MERCK

ENSURING HEALTH SECURITY:

HOW THE EU CAN WIN THE COMPETITION FOR BIOPHARMA LEADERSHIP

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Acknowledgements

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summary

Without rapid and decisive action, Europe will not achieve its long-term strategic goals in biopharmaceutical technology leadership and health security. The biopharma sector has long been an industrial powerhouse for the continent, in addition to its essential contribution to the welfare of European citizens. Today, however, its future success is far from assured.

European biopharma leaders must cope with growing risk and increased competition in the global market due to factors like protectionist trading practices and subsidies, novel pathogens, armed conflicts, and geopolitical tension. They face an uncertain business environment at home, with regulatory incoherence, fragmentation, inadequate policy impact assessments, and pressure to reduce IP protection. In addition, the science of developing new medicines and vaccines is becoming more complex.

The European biopharmaceutical sector's position relative to that of other countries, notably the United States (US) and China, is in decline in recent years despite its important contributions to the European economy, job market, and trade balance. New treatments are most often launched first outside of Europe, and European companies are falling behind in growth areas like innovative biologics and orphan medicines. Unable to secure the necessary funding to scale in Europe, promising small and mid-sized biopharma companies are moving abroad. Biopharmaceutical spending for research and development (R&D) in Europe, both public and private, lags behind the United States.

Fortunately, it is possible to reverse these trends. Europe enjoys a centuries-old legacy of innovation in pharmaceuticals, quality R&D institutions and a talented workforce, among other strengths. The European Commission should prioritize the biopharma industry, expand engagement with the private sector, and make competitiveness a guiding principle of its work. Creating the right conditions for the emergence of a network of biopharma R&D hubs should be a primary focus.

In line with recent analyses from the Draghi Report (2024) on competitiveness and the Letta Report (2024) on enhancing the single market, this paper presents strategies being deployed by biopharma leaders to boost innovation, supply resilience, and competitiveness. It also identifies ways in which policymakers can enable a strong, globally competitive, and innovative European biopharma industry in the coming decades. To this end, the report suggests specific actions for 2025 and beyond.

section 1

The Biopharma Industry and Long-term EU Strategic Goals

Health security, economic security, and Europe's place in the world are top of mind for the new EU Commissioners. This paper focuses on maintaining European leadership in the biopharma space to achieve these goals. The analysis focuses on two key questions:

- First, how can European policymakers support innovative European biopharma companies to compete on the global stage in the coming years?
- Second, what can they do to ensure Europe remains an attractive option for investing in R&D and innovation, and for bringing new health products to market?

To answer these questions, this paper reviews industry challenges and strategies adopted by biopharma innovators. It also reviews how policymakers can support them by creating an enabling environment in Europe for biopharma leadership while also contributing to a level playing field internationally, with legally certain rules for international trade and regulations.

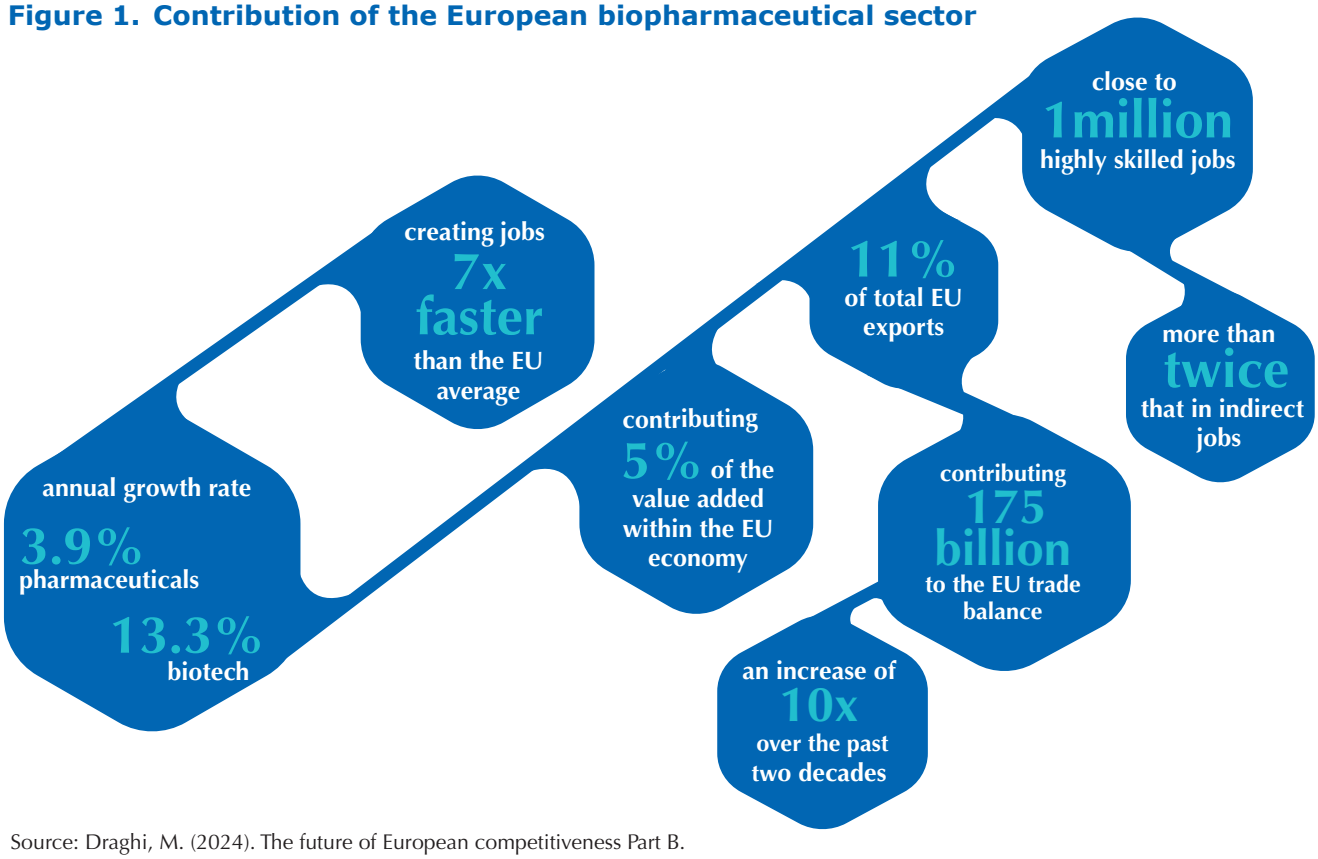
The foundation for achieving critical long-term European priorities has already been set out in publications by the European Commission – in the Industrial Innovation for Open Strategic Autonomy concept note[1] and the Joint Communication to the European Parliament, the European Council and the Council on "European Economic Security Strategy"[2]. More recently, flagship reports published in 2024 by Mario Draghi ("The future of European competitiveness") and Enrico Letta ("Much more than a market, empowering the Single Market to deliver a sustainable future and prosperity for all EU citizens") have made further contributions.

With the publication of the Draghi Report, the EU Commission has additional analysis to embrace competitiveness as a guiding principle and take decisive action to prioritize and bolster Europe's competitive position. The Draghi Report concludes that the EU's business and innovation environment is lacking in several areas, particularly within critical sectors of biopharma, energy, critical raw materials, computing and artificial intelligence (AI).

The report endorses urgent action – and enormous public investments in the coming years (EUR 800 billion annually) – to improve productivity, catalyze investments in cutting-edge R&D, boost innovation, and reduce the cost of doing business in the EU while accelerating and leveraging the green transition[3]. In addition to sounding the alarm on waning European competitiveness and technology leadership, the Draghi Report underscores that it is not too late to reverse this alarming trend. It calls for concerted action involving the public and private sectors, EU and national financing, and the political will to set the EU on the path to a successful future.

The innovative biopharmaceutical sector will necessarily be one focus as lawmakers act to safeguard EU competitiveness. The sector is integral to human welfare. It contributes to European economic growth, trade, job creation, manufacturing prowess, innovative capacity, and technology leadership. (Figure 1.) Biopharma is more than solely an economic consideration. This sector is intimately tied to European values of social fairness and quality of life for all citizens.

Figure 1. Contribution of the European biopharmaceutical sector



Source: Draghi, M. (2024). The future of European competitiveness Part B.

- The pharma sector accounts for 5% of total value added to the economy from all manufacturing and 11% of total EU exports (as of 2024)[3].
- Exports of medicinal and pharmaceutical products from the EU grew 10% annually between 2002 and 2023[3].
- 937,000 people employed by the pharma sector (as of 2023)[3].

Despite this performance, the relative decline of the industry has accelerated in recent years. The evidence is particularly compelling in the areas that have seen the strongest growth, such as orphan medicines, where the EU has become a marginal player[3]. Just two of the top ten best-selling biological medicines were marketed by Europe-based companies in 2022, and none of the top ten best-selling orphan medicines were marketed by EU-based companies[3]. Across Europe, inventors – particularly in academia and the SME (small and medium-sized enterprises) communities – are struggling to transition from innovation to successful commercialization. Fragmentation, the lack of a coherent EU-wide biopharma strategy, and undue regulatory complexity are marring the European landscape for developing and bringing new medical technologies to patients. Talent, R&D activities, and other investments are leaving Europe and moving towards more attractive environments for biopharma investment and innovation, including the United States and, increasingly, China.

Fragmentation, the lack of a coherent EU-wide biopharma strategy, and undue regulatory complexity are marring the European landscape for developing and bringing new medical technologies to patients.

