmful provisions that the GPL will introduce. In particular, innovative companies will have to face a weaker and less predictable incentive framework, alongside increased obligations (e.g., access requirements, reporting related to shortages and supply, or environment risk assessment) that do not consider the specificities of different kinds of companies and products, but rather follow a blanket approach. Extremely concerning is the new access provision, that could lead to an unrealistic request to launch in a short timeframe in all EU 27 Member States, putting all the burdens in the hands of innovative companies and not recognising the role of other stakeholders, nor the competences of Member States in making decisions on pricing and reimbursement (P&R). This will create significant needpressure and uncertainty especially on smaller developers, who have limited resources and knowledge of the EU market.

The revised GPL is a clear example that legislative proposals without a holistic vision, spanning from health to industrial policy and

access, make the EU pharmaceutical sector less competitive and attractive. Unfortunately, the CMA has also followed a similar process: by trying to tackle two completely distinct issues, such as shortages of critical medicines and access to innovative medicines, it risks compromising any successful outcome for both objectives. Measures related to critical medicines are positive, with the strategic projects aiming to promote manufacturing in the EU through administrative and financial support, as well as the introduction of more resilient criteria (beyond the lowest price) in public procurement. On the contrary, the introduction of collaborative procurement mechanisms, with a specific focus on orphan medicinal products (OMPs), creates unnecessary operational burdens and uncertainty. Access pathways for OMPs are complex: a blanket approach, which prioritises giving Member States more bargaining powers and lowering prices, is unlikely to deliver meaningful benefits and will only introduce additional risks. This is even more concerning in the context of ongoing geopolitical shifts, such as the US Most Favoured Nation (MFN) pricing policy, and their potential spillover effects on global reference pricing dynamics.

The EU should leverage more appropriate legislative tools to improve the R&D and access framework – rather than introducing additional hurdles, especially when significant changes are already underway. For instance, the application of the timelines under the Transparency Directive, or the proper implementation of the Cross-border Healthcare Directive and S2 Regulation, would bring far-reaching results, especially for therapies – such as OMPs and ATMPs – where patients populations might be dispersed or excellency

infrastructures limited to only a handful Member States. Importantly, any access proposal should recognise the role of Member States, which are the final decision-makers on access to medicines. Their decisions are based on national health priorities and budgets, as well as infrastructure and expertise on some diseases (especially rare ones).

The Biotech Act has the potential to strengthen the healthcare research ecosystem as a whole when seen with a long-term horizon. The proposals follow a holistic and lifecycle approach, from early-stage research to manufacturing, intertwining health, industrial and financial considerations. Strategic projects can support various stages of R&D and manufacturing, and foster (cross-border) public-private partnerships. The review and simplification of the clinical trials framework is a welcome step to attract more clinical trials in the EU – which sometimes is the only way to guarantee access to a therapy, in areas such as rare diseases where no other treatment options are available. The proposal for an SPC extension, although strict in scope, recognises the need to support innovation with IP incentives. Nevertheless, the Biotech Act falls short of addressing the most critical underlying challenges, such as existing structural barriers, and ongoing geopolitical tensions positioning the EU behind the US and China.

Despite positive developments such as the Biotech Act, the innovative pharmaceutical sector faces several challenges: those related to the aforementioned EU legislations, as well as generally burdensome, lengthy (EU and national) processes; reduction in Member States' healthcare budgets and more restrictive access frameworks; external geopolitical challenges, such as MFN and tariffs,

alongside increased competition from other world regions.

Thus, the EU finds itself at a crossroads regarding the present and future EU pharmaceutical policy: acting now, to build a more resilient, competitive and attractive ecosystem for innovation, or continue seeing an increased gap towards other regions. EUCOPE urges EU Institutions and Member States to take bold actions, building on the positive elements and strengths we have, and addressing existing barriers. A long term and forward-looking vision is pivotal to build such a predictable and innovation-friendly ecosystem. It requires coordination across various policy areas and ministries: healthcare, industry, research, finance, environment, digitalisation. Policy actions must target the full spectrum: from early research to development, from regulatory pathways to diagnosis and market access – the latter being crucial to attract companies' investments in the EU. Particular attention should be given to small and mid-sized companies, often at the forefront of innovation but facing major hurdles, as well as most complex therapeutic areas, such as OMPs, ATMPs and antimicrobials.

The European Commission can play a key role in triggering such ecosystem. For instance, it could support convening a permanent dialogue between various Ministers (e.g., Health, Industry, Finance), Prime Ministers and CEOs, about the needs of the innovative pharmaceutical sector. Moreover, the Commission should explore the use of the European Semester and Economic Governance Framework to support Member States to spend appropriately on healthcare investment; for instance, the Commission could issue annual country-specific recommendations for healthcare systems, which include but are not limited to public investment in, and expenditure on, biotech innovation and rare diseases. Finally, the EU should adopt a switch in its mindset, by not viewing healthcare expenditure merely as a budgetary cost, but as a strategic investment in the EU's future competitiveness and resilience.

