EUROPEAN POLICY CENTRE

MSD

EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

EUROPEAN ALLIANCE FOR PERSONALIZED MEDICINE

DISCUSSION PAPER

SOCIAL EUROPE AND WELL-BEING PROGRAMME

25 NOVEMBER 2025

Europe's competitiveness challenge: Ensuring patient access to transformative therapies in Europe

Elizabeth Kuiper

Credit: CANVA

Table of contents

ABOUT THE AUTHOR

Elizabeth Kuiper is an Associate Director and Head of the Social Europe and Well-being programme at the European Policy Centre.

ACKNOWLEDGEMENTS / DISCLAIMER

This Discussion Paper is part of the European Policy Centre (EPC)'s project on disruptive technologies and is the outcome of a dedicated roundtable held in Spring 2025 and a session on "Equitable access to disruptive technologies in Europe. Resolving the access-innovation-affordability conundrum", organised during the European Health Forum Gastein on 2 October 2025.

This project is financially supported by MSD, the European Federation of Pharmaceutical Entrepreneurs (EUCOPE) and the European Alliance for Personalised Medicines (EAPM). The author would like to thank project partners Denis Horgan (EAPM), Matias Olsen (EUCOPE) and Alexander Roediger (MSD) for their constructive feedback throughout the project.

The author is very grateful for the insights of Elisabetta Zanon (Chief Executive Officer, European Cancer Organisation) and Paweł Świeboda (EPC Senior Visiting Fellow and Co-Director of the Brussels Economic Security Forum) and for their valuable contributions to this paper.

Executive summary and recommendations

The EU recognizes health as fundamental to its economic security and competitiveness, with initiatives like the Competitive Compass, Life Science Strategy and upcoming Biotech Act designed to strengthen these objectives. However, transformative innovations such as gene therapies and genomic testing remain unevenly accessible across the EU, challenging the Union's commitment to solidarity.

Europe's competitiveness challenge extends beyond attracting investment to ensuring equitable and timely patient access to innovations. The shift of research and design (R&D) and manufacturing to other parts of the world risks leaving European patients last in line to benefit from transformative therapies.

Demographic change and an ever-aging workforce add additional challenges not only to competitiveness but also underpinning the need for healthy aging to ensure long-term fiscal and social security. Investments in healthy populations can generate healthcare system savings through reduced treatment complexity, shorter hospital stays and lower staffing needs.

Realising this potential requires a fundamental shift in political and policymaking mindsets and structural healthcare system reforms. A vision for a resilient, competitive and innovative European pharmaceutical sector remains incomplete when transformative technologies fail to reach national markets and patients across EU member states.

This discussion paper outlines **10 key policy recommendations** as to how to make this vision a reality:

Recommendation 1: Harness the competitive strengths of the EU in health via the MFF and the European Competitiveness Fund

Ongoing negotiations on the next Multiannual Financial Framework (MFF) and the European Competitiveness Fund offer an opportunity not only to promote innovation in health technologies but also to facilitate the uptake of innovative technologies across EU member states. In the proposed National and Regional Partnership Plans (NRPPs), access to innovative treatments should be prioritised as part of the Commission's ambition to become the most attractive place for life sciences by 2030.

Recommendation 2: Strengthen Single Market coordination in health

The Single Market for pharmaceuticals is highly complex, as most activity in the pharmaceutical sector is defined at the national level. The link between EU spending and national-level reform should be reinforced via EU instruments such as the European Semester; the role of the EU in facilitating equal and timely access should be discussed and enforced in this context and spill-over effects from EU funding instruments should be considered.

Recommendation 3: Address the nexus between industrial and pharmaceutical policies

In a world dominated by increased competition from the US, the UK and China, a higher degree of coordination by the EU is needed to close the innovation gap with other regions and ensure a level playing field among EU countries to attract biopharmaceutical investment. Industrial policies need to go hand in hand with pharmaceutical policies, to ensure real-world application and an end-to-end pathway from research and innovation to timely patient access.

Recommendation 4: Unlock the potential of health data and emerging technologies like AI

More clarity, substantial resources and practical preparations are needed to ensure a strong legal basis and a coherent interpretation of the European Health Data Space (EHDS). In addition, the interplay between the EHDS, the General Data Protection Regulation (GDPR) and the AI Act is crucial to enabling the use of health data for research. With artificial intelligence (AI) driving research and reshaping clinical trial design for new and transformative technologies, data collection and utilisation is essential to advance science, incentivise R&D in disruptive technologies and improve patient outcomes.

Recommendation 5: Establish a European Life Science Council to promote 360° multistakeholder engagement

European coordination and diverse and comprehensive representation of the entire life science ecosystem is a precondition to translating the ambition for a more innovative and competitive European biopharmaceutical sector into concrete action. This will ultimately enhance patient access and the affordability of new therapies at an early stage.

A European Life Science Council should therefore be established. It should represent the entire life science ecosystem, including authorities, industry, various patient associations, foundations, clinicians and universities.

Recommendation 6: Increase the share of Clinical Trials in Europe, particularly for transformative treatments

More uniform and harmonised regulatory frameworks have the potential to make the EU a more attractive place for investment in clinical trials. With rising competition coming from Asia – particularly China – and the US, the EU must act quickly. Reconsidering and strengthening investment in clinical research, along with streamlining the regulatory framework, is vital for advancing innovative clinical trials across Europe. This can be achieved through announced flagship initiatives in the EU Life Sciences Strategy and through the upcoming Biotech Act, which aims to make the EU regulatory system more conducive to innovation, including by facilitating the conduct of multi-country clinical trials to boost EU competitiveness.