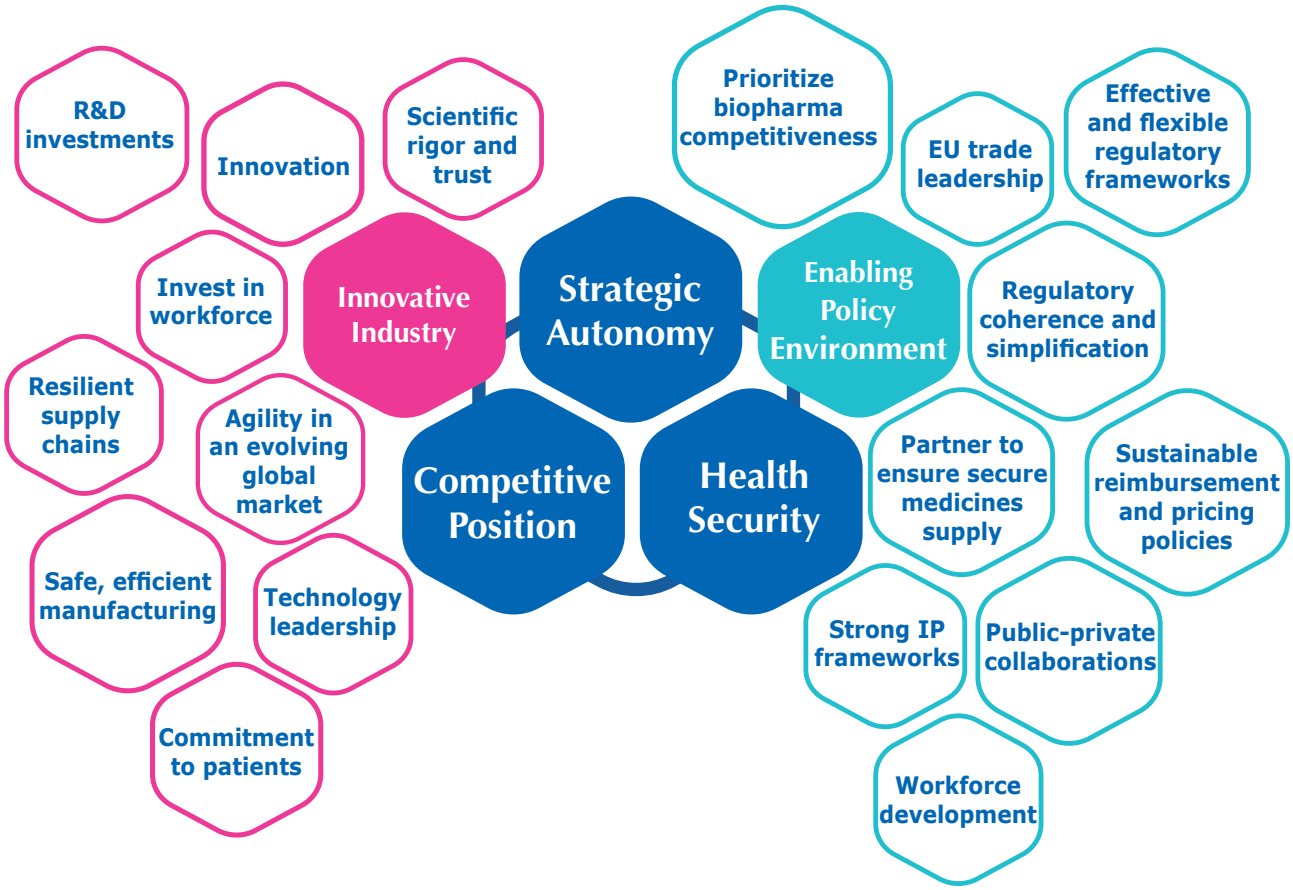
European biopharma competitiveness requires: strengthening supply chain resilience, increasing public R&D expenditure and improving coordination of these funds, creating a better enabling environment for biotech SMEs, reducing unnecessary bureaucracy, shifting more policymaking to the EU level ("more Europe"), and forging strategic international partnerships on trade.

To address these challenges, it is essential that EU policymakers adopt a full value chain approach, given the interlink between all stages of medicines development and commercialization.

This paper offers perspectives from the private sector on what is needed from European policymakers – for the short- and long-term – to strengthen the European competitive position in the biopharma sector in the coming decades. A competitive position entails: (1) a strong, innovative industry able to lead on the global stage and (2) an environment in Europe that is conducive to R&D, innovation, commercialization, and access to new health innovations. Increased resilience and competitiveness do not equal protectionism; rather, open trade has a critical role to play in achieving these goals.

The analysis in this paper is based mainly on interviews with leaders in the innovative biopharma sector in Europe and the United States, primarily from Merck Healthcare and Merck Life Science. Their insights and recommendations align with those in the pharmaceutical section of the Draghi Report, which endorses strengthening supply chain resilience, increasing public R&D expenditure and improving coordination of these funds, creating a better enabling

Figure 2. Building European competitiveness in biopharma



environment for biotech SMEs, reducing unnecessary bureaucracy, shifting more policymaking to the EU level ("more Europe"), and forging strategic international partnerships on trade. These steps will help to safeguard the availability of innovative medicines for Europeans today. More importantly, they will position the EU's success in securing access to the innovative medicines of the future.

Section 2 provides a brief overview of the growing complexity and risk in the environment for biopharma innovation and commercialization. **Section 3** reviews challenges and solutions across the entire biopharma value chain, from the lab to regulatory approval, and from manufacturing to patient access and supply security. Specific actions for boosting European competitiveness are suggested throughout. **Section 4** summarizes recommendations and identifies priority actions for the near term.

section 2

Growing Risk and Challenges in the Biopharma Landscape

The global economic landscape is particularly challenging at the moment. European companies across sectors face rising competition, in some cases due to protectionist trading practices and subsidies. Multi-faceted risks related to trade protectionism, pathogens, environmental disasters, armed conflict, a fractured international order, and geopolitical tensions are on the rise, affecting innovators from all sectors and parts of the world.

Biopharma innovators also face challenges specific to their industry. The science of developing new treatments is getting more complex as treatments like gene therapy, biologics, CAR-T (chimeric antigen receptor T-cell therapy), and personalized medicine take center stage. The scientific community must also solve daunting global challenges like drug-resistant pathogens. And, our understanding of some diseases for which new treatment options are urgently needed remains limited. Health budgets are under pressure in every part of the world, while regulators and patients demand faster time to market, fewer side effects, and more transparency around R&D and the launch of new treatments. Additionally, with the pandemic still fresh in their minds, government officials in many countries are pushing for local manufacturing of health products.

Multi-faceted risks related to trade protectionism, pathogens, environmental disasters, armed conflict, a fractured international order, and geopolitical tensions are on the rise, affecting biopharma players from all parts of the world.

Within the EU, biopharma innovators must manage substantial fragmentation. As noted in both the Draghi and Letta Reports, the promising EU single market is far from being fully realized, with Draghi attributing the widening gap in per capita Gross Domestic Product (GDP) compared to the United States to lower productivity in the EU[4,5]. Public R&D spending is not only suboptimal – it is not adequately coordinated to enable Europe to innovate and compete on par with other nations. Financing, like venture capital (VC) and equity capital, similar to European public R&D funding, is available at a much smaller scale in Europe than elsewhere. Healthcare systems in the EU are national, and industrial policy is only partially in the hands of the EU Commission. The solution, in many cases, may be better coordination and "more Europe", that is, consolidation of greater decision-making authority and more rulemaking at the European rather than the national level.

But "more Europe" is not enough if not also accompanied by simplification, that is, the elimination of undue red tape and a reduced overlap between European and national regulations. Crucially, this must be supported by coherent policy frameworks and a robust strategic plan that aligns the specific needs of the biopharmaceutical sector with broader EU industrial policy objectives.

Consensus-based EU decision-making takes time but does not generate predictability. In part, this is caused by undue complexity and fragmentation in European regulation, as noted above. It also derives from other factors, notably a lack of clear overarching goals and a common roadmap. Further, successive EU presidencies have set different priorities every six months. As companies make business decisions, they require legal certainty and predictability. If the EU doesn't reinforce both of these principles, its business environment will remain relatively unattractive to companies, which may choose to prioritize other regions.

EU governance can exacerbate the challenges derived from European fragmentation. For instance, policies made in silos can affect biopharma innovators' license to operate in Europe, in addition to undermining their competitive position on the global stage. In addition, the EU sets important political and strategic goals without consistently speaking and acting in unity, a problem recently on display in the run-up to the imposition of definitive countervailing tariffs on electric vehicles from China.

Policies and projects with broad application to many industrial sectors ("horizontal" policies) impact the biopharmaceutical sector alongside relevant national and EU policies. Horizontal policies are enacted without a comprehensive evaluation of their impact on biopharma innovation and future health security. Certain pending or recently approved legislative initiatives, such as the Urban Wastewater Treatment Directive, have not been fully vetted for impact.

To ensure the effective allocation of resources and to bolster the biopharma sector, it's advisable that EU technical experts prioritize work programs with demonstrated necessity, clearly defined goals, and effective targeting of challenges within the biopharma innovation ecosystem. Sustained, two-way engagement can help to build understanding among policymakers about the complexities of the sector. Better dialogue and an appropriate platform to present the dynamics of the innovative biopharma sector to policymakers are necessary for the development of long-term strategies for the success of this industry.

As noted, legal certainty and predictability are essential for businesses' decision-making, especially in the biopharma sector, where the innovation model is characterized by long timelines, high risk, and high costs for R&D including extensive testing to confirm the safety and efficacy of new drugs. The EU's biopharma innovation ecosystem suffers from shortcomings – such as fragmentation and regulatory incoherence – that contribute to uncertainty. A persistent lack of clarity regarding the content and execution of legislative initiatives complicates strategic planning.

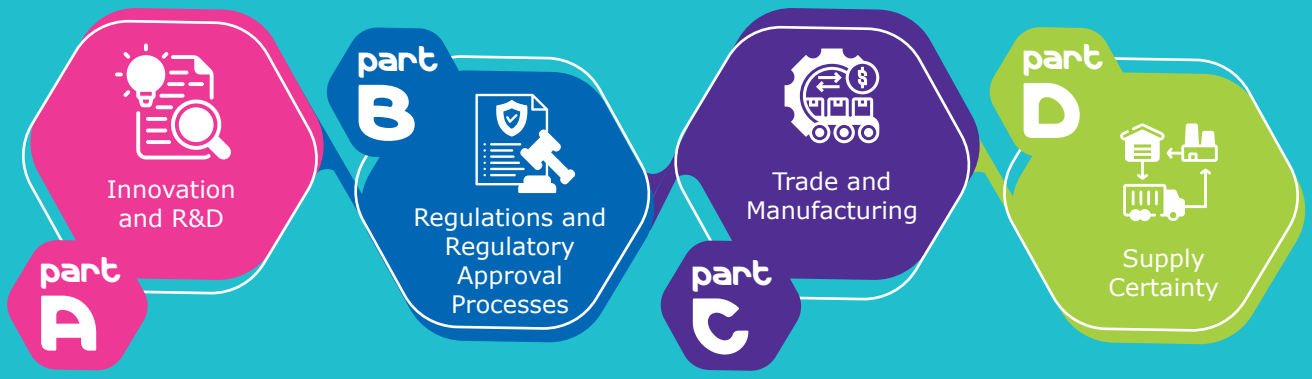
Developing a coherent, long-term EU strategy for the biopharma sector will be essential.

An increasingly dense web of regulations has a strangling effect upon the sector directly and indirectly, contributing to the exodus of innovative biotech SMEs as they scale. The Draghi Report notes that 55% of SMEs flagged regulatory obstacles and administrative burdens as their greatest challenge in 2023[3]. Innovators of all sizes are facing more complexity in European regulations, including more legal obligations and reporting. This is impacting their ability to operate in Europe when what is needed is simplification and streamlining of the regulatory frameworks.

Coherence is urgently needed among policy initiatives to avoid unintended consequences. As noted in the Draghi Report, this is not just any sector: a thriving biopharma industry is essential for European prosperity and citizens' well-being. To address this need, the European industry group EFPIA (European Federation of Pharmaceutical Industries and Associations) has proposed the creation of a Life Science office to provide oversight and monitor the impact of policies on the biopharma sector[6].