A combination of these EU and national actions can help fill existing gaps and make the EU again more attractive and supportive of an innovative biopharmaceutical sector.





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# How the Biotech Act should reinforce the public trust in Europe's health systems

**T**oday, European patients wait on average more than 578 days to access new medicines after approval from the European Medicines Agency with a significant variation between the EU member states. At the same time, less than half of innovative medicines approved between 2020 and 2023 were available for patients in 2024. Most recently, drug launches in EU countries fell by 35% in the 10 months since Trump's Most Favoured Nation policy came into effect.

In other words, the EU stands at a crossroads where we risk eroding trust in our healthcare systems if we fail to act. This is not only about strengthening our economy – it is equally about strengthening citizens' confidence that Europe can continue to deliver access to high-quality and innovative healthcare when it matters most – to save and to improve lives.

In Europe, we have a long-standing tradition of world-leading research and innovative health care systems. In addition to supporting a high quality of life in Europe, this has given us a unique competitive edge in biotechnology and medical innovation. However, we are still behind when it comes to letting our patients get access to this innovation. With the US and China increasingly hostile trade policy and massive investments in life sciences, we can no longer take our competitive edge for granted. Without stronger investment in biotechnology and faster access to innovation, Europe risks falling behind in the global race for next-generation therapies. This is a question of security, autonomy and the credibility of our promise to deliver equitable access to health care for our citizens.

This is why the Biotech Act must not become a half-hearted attempt to support the European pharmaceutical industry. It must become a fully-fledged strategic response to a new geopolitical reality. Europe cannot afford another piece of legislation that recognises the

problem without fixing it. This is why one of my key priorities for the Biotech Act is to deliver a faster, predictable and coherent European pathway from discovery to patient access. In my view, the smartest way to achieve this is by creating a more joined-up European approach to working with for example clinical trials. We need more, and not less Europe, to deliver on this.

In response to fierce global competition and harmful policies such as Most Favoured Nation, a more centralised decision-making process is long overdue. Right now, our companies still have to navigate through 27 different systems across Europe – consequently slowing down ethics approvals, clinical trials, delaying patient access, and pushing investment towards regions that can offer a clearer and faster route from discovery to market. To me the response to this is clear: we need a 28th regime for biotechnology and a real single market for clinical trials. This is the level of ambition that we need in order to remove barriers and give companies the predictability they need to make long-term decisions to continue to invest in Europe.

Europe's share of global clinical trials has halved over the last decade. This amounts to approximately 60,000 fewer clinical trial opportunities for European patients between 2013 and 2023. For many European patients, clinical trials are not an alternative – they are their only option to get access to life-saving medicines, especially when it comes to rare diseases, cancers and paediatric diseases. We cannot allow them to be left behind. This is just another reason why a more centralised and more coordinated European approach to approving and running multi-country clinical trials must be the answer. Our patients count on Europe finally moving beyond fragmentation and building a system that delivers

faster access and clearer rules. A system that would save lives.

At the same time, access to innovation must not depend on where a patient was born or where they live. Yet today, geography still determines treatment opportunities across Europe. Now, we have an opportunity to both build equitable access to medicine and to solve the patient volume and data volume problem that holds back our research and development of next-generation treatments like cell and gene therapies – the personalised medicines of the future. By establishing and funding European strategic projects and centres of excellence for advanced therapies (ATMPs), the Biotech Act must therefore build infrastructure that will benefit every European in every EU country by supporting multi-country clinical trials and cross-border pathways for both diagnosis and clinical care. Because a Europe where innovation and access to life-saving care is unevenly distributed is a Europe where citizen trust will inevitably erode. With the Biotech Act, delivering for every European is our democratic and moral imperative.

Ultimately, the Biotech Act is a test of whether Europe can deliver on its promises to our citizens. If we want to rebuild trust in our health care systems, we must show that we are able to act with urgency, coherence and ambition. The choices we make now will not only shape our future competitiveness, but the lives and livelihoods of millions of people across Europe. I will fight for a high level of ambition when I negotiate this seminal legislation, and I hope my fellow legislators will join me in sharing this responsibility.

# The European Biotech Act

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#EU4Health #HealthUnion

## KEY FIGURES

- ▶ The EU biotechnology industry has grown more than **twice as fast** as the overall EU economy.
- ▶ **75% of biotechnology jobs** in the EU are in health biotech, totaling 685 000 jobs.
- ▶ **21% of the world's top biotech publications** are authored by EU scientists.
- ▶ **40% of all medicines** sold in the EU are bio-medicines (including biosimilars).

## WHY A BIOTECH ACT ?

- **EU Competitiveness** - Enhancing the EU's ability to compete globally and as a leader in biotech.
- **Availability of treatments** - Accelerating the development and delivery of groundbreaking treatments.
- **Job Creation** - Creating thousands of quality jobs and boosting European economies.
- **Innovation and Investment** - Enabling innovative companies to thrive and drive healthcare and tech breakthroughs.
- **Biosecurity** - Ensuring clear rules preventing the misuse of biotechnologies.



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