Recommendation 7: Recognize the potential of the health technology assessment (HTA) regulation and the role of Real-World Evidence (RWE)

For new technologies launched with limited evidence, RWE will be crucial to assess the value of new products in a timely manner. The challenge lies in current uncertainty surrounding the acceptance and utilisation of RWE, as well as the implementation of the joint clinical assessment framework and real-world data within it. To address this gap, alternative pathways akin to regulatory sandboxes are needed. These frameworks facilitate access to innovation while data is still being generated, ensuring a balance between timely patient access and evidence-based decision-making.

Recommendation 8: Draw on the strength of national best practices with the upcoming Biotech Act

Pricing and reimbursement systems in EU member states play a crucial role in signaling willingness to invest in innovation. Currently, there is a disconnect between the EU's aspiration to attract the life sciences sector and the adoption of new technologies at the national level. To bridge this gap, the upcoming EU Biotech Act should draw on national best practices and innovative funding mechanisms to help the EU overcome the current fragmentation in reimbursement policies.

Recommendation 9: Invest in talent attraction and a skilled health workforce

In addition to educational mechanisms and training, talent attraction is key in the current geopolitical context to create a vibrant health ecosystem. Investment in a skilled workforce is a prerequisite to robust healthcare systems and ensure healthcare professionals are ready to embrace new technologies. As Europe's working-age population is shrinking, sustaining economic growth requires drawing more people into the labour market and increasing productivity through healthy aging, technological advances and skills development.

Recommendation 10: Strengthen the EU's policy framework for health innovation

The EU's policy framework for health is not designed for innovation and offers a patchwork of multiple policies and instruments with sometimes contradictory objectives. There is an urgent need for more coordinated regulatory and policy frameworks; without aligned policy frameworks, innovative technologies risk becoming a privilege rather than a standard of care for EU citizens. An overarching health innovation strategy is needed, spanning all elements from EU-level incentives for innovation to clinical trials, the role of health data and emerging technologies, and access to treatments at the national level.

Introduction

In a world defined by external shocks and trade disruptions – leading the US and China to rebalance their economies[1] and the "smartest minds in the US beckoned to other regions"[2] – the biopharmaceutical sector is one of the key drivers of innovation and economic growth within the EU. As stated by the EU's Competitiveness Compass,[3] the sector contributes to enhanced economic security and economic growth, but it also offers great potential for healthcare systems and societies writ large. Key demographic indicators such as an ageing workforce and general population contribute to the importance of the sector, driving sustainable growth and prosperity.

It is precisely for this reason that innovation and health play an important role in Europe's future. For the same reason, the life sciences sector is experiencing renewed momentum, confirmed by the recent launch of the European Commission's "Choose Europe for life sciences" strategy.[4] If anyone was in doubt about the need to accelerate innovation within the EU, the strategy's subtitle makes the ambition explicit: "to position the EU as the world's most attractive place for life sciences by 2030".

The Covid-19 pandemic showed the immense potential of innovative health technologies that build on our growing understanding of molecular biology, with the clinical application of Messenger RNA (mRNA).[5] After decades of research, Katalin Karikó vividly explains in her book *Breaking Through: My Life in Science* how the breakthrough discovery of mRNA transformed our ability to prevent disease and saved millions of lives during the pandemic.[6]

Moreover, recent years have seen the discovery of disruptive technologies:[7] these include mRNA-based technologies – such as Individualised Neoantigen Therapy (INT) and Radioligand Therapies (RLT) – as well as genome-based technologies[8] – such as CAR-T therapies or other Advanced Therapy Medicinal Products (ATMPs) – and molecular-based advanced diagnostics such as Comprehensive Genomic Profiling and liquid biopsy.

BOX 1: The **Italian Innovation Fund**, with a total budget of €1 billion, acts as an interim solution until regional funding commences and addresses the disparities in access times between regions. This initiative aims to enhance decision-making, shorten negotiation periods, and ensure quicker availability of innovative therapies.

These new, increasingly personalised technologies offer great opportunities for patients with the potential to change the course of cancer. The first therapeutic cancer vaccines are forging ahead[9] and more significant developments are expected in the years to come, possibly facilitated by AI-enabled drug discovery.

The 100,000 Genomes Project,[10] a UK initiative to sequence and study the role genes play in health and disease, offers interesting lessons about implementation of genome-based technologies. These range from gaps in understanding research, a limited specialised workforce, a lack of training in interpreting and handling genomic data, and clinician unwillingness to order genetic tests.[11] This illustrates how rolling out new and transformative technologies requires not only various educational mechanisms and trainings for healthcare professionals; provisions need to be in place to ensure healthcare systems are ready to deal with disruptive technologies.

For the EU, there is a lot at stake when it comes to the introduction of new technologies in today's geopolitical and demographic context. The pharmaceutical industry is uniquely global, but currently there is a high degree of uncertainty because of geopolitical shifts. As Enrico Letta and Mario Draghi pointed out in their landmark reports,[12] the EU needs to become more globally competitive, secure and resilient by excelling in research, improving access to funding and investing in disruptive health technologies.

BOX 2: The **UK's Cancer Drug Fund (CDF)**, with an annual budget of £340 million, is a mechanism for funding cancer medicines in England before the National Institute for Health and Care Excellence (NICE) approves treatments for use in the NHS. It allows for patient access while further evidence is developed for two years before the HTA assessment and funding decision. In addition, the UK also has the **Innovative Medicines Fund**, which supports faster access to non-cancer drugs and, alongside the CDF, provides a total of £680 million in ringfenced NHS funding for innovative medicines. Moreover, the **Cancer Vaccines Launch Pad (CVLP)** is a way to accelerate access to clinical trials for disruptive technologies such as personalised cancer vaccines.

Europe's economic strength and ability to attract innovation is in question. Although the EU still excels in research, a confluence of factors leads to innovation happening elsewhere in the world instead of in Europe: these include regulatory complexities, funding shortfalls, risk-adverse attitudes and insufficient partnerships between academia and the private sector.