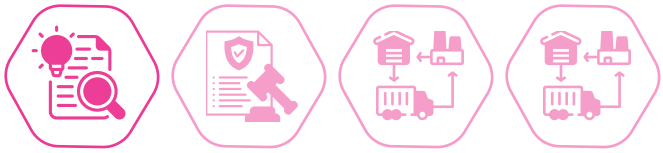
The European biopharma industry is using a range of strategies to navigate the EU and global competitive landscapes. Many of the strategies were put in place after the COVID-19 pandemic based on lessons learned. During the pandemic, there was continuous, expedited public-private dialogue; this was one factor that helped to bring treatments and vaccines to patients in record time. Data could be submitted to regulators on a rolling basis as digital dossiers and more cooperation were embraced by regulators.

Today, European biopharma innovators count on European policymakers to enact enabling policies – vis-à-vis the rest of the world and also at home – to support them in continuing to bring new treatments and other health technologies to patients everywhere quickly and efficiently. To this end, developing a coherent, long-term EU strategy for the biopharma sector will be essential.



section 3

Challenges and Solutions Along the Biopharma Value Chain



PART A. Innovation and R&D

This analysis starts at the beginning of the biopharma value chain, where ideas originate and are refined by scientific researchers: innovation through R&D.

Biopharma innovation – already notoriously risky, expensive, and complex – is becoming even more challenging over time. Developing a new medicine can take 12-13 years and is estimated to cost an average of EUR 3,130 million when failures are factored in, with only one or two of 10,000 synthesized substances progressing to approval[7]. The low-hanging fruit has been picked from the biopharma tree, as gene therapies, biologics and personalized medicine, all of which rely on more complex R&D processes, move to center stage. Additionally, while AI-enabled drug discovery is showing promise within the biopharma sector, the EU data architecture needed for companies to pursue this approach to innovation across molecular structures, clinical operations, and patient data lags behind other regions[3]. At the same time, emerging global threats like antimicrobial resistance (AMR) pose substantial scientific and commercial challenges.

The era in which companies could develop new health technologies primarily in-house has ended. Collaboration is now a central – and necessary – feature of R&D and commercialization across the industry. During the COVID-19 pandemic, this trend was on full display as innovators, large and small, rapidly moved to work together, share their know-how and technologies, develop innovative vaccines and treatments, then transfer technology to partners around the world as they created geographically distributed manufacturing networks able to quickly produce billions of doses of vaccines and therapeutics. European innovators contributed technology, highly trained personnel, and know-how to the COVID-19 innovation response.

IP-enabled collaboration is now a central – and necessary – feature of R&D and commercialization across the industry.

Biopharma Collaboration for Health Security

European biopharmaceutical innovators were instrumental to health security during the pandemic, contributing technology and know-how that accelerated the development and delivery of COVID-19 vaccines and therapeutics. Merck Life Science rapidly pivoted operations to prioritize the pandemic response. The company accelerated its existing lipid nanoparticle research program and, nine months ahead of the original R&D schedule, it was able to supply these essential components for the COVID-19 mRNA vaccines. Intellectual Property (IP) protection allowed innovative firms like Merck to share proprietary information and technology with partners. Collaboration was essential for bringing novel COVID-19 vaccines and treatments to society in record time – and it will undoubtedly underpin future pandemic preparedness and response.

Intellectual Property

The glue that binds collaboration and technology transfer initiatives together is IP protection, including patents (protecting inventions that are novel and that have industrial application), trade secrets (protecting confidential business information that has been kept secret), and regulatory data protection (RDP) (protecting data submitted to regulatory authorities).

Systems for intellectual property protection and enforcement make it possible to invest huge sums of money in risky, long-term innovation projects, since the owner of the relevant IP rights can monetize the investments upon success in the marketplace. IP drives breakthroughs as well as incremental innovation, an approach that delivers value for patients and healthcare systems.

IP frameworks enable partners to share what they know without losing their competitive advantage. A strong IP position can enable a smaller player, such as an SME, university research team, or startup, to collaborate with an established player to move an invention to market. One example of this type of partnership was that between BioNTech and Pfizer to develop a COVID-19 vaccine based on the novel mRNA platform. IP rights are not just tools for established players. SMEs rely on IP rights to secure financing in order to scale, and successful partnerships require clear IP ownership.

Europe has long been home to effective IP protection and enforcement frameworks and, critically, this remains the case today. However, numerous proposals to weaken European IP protection and enforcement frameworks are pending, and these must be carefully assessed. Positively, in Europe, the overall trend is towards regional coordination, which can improve efficiency, legal certainty and predictability and bolster innovation. Harmonization among European IP systems continues to grow, and this is expected to continue.

The trend towards centralizing aspects of patenting at the regional level boosts the EU's attractiveness for investment, including in biopharma.

IP systems in Europe were previously purely national in scope, with patents delivered and litigated country by country. The creation of the EPO (European Patent Office) in 1973 marked an important step towards harmonization in granting patents. The EPO was established to coordinate the review of patent applications when patents were still issued and litigated at the national level. Today, there are 39 signatories to the European Patent Convention. Since September 2024, European patents with effect in 25 EU countries began to issue under the new Unitary Patent System (UPS). The UPS has an associated Unitary Patent Court system, with specialized venues for litigating unitary patents in different fields of technology.

This trend towards centralizing aspects of patenting at the regional level boosts the attractiveness of the EU for investments including in biopharma. A proposal to centralize the granting of Supplementary Protection Certificates (SPCs) in Europe, linking SPCs not just to national patents but also to European unitary patents, is another positive step. This was proposed in the Commission's 2023 "IP package". SPCs help to offset the loss of effective patent protection resulting from delays in testing and regulatory approval for biopharma products.

Improvements in the ecosystem have been accompanied by threats – including some that are unintentional – to IP protection. For example, post-pandemic, the EU launched an effort to secure an EU-wide compulsory licensing regime; prior to that time, patents could only be compulsorily licensed country by country. The argument for an EU-wide regime was that, in the event of another health crisis, the EU could enhance efficiency as well as bargaining power if it had the possibility to override patent protection to provide access to the relevant technology for the entire EU at once. However, threatening compulsory licensing can signal to innovators that they should avoid investing in R&D or facilities in a given jurisdiction. Actual or threatened IP weakening can deter investment.

Regulatory data protection is a critical form of IP protection in the biopharma sector. The Commission's 2023 "pharma package" proposes downgrading the length of time for regulatory data protection, that is, the statutory period of time during which a competitor cannot rely on another company's proprietary test data to support their application for regulatory approval for their follow-on product. RDP provides separate protection from patents, in recognition of the additional time and cost required to generate test data. This cannot be kept secret from competitors because it must be submitted to authorities to demonstrate the safety and efficacy of new products. The pharma package proposal is for this protection to be reduced from a baseline period of eight years to six years. A modular approach would provide for potential extension to ten years, depending on various indicators such as addressing an unmet need, or launching in every one of the 27 EU Member States.

The pharma package also proposes amendment of the "Bolar exemption" to patent protection (and SPCs), which allows generic firms to carry out trials for the purpose of seeking regulatory approval before the patents on the relevant originator product expire. The proposal would expand the scope of the Bolar exemption in Europe so that generics and biosimilar companies can carry out "necessary studies, trials, and other activities" in view of regulatory approval – and also in view of engagement on pricing and reimbursement with health authorities. The proposal is likely to make it harder for IP owners to address possible imminent infringement and unlawful premature launches.

Unmet Medical Needs

The 2023 EU pharmaceutical package focuses, in part, on driving innovation for "unmet medical needs". It proposes incentives to bring treatments to society in cases where no treatment exists for a given condition, the introduction of a new treatment tackles high morbidity or mortality due to a given condition, or the innovator delivers an exceptional therapeutic advancement over an existing medicine. High unmet need is associated with "orphan medicines", that is, treatments that target diseases affecting a relatively small number of patients.

The pharma package proposes new incentives for the development of treatments for unmet and high unmet medical needs that include expedited regulatory approval, benefits linked to health technology assessments (HTA), and extension of regulatory data protection periods. However, the narrow definitions in the draft legislation – notably, "exceptional therapeutic advancement" – may undermine impact by (a) failing to direct investment towards conditions where it's most urgently needed, (b) inadequately rewarding incremental innovation for unmet medical needs, and (c) negatively impacting the selection of drug candidates in pipelines. Multi-stakeholder dialogue is needed to ensure the legislation delivers the intended impact.

The current scope and use of the Bolar exemption do not create obstacles to the timely launch of generics or biosimilars upon the end of IP protection. According to data from IQVIA, the generics industry launches at or near "day 1" of the expiration of IP protection in the four largest EU markets, with launches in other EU markets on a similar timeline[8]. Furthermore, the justification for expanding Bolar relates to the generation of health technology assessments for pricing and reimbursement. This is at odds with the reality that such data are not required of generics and biosimilars manufacturers. Whether for HTA or pricing and reimbursement, the burden is always on the innovative biopharmaceutical company that first launches a new therapy to generate and submit such data as required.

A weakening ecosystem for bringing new treatments to market makes it harder for European companies to stay invested in Europe while also remaining globally competitive.

The proposed EU changes to the Bolar exemption would likely make Europe less attractive for investment by innovator companies, and less resilient in terms of supply. According to recent EFPIA analysis, although shortages affect both innovative and generic medicines, only 4% of them occur for patented products. Once patents expire, shortages can become more common as healthcare payers' singular focus on lowering prices reduces the number of companies offering specific products. Pricing pressures threaten resilience, as healthcare systems and patients may come to depend on no more than a handful of suppliers operating at the limits of economic sustainability.

Enactment of patent linkage, which provides legal certainty to innovator companies and their competitors alike, should be a priority for Europe. With such a system in place, regulatory agencies do not approve the market entry of generic versions of products that are still under patent. Linkage at the European level could link EMA approval procedures with unitary as well as national patent registries. Currently, the EU is out of step with other jurisdictions that are home to significant biopharma R&D investments, because it lacks central patent linkage. The United States has a patent linkage system in place, as do many other countries. More recently, China has also taken steps to implement a linkage system.

Biotech Innovation and the EU Ecosystem

Maintaining a strong pipeline for innovation is the core focus of any biopharma company at the forefront of medical innovation. Strong R&D performance generates new health solutions and enables an organization to maintain a competitive edge.

At a national or regional level, a strong innovation pipeline requires a combination of research institutes, legacy companies and up-and-coming biopharma companies. A robust ecosystem features a range of potential partners and technologies for in-licensing, buying, and otherwise bringing to market, whether in partnership or in-house.

Unfortunately, right now in the EU, the ecosystem appears to be hollowing out as SMEs depart, leaving fewer chances for innovation collaboration and potentially undermining the entire European biopharma sector's performance over time. European legacy companies are committed to Europe – for instance, Merck has invested roughly EUR 2.5 billion in Germany in the past decade in R&D programs, workforce training, and manufacturing facilities in Germany. Merck's healthcare business sector, which brings innovative pharmaceuticals to society, maintains 12 out of its 18 manufacturing facilities in Europe. However, a weakening ecosystem makes it harder for European companies to stay invested in Europe while also remaining globally competitive.