The current geopolitical situation should act as a wake-up call for the EU to reverse this pattern. The issue is not just about attracting investment; it is about ensuring equitable and timely access. If R&D and manufacturing relocate to the US or China, there is a real risk that European patients will be at the end of the line for innovative treatments. This is the real test for the EU's competitiveness.

If R&D and manufacturing relocate to the US or China, there is a real risk that European patients will be at the end of the line for innovative treatments.

The most obvious way to reverse this pattern is to focus on economic and technological advantages and create a better ecosystem for health innovation in the EU. This in turn will not only result in improved wellbeing of citizens – key in a time of demographic change – but equally in a healthier and more productive population, and thus a more competitive Europe. Carrying on as usual is not an option; the costs of inaction – both economically and socially – are high and should be mitigated by investing more strategically in health.[13]

2. The opportunity: a thriving European life sciences ecosystem by 2030

To establish a flourishing European life sciences ecosystem by 2030, Europe must build upon its current strengths and tools. Leveraging disruptive technologies such as AI, alongside the effective implementation of regulations like the Clinical Trials Regulation (CTR) and HTA Regulation, will be pivotal in achieving this goal.

2.1. THE DISRUPTIVE POTENTIAL OF AI AND HEALTH DATA

In the post-pandemic era, the potential of data is disrupting, if not transforming, the healthcare sector. For good reason, Mario Draghi highlighted the importance of prioritising AI vertical applications for the EU, emphasising the region's competitive edge over global counterparts.

In the global race for AI leadership and amid intensifying competition between regions, the policy challenge for the EU and its member states is to balance efficiency and privacy when leveraging emerging technologies for scientific progress and personalised healthcare.[14] Moreover, the importance of patient-experienced data cannot be underestimated and must be better integrated into research and clinical practice.[15]

From AI driving research to reshaping the design of clinical trials for new and transformative technologies, data collection and utilisation are crucial to advance science, incentivise R&D into disruptive technologies and improve patient outcomes.

BOX 3: Belgium's Pact for the Future (2016), a multi-year budgetary framework, consisted of four central pillars: accelerating patient access to innovative medicines, facilitating predictability in the funding of a sustainable healthcare system, strengthening Belgium's R&D leadership and forging more transparent interactions between industry and stakeholders.

The implementation of the European Health Data Space (EHDS)[16] – the first common EU data space – will be transformative for cross-border data collection and data sharing in the EU. Crucially, the EHDS provides the infrastructure to facilitate the sharing of anonymised or pseudonymised health data for research purposes, including genomic data. The EHDS will unlock access to an unprecedented amount of data for researchers and companies and will support not only development of new innovative therapies, but also patient access to innovation by potentially closing remaining data gaps. This increases the possibility for post-launch evidence generation.

Key parts of the EHDS will enter into application in 2029. As the recommendations of the EHDS Pilot showed,[17] more clarity and resources are needed to ensure that there will be a strong legal basis for and coherent interpretation of the regulation. This will be crucial to ensuring that member states balance efficiency and privacy and avoid imposing overly restrictive policies on genetic data sharing, while at the same time creating trust in the system.

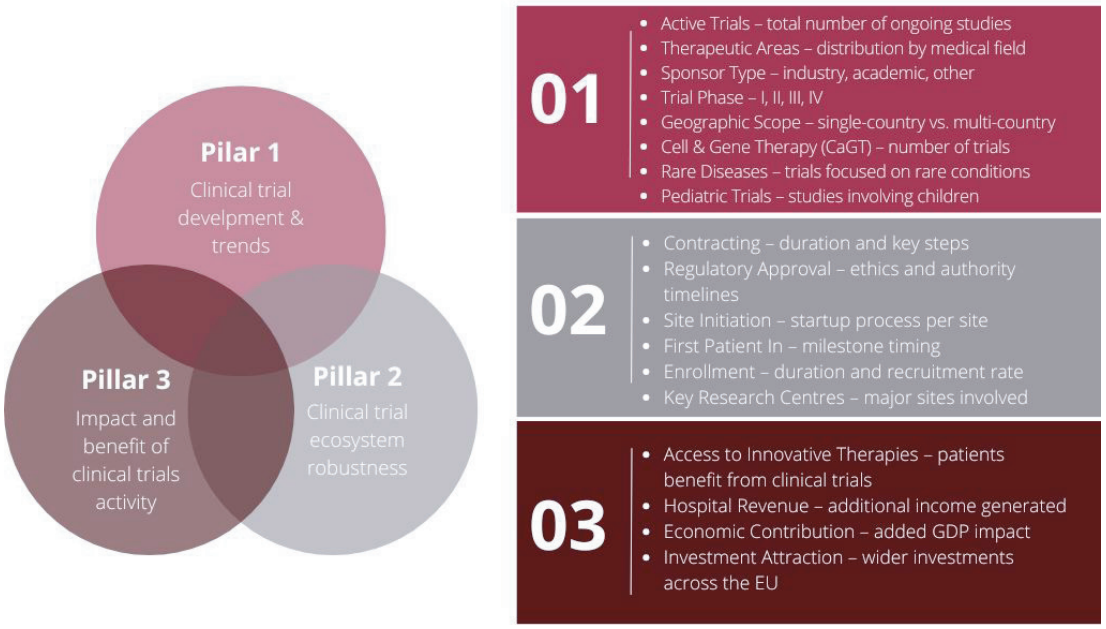
The European Institute of Innovation and Technology (EIT Health) has illustrated how the complexity of decentralised healthcare systems, such as in Germany, hinders the digitalisation and interoperability of healthcare systems in the EU.[18] Currently, member states' own legal provisions add even more complexity to the patchwork of policies dealing with data and data privacy. Moreover, whereas cross-border sharing – for example for genomic data but equally for brain data and imaging – is vital for harnessing research, genetic data falls under sensitive categories of the GDPR, where member states may apply stricter rules.[19] This underscores how establishing harmony among the EHDS, the GDPR and the AI Act is crucial to ensure the use of data for research purposes.

2.2. CLINICAL TRIALS IN THE EU: OPPORTUNITIES FOR ACCELERATING INNOVATION

With China surpassing the US in the annual number of clinical trials,[20] there is a strong incentive for the EU to become a more attractive region for clinical research, as the European Life Sciences Strategy stipulates. Covid-19 led to the broader use of so-called platform trials, allowing for more flexibility in monitoring multiple disruptive new treatments at the same time.[21] Yet, the speed of set-up and scale of clinical trials remain an issue for the more fragmented EU, compared with vast global powerhouses for clinical trials such as China and Australia.

Figure 1

CLINIC TRIAL ECOSYSTEM IN EUROPE



Source: EPC elaboration on IQVIA analysis featured in EFPIA report "Assessing the Clinical Trial Ecosystem" (2025), p.8,[22] using public clinical trial entries from CT.gov, EudraCT, ISRCTN and other registries.

The Clinical Trials Regulation (CTR) aims to harmonise and streamline trial approval processes across the EU. Uneven implementation and differences in national interpretation, however, have led to complexity and unpredictability, making Europe less attractive for clinical research compared to regions like the US and Asia. Despite a 38% increase of clinical trials globally over the past decade, Europe's global share of clinical trials has reduced from 22% in 2013 to 12% in 2023.[23]

In addition, there is a slight decrease in Phase 1 trials over time, which may reduce the future 'pipeline' of trials, particularly in areas where specialised knowledge or equipment is required to deliver the investigational therapy and is often established during Phase 1.[24]

With technologies becoming more complex and integrated, they end up being governed by different regulatory frameworks simultaneously. This happens, for example, when a clinical trial for investigational medicine is being used in conjunction with a companion diagnostic. Additionally, the lack of uptake of innovative advanced diagnostic tests could limit the ability to conduct trials for targeted therapies in the EU. This creates a very complex and fragmented regulatory framework which limits the interest of study sponsors in conducting clinical trials in the EU.

It is therefore commendable that at the recent LifeSciences4EU conference, streamlining approval of clinical trials was mentioned as one of the most concrete opportunities for accelerating innovation in the EU.[25] The Commission mirrors this ambition in its recent Life Sciences Strategy, a flagship initiative in the form of an investment plan for clinical research to facilitate funding for multi-country clinical trials.

In the global race for AI leadership and amid intensifying competition between regions, the policy challenge for the EU and its member states is to balance efficiency and privacy when leveraging emerging technologies for scientific progress and personalised healthcare.

BOX 4: Healthcare Innovation 2030 strategy illustrates France's ambitions in innovation in the health sector with a budget of €7.5 billion, including tax credits for biopharmaceutical companies

There is an urgent need to make the EU a more appealing region for investment in clinical trials and transformative treatments. To this aim, a more coherent regulatory framework that increases regulatory predictability, reduces duplication and supports innovative designs involving multiple product types through faster review and approval processes is needed. Moreover, improving access to the financing necessary to launch and grow technology-driven innovative companies, as stipulated in the EU Startup and Scaleup Strategy,[26] should help make the EU a more attractive place for investment in clinical trials.

2.3. HEALTH TECHNOLOGY ASSESSMENT REGULATION: A GAME CHANGER?

The evaluation process for pricing, reimbursement and value assessment for the next generation of medical technologies requires more flexible HTA frameworks than previous generations of medicines. Firstly, because they are often personalised treatments based on genetic makeup, involving biomarkers and tissues, clinical trials and manufacturing processes are increasingly complex; these highly specific biological products are often less stable and may be used in combination with other treatments. Secondly, comparative evidence of these products is often limited; long-term uncertainty could be reduced via the use of real-world data for pricing and reimbursement.

BOX 5: Germany's Medical Research Act aims to attract innovation and clinical research, as well as facilitate approval processes. The aim of the law is to increase Germany's attractiveness as a location for innovative medical research by improving the legal framework for conducting clinical trials and simplifying bureaucratic processes and approval procedures.

In the process of value assessment of new products, current HTA assessments require the availability of existing evidence to inform health technology decisions. For disruptive innovation launched with limited evidence, real-world evidence is needed as part of the regulatory decision-making process. To date, there is uncertainty about whether Patient Experience Data (PED) and real-world evidence will be sufficiently recognised and used in the Joint Clinical Assessment (JCA) process. Other pathways, like "regulatory sandboxes" which allow access while evidence is generated, are needed.[27]

In early 2025, the new EU Regulation on Health Technology Assessment became applicable, aiming to ensure that innovative and effective health technologies reach patients across the EU.[28] This new regulation could be a game changer for the value assessment of medicines, but implementation so far is not reassuring. There is a risk that the new regulation will become an additional hurdle for innovation, rather than improving outcomes and accelerating patient access to innovative therapies.

In addition, initiatives such as the European Medicines Agency's (EMA) Data Analysis and Real-World Interrogation Network (DARWIN EU)[29] and PRIority Medicines (PRIME)[30] aim to use the EU's convening power to facilitate the use of real-world evidence in clinicals trials and support early engagement with companies. Although DARWIN and PRIME are excellent tools and underline the need to more adaptive approaches for new innovations, they are limited to the regulatory process – specifically, the EMA's marketing authorization assessments. Positive outcomes from EMA processes do not guarantee that patients ultimately gain access to new therapies, as access decisions remain at the national level.

Moreover, there is untapped potential in genomic testing and advanced diagnostics, such as next-generation sequencing (NGS) and innovative techniques like Comprehensive Genomic Profiling (CGP), which could improve patient outcomes.[31] The current lack of access to the most innovative genomic tests – such as CGP, covering a large number of actionable mutations compared to single-gene testing and hotspot testing – hampers the uptake of new therapies. In addition, diagnostics are not universally accessible and often face long delays in reimbursement across the EU, impeding patient access.