First, innovation talent is leaving Europe. Anecdotally, senior talent from biopharma leaders is now routinely located abroad, notably in the United States. As for academic talent, studies tracking the movement of inventors find that many move from their European home base over time; for instance, a recent study uncovered a steady, sizeable outflow of academic inventors from Italy[9]. This brain drain offshores innovative and research capacity to other countries, undermining the competitive position of Europe[10].

Second, innovative biopharma small and medium-sized enterprises (SMEs) are leaving Europe. SMEs represent over 99% of all businesses in Europe, and they are critical drivers of growth and job creation, across sectors[11]. In biopharma, SMEs have an outsized role. Globally, early-stage drug development is increasingly driven by emerging biopharma companies with under USD 50-400 million in sales and/or under USD 200 million in R&D annual spending. These companies are responsible for 65% of the molecules in the global R&D pipeline[12]; 59% of trial launches 2021 were from emerging biopharma companies (compared to 29% in 2011), while large pharmaceutical companies accounted for 28% of trials.

Increasingly, these companies are choosing to situate their operations outside of Europe. The share of Europe-based emerging innovative biotech companies is small – around 20% of all companies globally – and declining steadily over time[12]. In comparison, 46% are located in the US, while China is home to 17%, a share that is rising rapidly.[12]

Investors interviewed for this paper believe SMEs are leaving Europe primarily due to a lack of financing options. US-based biotech companies accessed USD 62.5 billion in venture finance, compared with the USD 11.2 billion received by European companies (2021-2022). They also attribute the loss of innovative SMEs to the pull of robust biopharma hubs outside of Europe, particularly those located in the United States, and to the risk-averse culture in Europe which punishes failure in entrepreneurial ventures.

Private funding, such as venture capital and equity financing, is challenging to acquire in Europe. Particularly as companies get to Series B funding and require amounts above EUR 60 million, they all too often must move to the US. To encourage SMEs to stay in Europe, some have suggested tying funding to

M Ventures

M Ventures is a Merck-owned strategic venture capital fund that invests in emerging biotechnology and technology in the healthcare space, among other areas. M Ventures invests in and mentors global and European companies and entrepreneurial scientists solving pressing challenges in biopharma, helping them to reach commercial success. Its funding targets promising solutions in healthcare drug development, life science tools, electronics and frontier technology, and sustainability.

Figure 3. M Ventures in numbers

Source: https://www.m-ventures.com/

a contractual requirement that the company maintain operations in Europe. While this may work well at the early stage, the strategy would probably falter in the later stages of growth because the scale of funding needed is not available in Europe.

Public funding for innovative emerging companies in Europe has also been critiqued as fragmented and inadequate. Funding provided by Member States often requires that the projects be located in-country, rather than adopting a unified European approach. Several EU-level programs do exist to support small and medium-sized enterprises in biopharma, such as the Horizon Europe program, Directorate-General for Health Emergency Preparedness and Response (HERA), and EUREKA Eurostars. However, the programs provide insufficient funding to support the commercialization of promising health inventions. Facilitating matching could help; this involves private specialized investors carrying out the due diligence then providing finance to promising startups, with matching funds from public entities.

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Third, Europe is lagging in its creation of hubs and centers of excellence. This is noted in the Draghi Report, which points out that while there are biopharma hubs in Europe, such as BioValley in France and the Flanders region of Belgium, they do not reach the same scale as in other countries. Cambridge in the UK, or Boston in the United States, offer a rich environment where hospital systems interact with doctors, university researchers and professors, students, innovative startups, and financing partners. The Commission should work to create and coordinate the work of interlinking European centers of excellence for biopharma research and innovation clusters, bringing together universities and startups, while also boosting access to financing for collaboration and the commercialization of promising technologies.

There are specific actions that governments can take to establish favorable conditions for technology hubs to emerge. They can replicate strategies that worked elsewhere. In 2024, the World Intellectual Property Organization (WIPO) introduced a new methodology to support policymakers in assessing their existing national and local innovation capacity, then building on that to improve specific aspects of the innovation ecosystem in a targeted manner. Increased public funding, for R&D and also to support innovative SMEs, are examples of priority actions[13]. To illustrate this point, the Draghi Report cites Massachusetts, the US state that is home to the Boston biomedical hub. The report notes that Massachusetts receives 11.4% of US National Institute of Health (NIH) funding, a share much larger than its proportion of the US population (just 2.1%), to support this hub.

How to Create Innovation Hubs

The 2024 World Intellectual Property Report from WIPO offers valuable insights into the factors that contribute to the emergence of innovation hubs independent of the field of technology. WIPO research demonstrates that the concept of "relatedness" is at play in how an economy grows its innovative capacity over time[13]. Countries tend to develop capabilities in areas that leverage their existing innovation strengths. And regions tend to build out from areas in which they are already specialized, which was the case in Silicon Valley with information technology. Targeted policy actions can create a favorable environment for R&D, technology transfer, and manufacturing, by addressing gaps in areas like access to materials, technical skills, manpower, or regulatory frameworks, thus laying the groundwork for industrial development.

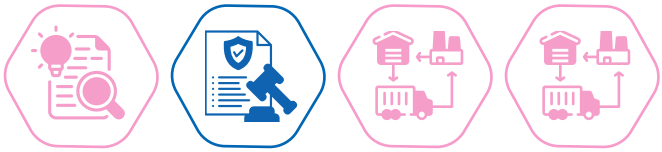
Fourth, the procedures in Europe for technology transfer, relied upon by universities and research centers for managing the patenting and licensing of promising research outcomes, are viewed by innovators as suboptimal. There is a need for deeper industry engagement with technology transfer offices (TTOs), to create stronger linkages with the marketplace, establish support and partnerships for commercialization, and potentially pool data. TTOs tend to focus on monetizing R&D outcomes rather than on guiding technology solutions to market in line with commercial realities. Due to this relative disconnect with the market, research with little commercial relevance may be prioritized while promising inventions are not taken through the necessary R&D, testing, and other steps needed to bring them to society.

Coordination if not harmonization of tech transfer rules for European universities and research institutes could provide more efficiency and legal certainty. Procedures for managing publicly funded R&D outcomes are not harmonized at the EU level. In the United States, the adoption of the federal Bayh-Dole Act provided for IP protection and the licensing of public research outcomes, stimulating massive commercialization of publicly funded R&D outcomes. Bayh-Dole is credited with launching over 1,000 innovative startups, creating 5.9 million jobs, and adding USD 865 billion to the GDP over a 22-year period[14].

The gap in R&D investment between Europe and the United States grew from EUR 2 billion in the early 2000s to EUR 25 billion in 2022.

Finally, innovation and tech transfer involving research centers and universities are underpinned by robust public funding for research. Public R&D plays a foundational role in the biopharmaceutical sector. The process of "blue skies" research, where real-world applications are not immediately obvious, can give rise to important insights about disease pathways. Outcomes from these research activities can then be translated into health technologies for patients, through tech transfer to companies or other partners with more experience bringing solutions through development and regulatory approval, and to market.

Europe lags behind other countries in public R&D spending. The Draghi Report notes that private R&D spending in Europe is also less than in other jurisdictions with strong innovative biopharma sectors, notably the United States. Overall, the gap in R&D investment between Europe and the US grew from EUR 2 billion in the early 2000s to EUR 25 billion in 2022[15]. To boost R&D expenditure, the Draghi Report endorses incentives like tax policies (such as the R&D Tax Credit or the Orphan Drug Tax Credit in the US, which are enacted at the federal level). In Europe, where tax policy is national, such incentives are less likely to be implemented. Moreover, European public funding is not coordinated at the EU level, which can result in duplication and sub-optimal targeting of R&D spend.



PART B. Regulations and Regulatory Approval Processes

IT and Data Regulations

Globally, companies in the biopharma sector are steadily digitizing their operations, and they are using information technology (IT) and other tools to accelerate R&D and other aspects of product development and commercialization.

For example, innovators use AI tools to more rapidly screen compound libraries, to enhance the efficiency of R&D programs, and to refine understanding of disease pathways. AI tools can also be used to facilitate diagnosis. As noted in the Draghi Report, unfortunately, Europe is falling behind in digital technologies including AI, with the bloc spending far less than the United States on AI research. And while the EU was a first mover globally in AI regulation, there is considerable uncertainty surrounding the AI Act. European biopharma innovators are struggling to anticipate how this legislation will affect their operations, particularly the use of AI for R&D and testing.

Companies are also combining the delivery of treatments and IT-enabled solutions for monitoring patients. These connected systems help optimize patient care while reducing time in hospitals and doctor offices. Data regulations, particularly those related to the collection and analysis of individuals' data and privacy, while not directed at the health sector per se, can affect the ecosystem for biopharma R&D and innovation, slowing the development of these offerings. Routine impact assessments focused on critical sectors could help policymakers avoid unintended consequences.

Biopharma companies are also applying sophisticated data analytics for supply chain monitoring, manufacturing, and other tasks. Data analytics rely on the quality and quantity of available data, and access to more quality data sets can drive better efficiency, improved performance, and more targeted innovation. Companies are creating data lakes containing their own information, while also creating platforms to share data with external partners.

The European Health Data Space (EHDS)

The EHDS is a platform that would combine data from across EU Member States' healthcare systems, anonymizing then making the information available in a standard format to improve health innovation and healthcare delivery. This is an important step towards making the EU a more attractive region for biopharma investment. It will bring Europe more in line with other jurisdictions such as the United States, where data is more readily accessible.

Policymakers must walk a fine line between upholding IP rights for data and, therefore, preserving incentives for generating data sets, on the one hand, and advancing the broadest possible access to available data, on the other hand. Initial proposals for the EHDS contained provisions that would mandate companies to share proprietary data about their research programs; these appear unlikely to remain in the final legislation. Clarity is required as to how secondary use data will be governed[16].

Among EU Member States, the Nordic countries are leaders in providing online record access (ORA) for patients. The large scale, international analysis of ORA in those countries carried out under the NORDeHEALTH project (Nordic eHealth for Patients: Benchmarking and Developing for the Future) resulted in the recommendation that ORA systems adhere to certain principles related to access control, patient and proxy access, and the rectification of errors and omissions[17]. Germany has also shown leadership not only in providing ORA but also in making data (anonymized) from its healthcare system available for R&D and other purposes. The Commission and EU Members can apply the learning from these experiences as they build out the EHDS and other data-sharing platforms.

Business Environment and Regulatory Coherence

European biopharma innovators are facing growing regulation targeting their sector, with biotech and healthcare regulations scattered across different governance levels within Europe. This often results in fragmentation and policy incoherence, creating an uncertain environment for investment in innovation.

Moreover, innovators are now confronted by a growing body of European horizontal legislation, that is, legislation that is applicable across sectors. Companies face interconnecting, overlapping EU regulations targeting sectors other than biopharma and enacted without consideration of the impact on health innovation. This web of regulations creates undue compliance burdens for biopharma companies and, in some cases, can even expose their confidential information to competitors. It undermines companies' ability to operate in Europe, by creating a less predictable and more complex business environment. European policymakers must aim for a simpler, more predictable and more coherent regulatory environment.

Regulatory incoherence is a problem across EU policy and legislative programs. One example is the EU Transparency Directive, which could require companies to share clinical trial data earlier in the development process. This could impact patenting strategies, forcing companies to file certain patents earlier in development in order to retain novelty. Premature sharing of clinical trials information can also undermine regulatory data protection, which takes effect only once a clinical dossier is filed, by forcing innovators to place information in the public domain before it can benefit from protection.

Policymakers must adequately consider the potential impact of environmental policies on the ability of companies to ensure a consistent supply of medicines for patients in Europe and abroad.

Environmental regulations also pose challenges for innovative biopharma companies. There is a need to balance the objectives of the EU Green Deal and the imperative to safeguard and improve health security for EU citizens. It is unclear how this balance will be maintained, given the lack of clear rules and expectations from EU policymakers as to how the green transition should be carried out. For example, legislative mandates that require companies to change their manufacturing processes or inputs make it necessary to seek regulatory approval for the new processes or inputs. This can take years to secure for the biopharmaceutical sector.

Policymakers must adequately consider the potential impact of environmental policies on the ability of companies to ensure a consistent supply of medicines for patients in Europe and abroad. This is, unfortunately, missing from the most recent EU Strategic Foresight Report (2023). If European biopharma companies can no longer manufacture in Europe due to unduly burdensome environmental legislation, this would set back resilience and the security of medicines supply.

In some cases, environmental regulations have timelines and approaches that are misaligned with conditions in the economy and with operational and regulatory dynamics. One example is Per- and polyfluoroalkyl substances (PFAS) regulation. Alongside action by the Commission (under Registration, Evaluation, Authorisation, and Restriction of Chemicals [REACH] and aligned with the Chemicals Strategy for Sustainability), the European Chemicals Agency is contemplating additional, far-reaching PFAS restrictions – so-called "universal PFAS restrictions" – following a proposal from five Member States. While the proposal exempts active pharmaceutical ingredients (APIs) from its scope, it fails to take into account the fact that PFAS components are critical in the manufacturing, packaging, and transport of medicines – and that there are no suitable replacements on the horizon. Any alternative replacement would need to be approved by regulatory authorities, through processes that would take between five and ten years. Also, it is worth noting that the definition of PFAS is not the same in the EU and US, which creates a risk of regulatory misalignment.

When promulgating green rules, the Commission is not consistently adhering to EU requirements for legislating, notably evidence-driven policymaking, and thorough and unbiased impact assessments. For instance, the 2024 Wastewater Directive appears unsupported by adequate data or a proper risk assessment; complete information related to its genesis and evolution has not been made public.

The Directive assigns responsibility for 80% of the cost for cleaning up water systems to companies in the cosmetics and biopharmaceuticals industries even though independent studies allocate just 10% responsibility to these two sectors[18]. It introduces a framework based on the "polluter pays" principle, with responsibility for the biopharmaceutical industry determined based on the consumption of medicines. The Directive does not focus on medicines manufacturing, for which companies have systems in place to ensure that only clean water is released.

The procedures for legislating in the EU include extensive consultations with affected stakeholders. This is necessary for anticipating and avoiding unintended consequences, and to ensure legislation is fit for purpose. In the case of the Wastewater Directive, dialogue with industry prior to legislating could have enabled policymakers to calibrate the rules so as to avoid possible interruptions to healthcare delivery. In the implementing phase of this legislation, engagement with industry will be critical to minimize potential supply chain disruption and risk to EU competitiveness.

Finally, companies face counterproductive regulations that are specifically directed at the biopharma sector. These proliferated during the last Commission. One example is the IP package, noted above, which endorsed an EU-wide compulsory license. Another example is the pharma package, which proposes a new EU Directive establishing an updated framework for regulating medicinal products for human use, and repealing existing Directives 2001/83/EC and 2009/35/EC. More recently, the Biotech Act was announced as a legislative priority of the current Commission; there is not yet clear content or parameters for this legislation, which is expected to be introduced during 2025. The Biotech Act, in combination with the 2025 Competitiveness Compass, offers the opportunity for the Commission to holistically address the challenges described in this report.

Effectively anticipating and monitoring the impact of EU regulations on the biopharma sector would bring significant benefits. The Draghi Report underlines the importance of EU governing bodies committing to ongoing monitoring and evaluation of policy actions. It also calls for ongoing dialogue with stakeholders, to inform policymaking and avoid unnecessary layers of regulation. In line with the Draghi Report, regulations should be assessed for their impact on biopharma competitiveness, and the Commission should consider carrying out regular competitiveness checks for this sector (perhaps every 5 years). It should track coherence across the broad range of regulatory initiatives that may affect the biopharma sector, by creating a dedicated European entity. A new Life Science Office could monitor policies and also assess their impact on the European biopharma sector's competitive position[19].

Boosting Regulatory Capacity

Formed in 1995, the European Medicines Agency (EMA) has steadily centralized the evaluation of regulatory approval applications for health products. During the COVID-19 pandemic, the EMA worked closely with counterparts in other nations to expedite the approval of COVID-19 vaccines and therapeutics, pioneering new approaches to information-sharing.

The EMA should permanently adopt the flexibility and practices deployed during the pandemic, including the submission of data using a rolling approach as it becomes available and, especially, international collaboration. It should pursue Memoranda of Understanding (MOU) with other World Health Organization-listed authorities, deepening ties through initiatives like the International Coalition of Medicines Regulatory Agencies (ICMA) pilot project involving the United States, Japan, Singapore, Korea, and Brazil, and replicating the US-EU mutual recognition agreement on veterinary products[20]. Mutual recognition agreements with close neighbors, such as the UK, could facilitate collaboration and efficiency. Ongoing workforce

training, ideally in conjunction with private sector experts, would also contribute to optimal performance at the EMA.

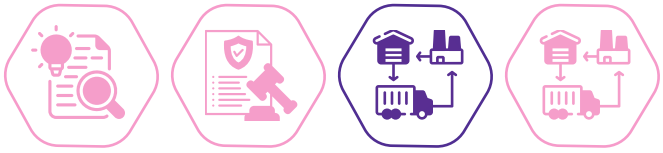
While it has historically shown leadership in areas like creating pathways for biosimilars to enter the market, the EMA follows other agencies more often than it forges a path in emerging areas of regulation. In contrast, the United States Food and Drug Administration (FDA) is a leader in addressing emerging areas; for instance, it is already in the process of developing non-binding guidance for the use of AI in testing. Also, the EMA reportedly provides for less interaction with applicants than does the FDA. Such exchanges proved critical during the pandemic for expediting the delivery of novel vaccines and therapeutics.

Evidence indicates the EMA is relatively less efficient than its peer agencies. Approval from the European Medicines Agency takes up to 28% longer than approval from the FDA (resulting in 430 days for a new product to reach society in Europe versus 334 in the US, on average). Because of this difference, and given that the US is a more lucrative and efficient market for introducing new health technologies, innovators tend to launch first in the US. The result is slower time-to-market for innovative treatments across Europe. Policy proposals that were included in the 2023 pharma package would compel the EMA to reduce the time it takes to evaluate dossiers from (on average) 210 days to 180 days, and to reduce the allowable time for granting or denying regulatory authorization by a third.

Clinical trials are an integral part of a novel treatment's pathway to market, and governments are eager to attract them. Trials can connect regulators and innovators earlier in the development process, providing an opportunity for them to discuss technical matters such as endpoints for testing. Despite the increasing number of clinical trials worldwide – growing 38% over the past decade – the European Economic Area's (EEA) share of trials has halved during this same period, falling from 22% in 2013 to 12% in 2023[21]. One explanation for this drop in clinical trials is fragmentation, since approval for clinical trials remains in the hands of individual Member States and can be slow. Europe-wide regulatory convergence around clinical trials could expedite the start of trials and help to speed time to market.

European policymakers are taking steps to attract more clinical trials to Europe. For instance, the 2022 Clinical Trials Regulation makes it possible to recruit clinical trials participants from across Member States. Cross-border recruitment enables innovators to recruit adequate cohorts of targeted patients, in line with the increasing specificity of treatments, and with suitable diversity. EU-wide collaboration to create an environment conducive to clinical trials is needed, and Member States should avoid adopting beggar-thy-neighbor policies to attract such investments.

The Commission should track coherence across the broad range of regulatory initiatives that may affect the biopharma sector, by creating a dedicated European Life Science Office.



PART C. Trade and Manufacturing

Manufacturing requires that companies create supply chains for sourcing consumables and equipment, establish manufacturing facilities, navigate the international trading system, and manage risks and possible supply chain interruptions. One device from Merck's portfolio, a reusable, electromechanical software-controlled auto-injector, consists of approximately 300 components, sourced from 60 suppliers based in 20 countries.

Strategies for Supply Chain Resilience

Prior to the COVID-19 pandemic, biopharma companies set up geographically distributed supply chains using approaches that maximized efficiency. This was possible in an era of globalization, relative certainty, and open trade. Supply chains were abruptly interrupted when the pandemic began, as borders closed to trade in goods and services, complicating transport, and countries enacted damaging export restrictions in response to the pandemic. As the crisis wound down, companies began reorganizing their supply chains to improve resilience. New risks continue to emerge, forcing companies to constantly adapt and recalibrate their strategies for supply chain management.

Today companies face overlapping sanctions regimes, armed conflicts, risks related to natural disasters and health crises, and rising geopolitical tensions. Poorly conceived trade policies with the potential to throw supply chains into chaos are still complicating the ability of biopharma innovators to develop and deliver health innovations. Today, companies proactively integrate risk management into their supply chain operations, alongside efficiency considerations, with increased resilience as the guiding principle.

In the years following the pandemic, innovators increased their use of data analytics to track supply, anticipate and manage shortages of consumables, equipment, and finished products, and appropriately allocate products to different customers. Modern IT platforms enable them to more seamlessly manage all aspects of supply and to hedge against interruptions.

Biopharma innovators have also adopted regionalization strategies, that is, the re-organization of supply chains along regional lines with built-in redundancy. They are double-sourcing critical inputs where possible. Companies use risk-based assessments, and focus on double-sourcing those inputs that are most difficult to replace in the event of an interruption. Nevertheless, some manufacturing inputs simply cannot be double sourced.

Localization policies that require companies to fully onshore supply chains for health technologies have not led to greater resilience or security of supply.

These strategies make it less likely that global supply will be dramatically affected in the event that one part of the supply chain is interrupted. Companies have significant visibility into potential gaps, and a strong focus on ensuring supply continuity for patients.

Policymakers can support the reinforcement of supply chains by expediting regulatory approval for alternative suppliers and components, and by maintaining open trade. Governments can work with industry – as the Administration for Strategic Preparedness & Response's Biomedical Advanced Research and Development Authority (BARDA) is doing in the United States – in order to identify gaps and risks in critical supply chains, for instance for antibiotics, then devise strategies to offset them. Promising measures to support supply chain resilience include the UK's Critical Imports and Supply Chains Strategy.

Localization policies that require companies to fully onshore supply chains for health technologies have not led to greater resilience or security of supply. The inevitable outcome of such policies, if they become widespread, will be to increase costs for all operators and healthcare systems, introducing inefficiencies that few countries can afford.