BOX 6: One of the first examples of cross-country collaboration is the **Baltic Procurement Initiative** established in 2012 (comprising Estonia, Latvia and Lithuania), followed by the Beneluxa initiative, launched by Belgium and the Netherlands in 2015. Over the years, other collaborations have emerged, such as the FINOSE initiative which recently has renamed itself to the Joint Nordic HTA-Bodies. FINOSE started as a bottom-up initiative by the HTA authorities in Finland, Norway and Sweden and was launched in Stockholm in 2018. The collaboration extended to include Denmark in 2023 and Iceland in 2024.

3. The Challenge: Launching therapies in the EU

To establish a thriving European life sciences ecosystem by 2030, attracting investment alone is not enough – it is crucial to ensure equitable patient access. When R&D and manufacturing migrate to the US or China, Europe risks its patients being the last to benefit from innovations. This is the true test of the EU's competitiveness. Key enablers, such as the Single Market and robust industrial policies, are essential to achieve this goal.

3.1. A FRAGMENTED SINGLE MARKET FOR PHARMACEUTICALS

In today's geopolitical context, discussions about tariffs for pharmaceutical products underline the importance of the biopharmaceutical sector for the EU. With pharmaceutical research and development in the EU in decline,[32] the European economic security doctrine offers a strong incentive to invest in the biopharmaceutical sector.[33] EU initiatives such as the Competitiveness Compass, the Life Science Strategy and the upcoming Biotech Act could help strengthen the attractiveness of the EU for innovation and offer strategic advance and increased competitiveness for the EU.

Yet, the Single Market for pharmaceuticals remains complex due to Treaty on the Functioning of the European Union (TFEU) Article 168, which gives member states the competences to decide the funding and organisation of their healthcare systems, leaving the European Commission largely with a coordinating role. As a result, pricing and reimbursement of medicines takes place within member states, making for a plethora of different national policies and funding practices as well as different levels of access and availability of medicines across the EU.

To establish a thriving European life sciences ecosystem by 2030, attracting investment alone is not enough – it is crucial to ensure equitable patient access. When R&D and manufacturing migrate to the US or China, Europe risks its patients being the last to benefit from innovations.

The traditional rhetoric about member states' wide competences in healthcare has transformed into a more nuanced debate about the EU's potential role in attracting health innovation to Europe. Given the need to respond to a rapidly changing global innovation landscape, a broader perspective on the EU's potential to create a market for innovation in the healthcare sector is required. EU instruments such as the Recovery and Resilience Facility (RFF), launched in response to the Covid-19 pandemic, and the Health Emergency Preparedness and Response (HERA) show the importance of the EU Single Market and how sectors like healthcare benefit most from the RFF's spill-over effects.[34]

BOX 7: WHO/Europe Access to Novel Medicines Platform: this initiative stems from the Oslo Medicines Initiative (2020–2022) and brings together private and public sectors to agree on and take concrete actions to improve patient access to novel medicines in the European Region.

At the same time, the European Investment Bank (EIB) notes that the EU needs to better integrate and simplify access to the Single Market,[35] which is especially true for the healthcare sector. To address these concerns, policy mechanisms such as the Strategic Technologies for Europe Platform (STEP)[36] have been established to support European industry and boost investment in critical technologies, including in the biopharmaceutical sector.

3.2. THE NEXUS BETWEEN INDUSTRIAL AND PHARMACEUTICAL POLICIES

The EU's industrial policy is undergoing a significant transformation, driven by the need to rethink its economic security, bolster sectors of strategic importance and key emerging technologies. The biopharmaceutical sector specifically has the potential to advance a range of policy objectives in the current geopolitical context, from excellent science to competitiveness and economic growth.

Whereas in recent years recognition of the importance of the biopharmaceutical sector has been growing, the nexus between industrial and pharmaceutical policies has traditionally been a critical weakness for the EU.[37] Recently, the Commission addressed this nexus more explicitly, with the Critical Medicines Act and the European Life Sciences Strategy aiming to boost both industrial strategy and economic security.

The focus of the Life Sciences Strategy is on competitiveness and aims to strengthen life sciences research and innovation in Europe, while the Critical Medicines Act focuses on health security, aiming to address medicine shortages by strengthening the security of medicine supply chains in the EU. It aims to reduce dependency on single suppliers, increase pharmaceutical manufacturing within the EU through strategic projects and improve access to critical medicines by facilitating joint procurement and the diversification of supply chains.

Moreover, the current framework for Important Projects of Common European Interest (IPCEIs) addresses the need to facilitate state aid for innovative and large-scale value-chain and infrastructure projects. A case in point is the IPCEI Med4Cure,[38] the first initiative by the European Commission to support innovation and research in the pharmaceutical sector. However, the current IPCEI framework of state aid decisions is not strong enough to ensure the full implementation of approved projects at the national level,[39] contributing to the health sector's funding fragmentation.

More is needed to future-proof the EU's industrial strategy for the biopharmaceutical sector and rebuild industrial strength. As the European Commission's Communication on the Single Market rightly states:

"At present there is little direct link between EU spending (focused on investment) and Member States undertaking regulatory reforms to remove Single Market barriers or promote European business cases and value chains".[40]

3.3. EU INVESTMENT IN ACCESS TO HEALTH INNOVATION

Whereas the European Health Union aims to ensure timely and equal access to medicines for all EU citizens,[41] funding of these medicines takes place at the national level. This creates a dilemma that must be resolved for the EU to become more competitive and deliver end-to-end approaches from research to real-world impact in terms of improving outcomes for patients.

The patchwork of reimbursement policies across the EU-27 often stands in the way of end-to-end approaches that would ensure medicines are launched and made available to patients as soon as possible. While EU industrial policies are needed to attract innovation and improve competitiveness, the pharmaceutical market will remain dysfunctional if medicines are not available to patients – that is, reimbursed at the national level. Biopharmaceutical companies will interpret reimbursement as a signal of how attractive the EU intends to be.