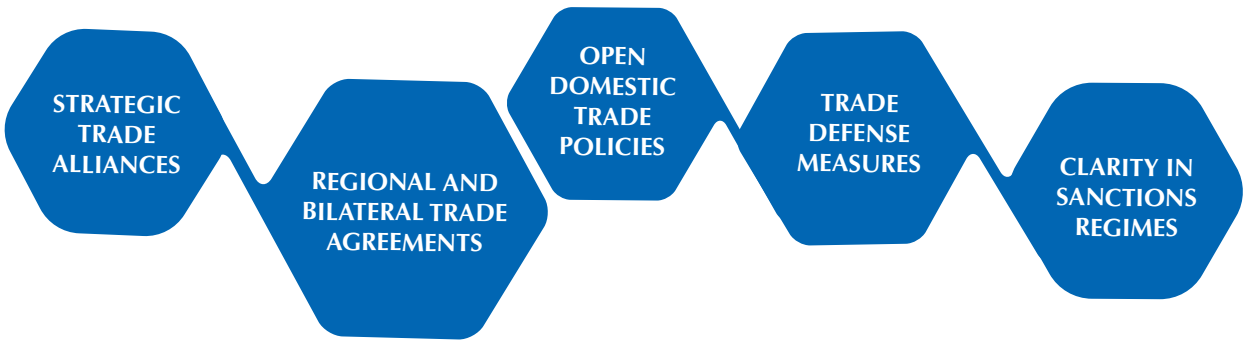
In the EU, there is little rationale for further localization. Data indicates that over 60% of the APIs that are used by innovator biopharmaceutical companies come from Europe, with 4% supplied by China. Analysis from the European think tank European Centre for International Political Economy and EFPIA reveals that the EU remains the largest exporter of pharmaceutical products, is resilient in pharmaceutical imports, and is not overly dependent on China for APIs (with China supplying 22.5% of the total API imported into the EU27, based on 2019 data)[22]. Other analyses highlight that while overall dependence on China is limited, it can be high for specific products or groups of products. This points to the need for a differentiated approach to addressing dependencies that is not based on the premise that there is a systematic problem to solve.

Stockpiling, like localization, is not a proven strategy for resilience or health security. While stockpiling manufacturing inputs may work in certain circumstances, stockpiling finished products often leads to overproduction and waste. Also, there are substantial financial and logistical challenges associated with the management of stockpiles, which is why the EMA does not endorse stockpiling in its guidelines on managing shortages. Rather, the EMA identifies stockpiling as a disruptive element that can distort the allocation of medicines to meet patient needs[23].

Companies choose to locate manufacturing and other activities based on the business case. Factors like effective IP protection, cost of energy, access to raw materials and components, the presence of a trained workforce, and appropriate trade policies (for instance, lower tariffs on upstream products required for R&D and manufacturing) can enhance the business case. An enabling policy environment helps to attract investment and can nudge the local industry, over time, towards higher value activities. In some cases, capex investments, tax relief, and other forms of industrial policy-related support further improve the business case for local manufacturing, positively influencing

An enabling policy environment helps to attract investment and can nudge the local industry, over time, towards higher value activities. Innovators require the right framework conditions in order to make investments in local biomanufacturing and R&D.

Figure 4. Elements of EU trade leadership



decision-making. More than cash handouts, though, innovators require the right framework conditions in order to make investments in local biomanufacturing and R&D. European policymakers must take into account – as do companies – the industrial policies of EU trading partners, especially subsidies and long-term strategic plans to build the biopharma sector.

The notion that more manufacturing capacity should be built in Europe then allowed to remain idle between health crises appears to have been largely discarded by policymakers. Governments can however encourage companies to maintain surge capacity. This aligns with the reality that excess capacity does typically exist across facilities. Companies leverage excess capacity as they constantly shift operations in response to changing demand and other factors. In addition, biopharma innovators may rely on trusted contract development and manufacturing organizations (CDMO) for production when in-house capacity is insufficient. Companies may also license their own idle production capacity to other companies.

Leadership on Trade

Geographically distributed biopharma supply chains are vulnerable in the face of diverse geopolitical and other risks. This means that a strategic, long-term European trade vision will be critically important for achieving health security, strategic autonomy, and competitiveness. Trade leadership has several facets:

Strategic trade alliances can facilitate access to raw materials, consumables and equipment, while helping to build influence among emerging countries. The Commission has taken action to strengthen access to raw materials with the Critical Raw Materials Act and Alliance. Free trade agreements (FTAs) and programs like the Global Gateway can cement alliances, as underscored in the Draghi Report.

Regional and bilateral trade agreements can upgrade IP protection and open up market access as well as investment opportunities. The Commission should continue to raise standards in its FTAs, while also paying attention to traditional elements of trade liberalization such as tariff elimination.

Domestic trade policies matter, and the EU should strive for consistency with its negotiating stances across forums. Its position in global forums like the World Trade Organization (WTO), for instance on IP rights, should align with domestic EU policies. There should be no export restrictions during future health crises, in line with the lessons from the pandemic.

Trade defense measures can help to maintain a level playing field. Here, caution is required, though, since trade wars can lead to cycles of retaliation and prove counterproductive to supply chain resilience. The US International Trade Commission (ITC) proactively supports American companies to address trade barriers and protect American intellectual property abroad. The creation of an EU Chief Trade Enforcement Officer in 2020 marked an important milestone in the development of the EU toolbox for ensuring trading partners uphold their obligations.

Clarity in sanctions regimes and in relation to other types of export restrictions, including those enacted on national security grounds, is essential. Extra-territorial application of sanctions regimes, and the proliferation of sanctions, has created major compliance challenges for companies across sectors. As is the case with domestic regulations, clarity is essential so that business leaders can plan and invest for the medium-to-long-term.

The EU should continue to exercise leadership at the WTO, safeguarding the multilateral trading system including dispute settlement procedures. It should reinvigorate the Trade and Health Initiative (TAHI), tabled in 2021 by the Ottawa Group of countries at the WTO. TAHI contains many elements that remain relevant, such as restraint in using export restrictions, enhanced transparency, trade facilitation measures, and actions to strengthen the resilience of supply chains and to create a foundation for responding to future health crises. EU trade leadership will be especially important in light of the current US administration's positions, and following the waning of US trade leadership in recent years.

National Security and Economic Interests

The blending of national security policymaking into economic activities is increasingly affecting companies in all sectors. The biopharma industry is particularly vulnerable to the effects of this trend, given the possibility of biological dual use technologies and the view across governments that this sector is critical to their citizens' welfare.

Unfortunately, national security decisions are often made independent of other parts of government. They can be hard to inform, much less influence, even when there will likely be detrimental impacts for commercial operators. Often this is because national security explicitly takes precedence over other considerations. As an initial matter, it is advisable that European policymakers consider the impact of national security actions on the economic prospects of critical sectors like biopharma.

Notably, European leaders are focused on China, and on "de-risking" economic relations in view of avoiding vulnerability, or "dependencies", that China could exploit. The EU has shown an appetite for using its trade defense tools, which include WTO dispute settlement, to manage its trade relationship with China and discourage protectionist trading practices. Such practices range from subsidies that generate overcapacity to judicial rulings targeting European IP rights, and from bans of European imports to biased domestic procurement processes that exclude European manufacturers. In January 2025, the Commission published findings from its investigation under the International Procurement Instrument, having determined that China's public procurement procedures discriminated against EU medical devices and suppliers[24].

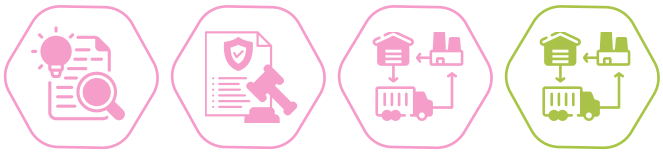
The blending of national security policymaking into economic activities is increasingly affecting companies in all sectors. The biopharma industry is particularly vulnerable to the effects of this trend.

Policies that risk fragmenting trade and data flows, including a trade war, are likely to set back European biopharma competitiveness and damage health security.

As is the case with any type of policymaking, rebalancing relations with China is not a black and white endeavor. Geopolitical and trade tensions could result in policies – enacted by China itself, or by European leaders – that cut China off from the rest of the world. This risk to supply chains has to be carefully managed. Companies manage risks related to supply chain interruptions using regionalization strategies and redundancy, as noted. The US has imposed restrictions on high-tech exports to China and added more companies to the entity list (by which the US Bureau of Industry and Security, within the Commerce Department, restricts trade with specific organizations for national security or foreign policy reasons).

European policymakers should tread with caution. For instance, the imposition of tariffs on imported Chinese electric vehicles (EVs) in 2024 sparked a nascent trade war with China that could ultimately affect the biopharma sector. Policies that risk fragmenting trade and data flows, including a trade war, could set back the European biopharma sector and ultimately damage health security.

China is increasingly home to cutting-edge scientific research, promising innovations, and potential partners for Western companies. McKinsey analysis of China's regulatory development and partnerships predicts a rise in "significant cross-border transactions", increased consolidation of China's innovation ecosystem, and a varied pipeline of novel modalities leading to an increase in international deals[25]. Already home to rapidly increasing biopharma ingenuity, as evidenced by the growing number of scientific publications, the Chinese government is steadily upgrading its regulatory capacity and IP protection framework. It will undoubtedly continue to focus enormous resources on building biopharma innovation and manufacturing capacity[26].



PART D. Medicines Supply Certainty

Following innovation and R&D, regulatory approval, and manufacturing, novel treatments and other health technologies are delivered to patients. In Europe, this occurs via national health systems. This part of the value chain is where companies, sometimes in coordination with governments, anticipate and manage shortages of inputs or finished products. The pandemic alerted officials from the EU and Member States to the need to more effectively plan for shortages, sparking the creation of public-private initiatives for this purpose. Governments and industry share a common goal: ensure the sustainable delivery of existing and innovative treatments and health technologies to patients.

Navigating Market Entry in Europe

Once a medicine has regulatory approval, typically granted by the EMA, it can be marketed across the EU (in addition to the EEA region). At this stage, developers of innovative health products face 27 different national pricing and reimbursement policies, along with varying capacities of the national healthcare systems to absorb the new treatment or health technology. EU Member States have different healthcare budgets and levels of economic development. This results in disparate launch times for EU Member States, with the speed of availability inversely related to the size of the country's health budget.

When European health officials resort to short-term cost-cutting measures for managing health budgets, this can create negative consequences for future investments in R&D and innovation in the EU. The large, unified market and favorable pricing and reimbursement policies in the United States make it a more appealing destination for commercializing innovations. The US offers the potential for greater returns compared to the challenges of navigating multiple pricing negotiations in Europe; this is particularly acute for generics producers, which operate on a high volume/low cost business model[27]. The disparity in market attractiveness is compounded by regulatory inefficiencies and longer approval times in Europe. This may be contributing to the exodus of innovative biotech SMEs from Europe, where funding is scarce and regulatory hurdles are high.

Last year, Germany was one of the many EU Member States facing medicines shortages. The then Health Minister Lauterbach acknowledged the role of governments in creating the situation: "Policies prioritizing cost-cutting and discounts have continuously worsened the drug supply for decades"[28]. Discount contracts and fixed-price regulations, with embedded cost-cutting requirements, contributed to the supply problems, as did the policy of German insurance companies to pay only for the cheapest supplier of generics based on contracts with fixed prices.

Across Europe, excessively low prices have made it difficult for many biopharma companies to stay in business. Reliance on manufacturing abroad has left Europe vulnerable to shortages when supply chains are interrupted.

> **Appropriate pricing enables innovators to re-invest earnings in R&D and innovation, while offsetting the many unsuccessful R&D projects that are a feature of scientific research targeting unmet health needs.**

Value-based pricing warrants more consideration across the board[29]. For now, pricing and reimbursement negotiations are based on health technology assessments, or HTAs. One step forward could be the development of EU-wide value-based procurement guidelines for Members that include criteria beyond price, such as environment standards and supply sustainability. Appropriate pricing enables innovators to re-invest earnings in R&D, innovation, and constant product improvement, while offsetting the many unsuccessful R&D projects that are a feature of scientific research targeting unmet health needs.

HTAs are evaluations of the cost-effectiveness of a new medicine and its likely impact on the healthcare system and budget. HTAs also assess the degree to which the disease targeted by the new medicine is prioritized by that government. They are carried out country by country, although the EU has now introduced the HTA Regulation which would allow for them to be carried out once, with the outcome applicable across all Member States for pricing and reimbursement purposes. Currently the parameters of each HTA, including the choice of comparator product, differ across Member States. The new EU-wide HTAs are expected to improve efficiency, starting in 2025.

Fragmented European Efforts for Supply Security

European policymakers are rightly concerned with ensuring the sustainable supply of medicines and other health technologies. To this end, they are seeking better visibility of biopharma supply chains, adopting new requirements and obligations for this purpose at both the EU and national levels. Such efforts have been plagued with fragmentation. This undermines effectiveness and efficiency, creating unnecessarily burdensome requirements for companies. Notably, each Member State has generated its own "critical medicines list" of priority products to track, with distinct reporting requirements and obligations such as local stockpiling.

Each Member State, and the EMA, have their own reporting obligations for supply chain security. Companies are requested to share information about the availability of different intermediate and finished products in their supply chains. This fragmented approach, coupled with complex data regulations such as the General Data Protection Regulation (GDPR) and uncertainty surrounding the EU AI Act, creates a substantial regulatory burden. Also, the focus on obligations rather than incentives risks making the European business environment less attractive to companies.

One challenging aspect of these reporting requirements is their application to business confidential information, such as the names of suppliers, or detailed information about available global manufacturing capacity. This information is not strictly necessary to anticipate and address potential medicines shortages. Further, each reporting platform uses different IT solutions, which are not inter-operable and, in some cases, not fully digitized. The platforms generally support the submission of a snapshot containing information that is quickly out of date, as opposed to real-time information.

Managing Shortages within Europe

EU policymakers are taking action to address shortages and build resilience, reflecting concerns about medicines shortages in recent years, and following the experience of the COVID-19 pandemic which highlighted the dramatic impact of supply chain interruptions for patients. Shortages have been the subject of numerous legislative initiatives, including Regulation EU 2022/123, which confirmed a "reinforced role" for the EMA in monitoring supply chains and mitigating shortages at the EU level, and for the EU Communication on addressing medicines shortages in the EU. The work of the Critical Medicines Alliance in 2024, which published its final recommendations in January 2025, is intended to pave the way for an EU Critical Medicines Act later in 2025.

Based on data from 2022 and 2023, shortages are most often attributable to unexpected changes in demand. A recent EFPIA internal survey revealed that the most frequent root causes of medicine shortages in the 2022/2023 period were unexpected increased demand, followed by manufacturing and quality issues.

In addition to agreeing on an EU critical medicines list, European policymakers should harmonize definitions like "shortages" and "demand". The Critical Medicines Alliance offers one avenue for improving coordination and reducing fragmentation across countries.

Attempting to prevent and mitigate stockouts, a number of European countries now require mandatory reserves of certain finished medicines (France, Finland, The Netherlands, Portugal, Switzerland, Germany, Czech Republic, Austria and Poland, Spain and Italy). France, for example, requires companies to hold two months of security stocks of their products in France if they fall under the category of medicines "of major therapeutic interest"[30]. Germany recently imposed a six-month stockpiling obligation for medicines. Failing to meet these requirements, or tapping into the stocks to serve patients, can result in significant fines and/or the public identification of the offending company by governments – even if no negative patient impact occurs.

These policies create a culture of protectionism at the national level when, in contrast, a single market approach would benefit Europe as a whole. To meet stockpiling requirements, companies must increase production, regardless of actual patient needs and with no guarantee that the production will be needed. This not only results in waste. It also introduces inefficiency into manufacturing and supply chain management. Furthermore, such regulations can prevent companies from reallocating excess stock from one European country to another based on patient needs, in real time. This can exacerbate shortages.

While dealing with shortages within the EU is not straightforward, it is entirely possible to facilitate the process more efficiently. Currently, if companies want or need to reallocate stock within Europe, products can only be re-boxed, relabelled, and shipped to another country under very specific circumstances and in facilities that comply with the relevant rules for good manufacturing practice (GMP). Such administrative and bureaucratic hurdles are not easy for companies to overcome in order to quickly respond to evolving needs within Europe.

EU policymakers should instead consider electronic leaflets to overcome the time-consuming, inefficient process of re-boxing and relabelling when reallocating supply within Europe. This might involve a QR code or other approach to accessing information that is stored online about the product, in different languages and in conformity with the labelling requirements for each Member State. Spain has been piloting this approach in relation to hospital products, which do not generally come with physical leaflets unlike products dispensed by pharmacies. Outside of Europe, Japan and Singapore are successfully piloting the use of electronic leaflets, and now additional countries like Thailand, Taiwan, and Korea are moving in the same direction[31].

Fragmentation can hinder efforts to ensure security of supply. European policymakers should harmonize supply chain policies and adopt risk-based solutions to increase reslilence. They should agree on common definitions like "shortages" and "demand", which should be based on documented patient need as opposed to market share or the latest orders. The Critical Medicines Alliance offers one avenue for improving coordination on such matters.

The Critical Medicines Alliance

Created at the start of 2024, the Critical Medicines Alliance (CMA) is an EU-level consultative mechanism bringing together representatives of EU Member States, industry, academia and civil society. The CMA's conclusions, published in January 2025, can play an important role in supporting effective, efficient action at the EU level to target medicines shortages. They can inform actions to address problems such as differential and incompatible reporting systems, and distinct critical medicines lists for different Member States.

The Role of the Critical Medicines Alliance

The Critical Medicines Alliance (CMA) was created to identify priorities for action and study possible solutions for strengthening the sustainable supply of critical medicines in the EU. To this end, two working groups worked in parallel. One focused on strengthening EU manufacturing capacity, and the other focused on the diversification of supply and international partnerships and cooperation, to secure materials and boost supply chain resilience.

Member States should reassess stocking requirements and allow for greater flexibility in reallocating medicines across Member States based on need.

The Critical Medicines Alliance provided a forum for dialogue between government officials and industry stakeholders at all levels. It helped to build trust and collaboration on shared goals related to the resilient supply and sustainable availability of medicines in Europe. CMA discussions focused largely on European manufacturing capacity, although this is just one aspect of sustainable availability. Securing access to raw materials and key components, negotiating trade arrangements that create new market opportunities and enable companies to set up resilient supply chains, and instituting an enabling policy environment for European biopharmaceutical innovation and leadership are also essential for ensuring sustainable access to the innovative medicines of the future. Moving forward, the platform could be strategically repositioned to address Europe's innovation capacity, a critical imperative in the evolving geopolitical landscape.

Member States should reassess stocking requirements and allow for greater flexibility in reallocating medicines across Member States based on need. The EMA Voluntary Solidarity Mechanism has been proposed by the EMA Medicines Shortages Steering Group (MSSG) as a way to facilitate intra-EU transfers of stocks, in limited circumstances and when all other measures have been exhausted[32]. Although not included in this mechanism, the pre-alignment of regulatory bodies can help to ensure that, in an emergency, red tape doesn't prevent shipping between EU Members.

section 4

Conclusions and Recommendations

With decisive, adequately funded strategies, backed by political will at every level of governance, European policymakers and stakeholders can deliver optimal conditions for a strong and resilient biopharma industry for generations to come. In doing so, they can reinforce the sector's competitive position and the health and well-being of European citizens. Reversing the worrying trends identified in the Draghi Report is entirely possible.

Below are six main recommendations for European policymakers that emerge from an assessment of industry trends, and of the global and EU-specific challenges for biopharma innovators today.

Identify the biopharma sector as a strategic priority for Europe. This is not merely an issue of economics and retaining a competitive industrial position – it is also about the prosperity and health of European citizens. Supporting the European biopharma industry safeguards access to future health innovations for the patients of today and tomorrow.

Reinforce public-private engagement to inform policymaking. Dialogue with the private sector enables policymakers to appropriately target legislative initiatives, while avoiding negative unintended consequences for critical sectors such as biopharma. Long-term objectives such as strategic autonomy, health security, technology leadership and competitiveness cannot be achieved without collaboration.

Create a simpler and more coherent EU regulatory environment. Policymakers should prioritize regulatory coherence and avoid creating undue regulatory burdens for biopharma innovators and their partners. A coordinating Life Science Office at the EU level can be created to track and evaluate the impact of various policies on the biopharma sector. All policies should be subject to a competitiveness assessment, and the Commission should carry out regular competitiveness checks.

Invest in the EU ecosystem for emerging and established biopharma innovators. The Commission should take steps to establish interconnected biopharma innovation hubs across the EU. It should work to increase the amount and coordination of public R&D spending in Europe, address funding constraints for SMEs, harmonize public-private tech transfer rules, and maintain strong IP frameworks to support R&D investments and collaborative ventures.