Current realities contrast sharply with the objective of the Health Union, with a persistent historic divide between Central Eastern European (CEE) and other member states. Less than half (46%) of centrally approved innovative medicines were available to patients in CEE – down from 48% in 2019.[42] In addition, pricing and reimbursement decisions in the EU take far longer than the 180 days set out in the EU's Transparency Directive. In 2025, the average time from approval to patient access reached 578 days – more than a month longer than in 2023.[43]

Less than half (46%) of centrally approved innovative medicines were available to patients in Central and Eastern Europe.

Processes at the EU level, such as the European Semester,[44] could incentivise member states to increase and strengthen investment in biopharmaceutical innovation with the aim to reform their healthcare systems. Especially for EU regions where health spending is below the EU average, current instruments such as the European Structural Funds – particularly the European Regional Development Fund (ERDF) and Horizon Europe,[45] the EU's key funding programme for research and innovation – offer a way to increase efficiency and contribute to closing the EU's innovation gap. Often unnoticed, these funds have become the main source of health infrastructure investment in the EU.

Ongoing negotiations on the next MFF and the European Competitiveness Fund[46] offer an opportunity for a new funding paradigm. This should facilitate a faster, more equitable uptake of transformative treatments and technologies into healthcare systems, which in turn transforms technological progress into improved patient outcomes and societal benefits.

4. Accelerating the introduction of new therapies - frameworks at national and EU levels

In the EU, very often the challenge is to accelerate market uptake and ensure timely patient access to new and innovative technologies. Currently, challenges frequently arise from the lack of existing frameworks for early access and national-level resource constraints and unwillingness to pay, as highlighted in prior chapters. To tackle the current fragmentation, the upcoming EU Biotech Act should integrate and build upon national innovative funding mechanisms.

4.1. FUNDING MECHANISMS AND PUBLIC-PRIVATE SECTOR COLLABORATION AT NATIONAL LEVEL

Achieving access to innovative technologies requires early dialogue between regulators and innovators as well as adequate reimbursement policies at the national level. Closer collaboration must be established between national regulators and innovators to address an increasingly complex regulatory environment. Yet, early dialogue also needs to extend beyond a purely regulatory focus and capture multistakeholder engagement and public-private collaboration.

Innovators face a patchwork of different pricing and reimbursement systems across EU member states, which signal the willingness of countries to pay for innovation. Often, there is a disconnect between the EU-level ambition to attract the life sciences sector and member state access provisions. This must be considered in the context of any EU life sciences strategy, since access is decided at national level, where new technologies should be applied and patients should have access to new and transformative treatments. European coordination and diverse and comprehensive representation of the entire

life science ecosystem is a precondition for translating the ambition for a more innovative and competitive European biopharmaceutical sector into concrete action.

European coordination and diverse and comprehensive representation of the entire life science ecosystem is a precondition for translating the ambition for a more innovative and competitive European biopharmaceutical sector into concrete action.

Innovative funding solutions and payment models by local and regional governments are therefore key and should be fostered as the way to achieve more agile regulatory systems.[47] Horizon Europe's Pay for Innovation Observatory (HiPrix) offers a comprehensive overview of pricing and innovative payment models which are used in different countries and regions,[48] including:

- Advance market commitment (AMC)
- ATMP funds
- Blended discount models
- Bundled pricing/payment models
- Combination-based pricing models
- Outcome-based payment models

These mechanisms aim to address the financial complexities associated with cutting-edge health technologies and provide avenues for sustainable funding and access to treatments. The upcoming EU Biotech Act should draw on these national best practices to help the EU overcome its current fragmentation. If scaled, such examples could enable the EU to create space for payers and innovators to discuss, earlier in the process, alternative forms of funding and reimbursement, thereby accelerating access to innovation.

BOX 8: Denmark's Life Science Council was established in 2021 as part of the Danish government's strategy to strengthen public–private collaboration in the life science industry. The Council includes members representing the entire life science ecosystem, ranging from government authorities, industry, foundations, clinicians, the Danish Association of the Pharmaceutical Industry, various patient associations and universities.

4.2. CROSS-COUNTRY COLLABORATION BETWEEN MEMBER STATES

Cross-country collaboration between member states offers a potential way for EU countries to pool resources and streamline procedures. The scope of these collaborations differs from country to country, depending on how healthcare systems are organised at national and regional levels. Their focus ranges from joint health technology assessments of medicinal products to joint horizon-scanning of new products. Some aim to strengthen the purchasing power of countries involved.

In the context of the ongoing revision of the EU's Pharmaceutical Legislation, EU member states have been exploring a role for the EU in stimulating innovation and guaranteeing access to, and availability of, medicines at the national level. The case of antibiotics offers an instructive example that could apply to other innovative technologies, particularly in lower-income or smaller countries.

A subscription model (dubbed the 'Netflix-model')[49] is being implemented in the UK. It introduces an incentive mechanism to support a sustainable market for innovation, ensure access to novel antibiotics within the health system and to patients, and embed these medicines within a stewardship framework to address the risk of antimicrobial resistance (AMR). While designed to address the challenges of antibiotic innovation and access, the subscription model offers inspiration for similar incentive mechanisms for other innovative products. Such an approach could help facilitate access and manage national budget constraints through a European coordination framework, with member states participating via subscription contracts at the national level.

In its Single Market Communication,[50] the European Commission argued that joint procurement and cross-border procurement have the potential to create lead markets, improve access and lower costs. The current experience at the EU level stems from the joint procurement of vaccines during the Covid-19 pandemic,[51] rather than from more innovative treatments. Despite this, several calls emerged in the aftermath of the pandemic to promote access and affordability by resorting to joint procurement for medicines beyond health crises.[52] In the context of disruptive innovation, however, this type of access collaboration should be designed differently to attract new innovations, ensure they become available to European citizens and position Europe as a competitive market.