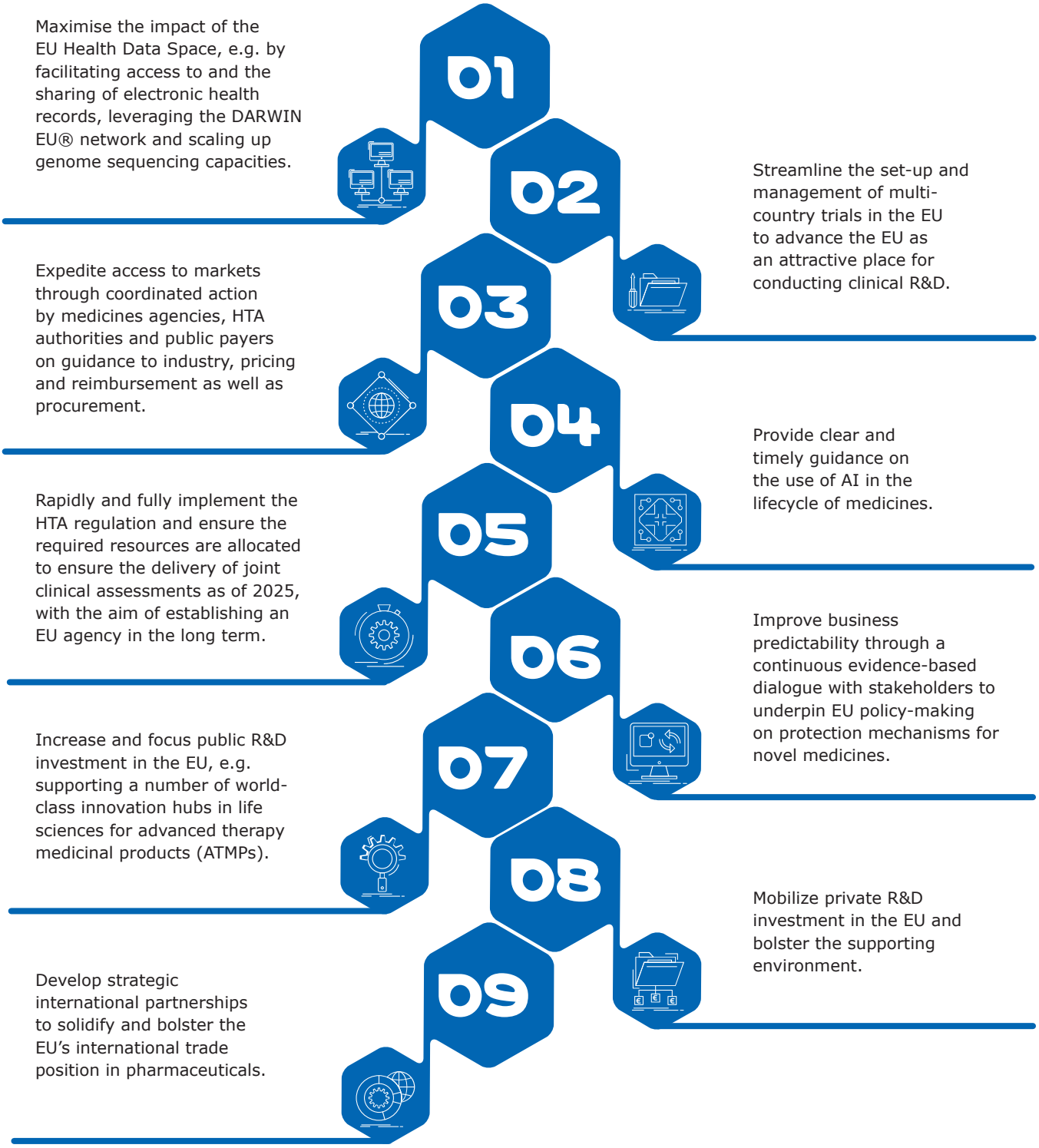
Reduce fragmentation in key areas like regulatory procedures and IP frameworks. Reducing fragmentation will enable companies to better benefit from the single market. Policymakers can build on successes like the EU-wide Health Technology Assessment, the Clinical Trials Regulation, and the Unitary Patent System. They can enhance coordination at the EU level, including by adhering to one common critical medicines list.

Adopt a balanced approach to economic security and the green transition. Policymakers must account for the impact of national security measures and green legislative initiatives on competitiveness, particularly for critical sectors like biopharma. Industry has the responsibility to brief policymakers about constraints, risks, and emerging best practices in biopharma supply chain management, and how these relate to sustainability and security-related policymaking.

Figure 5. Priority actions for European policymakers

Figure 6. Draghi Report recommendations for European biopharma competitiveness

Below are select recommendations from the Draghi Report (2024) to address the root causes of the EU's emerging competitiveness gap in biopharmaceuticals.



Source: Draghi, M. (2024). The future of European competitiveness Part B.

References

1. Domnick, C., Hervas, S. F., Gavigan, J., Moncada, P. C. P., & Rentocchini, F. (2023). A resilient, competitive, fair and sustainable EU: Industrial innovation for open strategic autonomy. *JRC Publications Repository*. https://publications.jrc.ec.europa.eu/repository/handle/JRC136221
2. European Commission. (2023). *Joint Communication to the European Parliament, the European Council, and the Council on European economic security strategy*. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023JC0020&qid=1687525961309
3. Draghi, M. (2024). *The future of European competitiveness Part B: In-depth analysis and recommendations.* European Commission. https://commission.europa.eu/document/download/ec1409c1-d4b4-4882-8bdd-3519f86bbb92_en
4. Letta, E. (2024). *Speed, security, solidarity: Empowering the single market to deliver a sustainable future and prosperity for all EU citizens.* European Council. https://www.consilium.europa.eu/media/ny3j24sm/much-more-than-a-market-report-by-enrico-letta.pdf
5. Draghi, M. (2024). *The future of European competitiveness Part A: A competitiveness strategy for Europe.* https://commission.europa.eu/document/download/97e481fd-2dc3-412d-be4c-f152a8232961_en
6. European Federation of Pharmaceutical Industries and Associations (EFPIA). (2024). *European pharmaceutical industry calls for competitiveness strategy and dedicated office for European life sciences.* https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/european-pharmaceutical-industry-calls-for-competitiveness-industrial-strategy-and-dedicated-office-for-life-sciences/
7. EFPIA. (2024). *The pharmaceutical industry in figures: Key data 2024.* https://efpia.eu/media/2rxdkn43/the-pharmaceutical-industry-in-figures-2024.pdf
8. EFPIA. (2023). *Assessment of main provisions and key EFPIA recommendations on the revision of the pharmaceutical package.* https://www.efpia.eu/media/gy5j1nkt/efpia-recommendations-on-the-revision-of-the-pharmaceutical-package.pdf
9. Karaulova, M., Kroll, H., Garcia Chavez, C., & Berghäuser, H. (2024). Researcher mobility and cooperation in the science system. *Studien zum deutschen Innovationssystem*, No. 9-2024, Expertenkommission Forschung und Innovation (EFI). https://hdl.handle.net/10419/284387
10. Sinha, K. (2007). Europe's brain gain. *Science*. https://www.science.org/content/article/europes-brain-gain
11. Thomson. (2024, September 10). *These charts show which businesses are driving the EU economy.* World Economic Forum. https://www.weforum.org/stories/2024/01/chart-drive-eu-economy-small-business-sme/
12. IQVIA. (2022). *Emerging biopharma's contribution to innovation.* https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/emerging-biopharma-contribution-to-innovation
13. WIPO (2024). *World Intellectual Property Report: Making innovation policy work for development*. World Intellectual Property Organization. DOI: https://doi.org/10.34667/tind.49284
14. AUTM. (2021). *AUTM's comments on 37 CFR Parts 401 and 404 (Docket ID Number: 201207-0327).* https://autm.net/AUTM/media/About-Tech-Transfer/Documents/AUTM-Comments-on-NIST-Bayh-Dole-NPRM-(Docket-no-201207-0327).pdf
15. EFPIA. (2022). *Europe's share of global medicines R&D shrinks by a quarter in 20 years – as sector's declining trends continue.* https://www.efpia.eu/news-events/the-efpia-view/efpia-news/europe-s-share-of-global-medicines-rd-shrinks-by-a-quarter-in-20-years-as-sector-s-declining-trends-continue/

16. EFPIA. (2024). *Position on regulation on the European Health Data Space (EHDS)*. https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/efpia-position-on-ehds/

17. Hägglund, M., et al. (2024). A Nordic perspective on patient online record access and the European health data space*. Journal of Medical Internet Research*, 26, e49084. https://doi.org/10.2196/49084

18. EFPIA. (2024). *EFPIA position on the Urban Wastewater Treatment Directive.* https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/the-urban-wastewater-treatment-directive-will-run-counter-to-the-commission-s-and-member-states-work-on-competitiveness-and-critical-medicines/

19. EFPIA. (2024). *A competitiveness strategy for European life sciences*. https://www.efpia.eu/media/fzkbhzoe/a-competitiveness-strategy-for-european-life-sciences.pdf

20. International Coalition of Medicines Regulatory Authorities (ICMRA). (2024). *Pharmaceutical Quality Knowledge Management System (PQKMS)*. https://www.icmra.info/drupal/strategicinitatives/pqkms

21. IQVIA, EFPIA. (2024). *Assessing the clinical trial ecosystem in Europe final report.* https://efpia.eu/media/3edpooqp/assessing-the-clinical-trial-ecosystem-in-europe.pdf

22. EFPIA. (2020). *Key trade data points on the EU27 pharmaceutical supply chain*. https://efpia.eu/publications/downloads/efpia/key-trade-data-points-on-the-eu27-pharmaceutical-supply-chain/

23. European Medicines Agency. (2023). *Good practices for industry for the prevention of human medicinal product shortages.* EMA/760980/2022. https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/good-practices-industry-prevention-human-medicinal-product-shortages_en.pdf

24. European Commission. (2025). *Factual findings of the IPI investigation on the procurement market for medical devices in the People's Republic of China*. https://ec.europa.eu/transparency/documents-register/detail?ref=COM(2025)5&lang=en

25. Algazy, J. et al. (2022) *Vision 2028: How China could impact the global biopharma industry*. McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/vision-2028-how-china-could-impact-the-global-biopharma-industry

26. Han, K., Deu, F. L., Zhang, F., & Zhou, J. (2021, October 29). *The dawn of China biopharma innovation.* McKinsey & Company. https://www.mckinsey.com/industries/life-sciences/our-insights/the-dawn-of-china-biopharma-innovation

27. EFPIA. (2022). *Medicine shortages*. EFPIA proposal of action. https://www.efpia.eu/media/676845/medicine-shortages-efpia-proposal-for-action.pdf

28. Kinkartz, S. (2023, February 18). *German health ministry confronts drug shortage*. DW.com. https://www.dw.com/en/health-ministry-confronts-germanys-dire-medicine-shortage/a-64733080

29. EFPIA. (2023). *A value-based approach to pricing. An EFPIA position paper*. https://www.efpia.eu/media/677284/a-value-based-approach-to-pricing-2.pdf

30. Medicines for Europe. (2024). *Medicine shortages and national stockpiling requirements in the EU*. https://www.medicinesforeurope.com/wp-content/uploads/2024/04/240327_Position-paper-stockpiling_FINAL3.pdf

31. Matsui, R., Yamaguchi, K., Lee, J. J. V., Ting, I., Khairilisani, D., Chang, J., Seo, J., Park, I., Chee, A. S. M., Quizon, P. M., Harnpramukkul, U., Sem, E., Nguyen, T., Padhye, A., & Mo, R. (2022). Survey results for e-labeling initiatives in Asia. *Therapeutic innovation & regulatory science, 57*(2), 251–260. https://doi.org/10.1007/s43441-022-00462

32. European Medicines Agency. (2023). *MSSG Solidarity Mechanism.* https://www.ema.europa.eu/en/documents/other/mssg-solidarity-mechanism_en.pdf

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