The EU's Critical Medicines Act offers a more concrete way forward to address access to medicines via three collaborative procurement models: facilitation procedures for cross-country collaboration (Article 21), Commission procurement on behalf of member states (Article 22) and joint procurement for critical medicines (Article 23).[53] These mechanisms aim to enable member states to pool their resources to increase their purchasing power and

improve access to medicines. However, member states' reception of the Commission's proposal has been critical,[54] ranging from concerns about the scope extending beyond critical medicines and emergency situations to worries about the national authority over procurement.

Joint procurement mechanisms have been questioned by the industry for not addressing underlying national factors contributing to access delays. As outlined before, these delays stem from differences in pricing and reimbursement procedures, budget priorities, disease prevalence and varying HTA requirements. For joint procurement mechanisms to gain broad acceptance, they should evolve beyond their role as a cost-saving tool.[55] Instead, they should function to attract new health innovations, akin to an innovation fund, and encourage companies to launch their products in Europe first.

Joint procurement mechanisms should function to attract new health innovations, akin to an innovation fund, and encourage companies to launch their products in Europe first.

Conclusions

The biopharmaceutical sector is a sector of strategic importance for the EU, contributing to its competitiveness and economic security in a world defined by geopolitical shocks. Geopolitical disruption and horizontal transitions like the triple technological, digital and demographic transitions not only require a paradigm shift from policymakers to redefine Europe's leadership in sectors like health; they equally require healthcare system reform and investment in patients' timely and equitable access to innovation.

The challenge for the EU in the current geopolitical setting is to raise its ambition for the biopharmaceutical sector and establish a more strategic and less fragmented approach to funding innovation – one that enables transformative change with societal and economic impact, rather than simply introducing new technologies.

Especially for new technologies, there is no end-to-end pathway from research to patient access. There is a disconnect between research into new technologies at the EU level and reimbursement practices in national contexts, related to uncertainties about the future effects of new treatments and technologies. This is less of a problem for traditional medicines, but a challenge for costly and complex disruptive technologies.

New technologies are an investment in healthier populations but can also generate savings for healthcare systems by reducing the need for multiple treatments, shortening hospital stays and lowering staffing needs. Investment in new, transformative technologies requires a shift in mindset among politicians and policymakers as well as structural reforms in how healthcare systems operate. This means introducing new payment models and overcoming rigid budget silos.

A vision for a resilient, competitive and innovative European pharmaceutical sector is incomplete if new technologies do not reach national markets and patients in EU member states.

[1] Ma, Damien and Lee, Lizzi C. (2025), "An Industrial Policy With American Characteristics: To Compete Like China, America Should Build Like China", *Foreign Affairs*.

[2] The Guardian (2025), "Australian Academy of Science global talent attraction program amid Trump research cuts", 17 April 2025.

[3] European Commission (2025), *A Competitiveness Compass for the EU*, Brussels.

[4] European Commission (2025), *A strategy to position the EU as the world's most attractive place for life sciences by 2030*, Brussels.

[5] National Institutes of Health (NIH) (accessed 12 September 2025), "Messenger RNA (mRNA)".

[6] Keller, S.C. (2024), *Breaking Through: My Life in Science, Emerging Infectious Diseases*, Vol. 30, No. 4, p. 839.

[7] Cambridge English Dictionary (accessed 12 September 2025), "Disruptive Innovation".

[8] Center for Advanced Genomic Technologies (CAGT) (accessed 18 September 2025), "Genome Engineering Technologies".

[9] Sheridan, C. (2025), "Individualized mRNA cancer vaccines make strides", *Nature Biotechnology*, Vol. 43, pp. 833–836.

[10] Genomics England (accessed 12 September 2025), "100,000 Genomes Project".

[11] Katie Snape, Wedderburn, Sarah, Barwell, Julian (2019), "The new genomic medicine service and implications for patients", *Clinical Medicine*.

[12] Letta, Enrico (2024), *Much More than a Market*, European Council, Brussels and Draghi, Mario (2024), *The Future of European Competitiveness*, Brussels: European Commission.

[13] Brady, Danielle and Kuiper, Elizabeth (2023), "Is the European Health Union ready for the challenges of the 21st century?", Brussels: EPC.

[14] Máthéová, Ivana (2024), "The Interplay Between the European Health Data Space Act and the GDPR: Secondary Use of Health Data and Its Protection", *EU Law Working Papers*, No. 88, Stanford–Vienna Transatlantic Technology Law Forum.

[15] Świeboda, Paweł and Kuiper, Elizabeth (2025), "Innovation across the lifecycle of brain health", Brussels: EPC.

[16] European Health Data Space (accessed 18 September 2025), "Implementation of the European Health Data Space".

[17] Hadea (2025), "EU-funded projects contributing to implementation of the European Health Data Space".

[18] EIT Health GermanySwitzerland (2024), *Recommendations for Further Action when Implementing the European Health Data Space in Germany*, Brussels: EIT Health.

[19] Shabani, Mahsa and Borry, Pascal (2017), "Rules for processing genetic data for research purposes in view of the new EU General Data Protection Regulation", *European Journal of Human Genetics*, Vol. 26, No. 2, pp. 149–156.

[20] Beaney, Abigail (12 February 2025), "OCT West Coast 2025: China surpasses US for annual number of clinical trials", *Clinical Trials Arena*.

[21] Meyer, E.L., Mielke, T., Bofill Roig, M. et al. (2025), "Why and how should we simulate platform trials? Learnings from EU-PEARL", *BMC Medical Research Methodology*.

[22] IQVIA & EFPIA-VE (2024), *Assessing the Clinical Trial Ecosystem in Europe*, Brussels: EFPIA-Vaccines Europe / IQVIA, August 2024.

[23] EFPIA (2025), "Clinical Trials".

[24] European Federation of Pharmaceutical Industries and Associations (EFPIA) & IQVIA (2024), *Assessing the Clinical Trial Ecosystem in Europe. Final Report*, Brussels: EFPIA / IQVIA.

[25] Świeboda, Paweł (ed.) (2025), *The Kraków Agenda for Europe's Life Sciences: LifeScience4EU Conference Report*, Brussels: LifeScience4EU.

[26] European Commission (2025), *EU Startup and Scaleup Strategy*, Research & Innovation – Jobs and Economy, Brussels.

[27] Eskola, Sini et al. (2025), "Innovative industry perspective: Assessing the proposed regulatory changes and their impact on innovation and competitiveness of the EU regulatory framework as part of the EU General Pharmaceutical Legislation revision", *Drug Discovery Today*, Vol. 30, Issue 10, 2025.

[28] European Commission (2025), "Commission Press Release".

[29] Darwin-EU (accessed 22 September 2025), https://www.darwin-eu.org.

[30] European Medicines Agency (accessed 22 September 2025), "PRIME – Priority Medicines".

[31] European Coalition for Access to Comprehensive Genomic Profiling (ECGP) (2025), *The Untapped Potential of Comprehensive Genomic Profiling*, Brussels: ECGP.

[32] European Federation of Pharmaceutical Industries and Associations (EFPIA) & PwC (2024), *Economic Footprint of the Pharmaceutical Industry in Europe*, Brussels: EFPIA.

[33] European Policy Centre (2025), *Turning the Tide: Towards Open Economic Security – Ten Reflections*, Brussels: EPC.

[34] European Commission, DirectorateGeneral for Economic and Financial Affairs (2025), *Economic Impacts of the Recovery and Resilience Facility: New Insights at Sectoral Level and the Case of Germany*, Discussion Paper 221, Brussels.

[35] European Investment Bank (2025), *EIB Investment Report 2024/2025: Innovation, Integration and Simplification in Europe*, Luxembourg: EIB.

[36] Strategic Technologies EU (accessed 28 September 2025).

[37] Kuiper, Elizabeth (2025), "Why health should be at the heart of building a more secure and competitive Europe", *European Policy Centre* (EPC), 19 March 2025.

[38] European Commission (2024), "Commission Press Release".

[39] Lausberg, Philipp; Folkman, Varg; Allen, Chris (2025), "Making IPCEIs a new vanguard for EU industrial policy", *European Policy Centre* (EPC), 13 May 2025.

[40] European Commission, DirectorateGeneral for Internal Market, Industry, Entrepreneurship and SMEs (2025), *The Single Market: Our European Home Market in an Uncertain World – A Strategy for making the Single Market simple, seamless and strong*, COM(2025) 500, Brussels.

[41] European Commission (accessed 28 September 2025), "European Health Union", *European Commission – Public Health*.

[42] European Federation of Pharmaceutical Industries and Associations (EFPIA) (2025), "New data shows no shift in access to medicines for millions of Europeans", 07 May 2025, *The EFPIA View*.

[43] European Federation of Pharmaceutical Industries and Associations (EFPIA) & IQVIA (2024), *Patients W.A.I.T. Indicator 2024 – Final Report*, Brussels: EFPIA.

[44] European Commission (accessed 10 October 2025), "European Semester Process".

[45] European Commission (accessed 10 October 2025), "Horizon Europe Funding Programmes".

[46] European Commission (accessed 10 October 2025), "European Competitiveness Fund".

[47] See Box 1-8 for examples of funding mechanisms and public-private sector collaboration at national level.

[48] HIPRIX Horizon (20232025), *Health Innovation Next Generation Payment & Pricing Models (HIPRIX)*, funded by the European Union.

[49] UK Parliament Commons Library (accessed 10 October 2025), "Netflix for Antimicrobials: The Antimicrobial Products Subscription Model".

[50] European Commission, DirectorateGeneral for Internal Market, Industry, Entrepreneurship and SMEs (2025), *The Single Market: Our European Home Market in an Uncertain World – A Strategy for making the Single Market simple, seamless and strong*, COM(2025) 500, Brussels.

[51] Kuiper, Elizabeth; Migliori, Michele (2025), "Preparedness rules: similarities between health and defence policies at EU level", *European Policy Centre* (EPC), 08 May 2025.

[52] Kuiper, Elizabeth; Brady, Danielle (2023), *Is the European Health Union ready for the challenges of the 21st century?* Discussion paper, Brussels: European Policy Centre (EPC), 12 September 2023.

[53] European Commission (accessed 10 October 2025), "Critical Medicines Act", Public Health – *Medicinal Products Legal Framework*, European Commission.

[54] Employment, Social Policy, Health and Consumer Affairs Council (2025), "Employment, Social Policy, Health and Consumer Affairs Council (Health)", 20 June 2025.

[55] Goodger, Samuel; Świeboda, Paweł; Kuiper, Elizabeth (2025), "Fixing the Chain: How to Secure the EU's Supply of Critical Medicines and Prevent Shortages", *European Policy Centre* (EPC).

The **European Policy Centre** is an independent, not-for-profit think tank dedicated to fostering European integration through analysis and debate, supporting and challenging European decison-makers at all levels to make informed decisions based on sound evidence and analysis, and providing a platform for engaging partners, stakeholders and citizens in EU policymaking and in the debate about the future of Europe.

The **Social Europe and Well-being Programme (SEWB)** is dedicated to achieving a stronger Social Europe fit to address the social, environmental, economic and political challenges facing the Union today. It focuses on policies that prioritise strong and resilient healthcare systems; modern and inclusive labour markets; eradicating inequalities; investing in the health and well-being of people; making European welfare states and social protection systems fit for the future.

With the strategic support of King Baudouin Foundation
Working together for a better society

Co-funded by the European Union