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Policy Brief

The European Biotechnology Renaissance

The Role of European Policy

By Vincent Clay, Cristina Moise and Katarzyna Szkuta

About this policy brief

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The policy brief builds on the insights gathered at the High-Level Policy Roundtable on 'The European Biotech Renaissance: The Role of European Policy' – convened by the Lisbon Council. The high-level roundtable brought together European decision-makers, researchers, investors, leading pharma companies and biotech startups and scale-ups.

The authors would like to thank all the interviewees listed in Annex 1 and the participants in the roundtable for taking the time to meet and share their knowledge and experience. Special thanks go to David Osimo for his valuable input and guidance.

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As the international order shifts from rules-based to more power-based, Europe needs to identify economic sectors where it holds strategic leverage in global markets. Biotechnology is critical in this respect, with pharmaceuticals serving as its primary commercial application and market sector. The pharmaceutical sector alone employs nearly one million people in Europe and remains the single largest positive contributor to the European Union's trade balance. Biotech is therefore no longer just a matter of pure innovation policy; it is now a vital strategic asset driving economic growth, public health sovereignty, international trade and national security.[1]

'Once viewed strictly through the lens of innovation policy, biotech is now a critical strategic asset driving economic growth, public health sovereignty, international trade, and national security.'

Yet, over the past decade, Europe's competitiveness in this area has steadily declined. The European Union has been overtaken by China and has fallen further behind the United States on several key performance indicators, including global clinical trials, new molecular entities being brought to market and venture capital investment in biotech. These headwinds are compounded by growing international protectionism, particularly in the United States, which threatens global supply chains.

European policymakers recognise the urgency. The European Commission has set an ambitious goal of positioning the European Union as "the world's most attractive place for life sciences by 2030."[2] Recent sector-specific policy proposals – such as the biotech act, the critical medicines act and wider initiatives including the startup and scaleup strategy, the scaleup Europe fund and the savings and investments union – signal a renewed political commitment to fortify Europe's life sciences ecosystem and restore its global competitiveness.

These policy measures undoubtedly help strengthen individual components of the innovation ecosystem. However, they do not yet resolve the systemic disconnect between fundamental research, venture capital financing, regulatory approval, market access and commercial scale-up. Even if Europe generates more scientific discoveries and mobilises additional capital, breakthrough therapies will inevitably be commercialised and scaled elsewhere unless the policy environment becomes radically more competitive, more predictable and more integrated.

The key questions are therefore: How can we make sure European policy initiatives are fit for the challenges and opportunities ahead? And how do we ensure their implementation keeps pace with fast-evolving markets?

1 European Federation of Pharmaceutical Industries and Associations (EFPIA), *Assessing Europe's Competitiveness as a Location for the Life Sciences Industry* (Brussels: EFPIA, 2026). Without the pharmaceutical industry, the European Union trade balance would go from a surplus of €133 billion to an €88 billion deficit. The latest Eurostat data show that both European Union pharmaceuticals exports (€366.5 billion) and imports (€145.5 billion) increased in 2025 compared to 2024.

2 European Commission, *Choose Europe for Life Sciences: A Strategy to Position the EU as the World's Most Attractive Place for Life Sciences by 2030*, COM(2025) 525 final, 02 July 2025.

This policy brief addresses these questions through desk research, interviews with experts and case studies of two leading biotechnology hubs (the United States, with a specific focus on the Boston ecosystem, and China) to benchmark Europe's current position. Based on this analysis, five structural challenges are identified and explored in detail:

1. Europe lacks the capital needed to scale high-growth companies. U.S.-based venture capital funds hold roughly six times as much as the European Union's €150 billion pool. This shortfall is most acute in late-stage growth financing. U.S. venture funds also allocate 11.4% of their capital pool to biotechnology, compared to just 7.5% in Europe.[3]
2. A complex regulatory landscape in Europe slows clinical trial approvals. For instance, regulatory and ethics approvals of clinical trials in the European Union take more than 100 days. While initial regulatory reviews in the United States and China can take roughly a third of this duration – partly enabled by 30-day implicit approval windows and parallel site-level ethics reviews – comprehensive comparisons of overall timelines are currently challenging to establish.[4]
3. Europe is not making full use of its clinical data. The high-quality, standardised clinical datasets necessary to take advantage of the artificial intelligence (AI) revolution are too often locked within fragmented, non-interoperable repositories that severely restrict cross-border access.
4. Biotechnology requires a dense ecosystem in which academic spin-offs, specialised legal service providers, leading university hospitals, deep venture capital and manufacturing infrastructure reinforce one another. Europe has several strong clusters, but they remain poorly connected, with competition within and across national borders often limiting collaboration and scale.
5. Finally, and fundamentally, if Europe is to become a global leader in biotechnology, it needs an end-to-end policy across the value chain that includes market conditions. Long reimbursement processes and delays, value assessments that focus narrowly on health outcomes rather than wider societal value and reference pricing all create challenges to successful commercialisation and therefore patient access.

To address these systemic challenges, this policy brief proposes a set of strategic policy recommendations. The objective is not to clone the U.S. or Chinese models, but to build on Europe's unique strengths with renewed ambition. Rather than advocating for incremental fixes, it argues for a unified European biotechnology strategy that seamlessly aligns industrial, innovation, capital market, trade, security and health policies.

'The objective is not to clone the U.S. or Chinese models, but to build on Europe's unique strengths with renewed ambition.'

3 Adam Baumann and others, "Europe's Venture Capital Gap and the Financing of High-Growth Firms," *ECB Economic Bulletin,* Issue 5, 2026.

4 An implicit approval is a regulatory mechanism where an application is automatically deemed approved if the regulatory authority does not issue an objection or a rejection within a strictly defined timeframe. In the United States and China, ethical approval is conducted in parallel at individual sites.

European Biotech Recommendations Roadmap

Challenge	Priority	Action
1 Lack of capital to scale	Mobilising significant long-term capital	• Complete the savings and investments union (SIU) to pool institutional and private capital. • Expand the European Union health biotech investment pilot designed to mobilise public and private capital for biotech startups and scale-ups into a long-term fund to close the funding gap between the European Union and the U.S.
	Anchoring capital investment and listings in Europe	• Introduce partial tax exemptions for corporate biotech investment. • Use tax incentives to encourage greater private investment in biotech research across Europe.
	Attracting global venture capital and founder talent	• Launch a unified *Choose Europe for Biotech* campaign and global investor roadshows. • Deploy fast-tracked national visa and return schemes for biotech founders.
2 Slow and complex regulation	Streamlining clinical trial systems to align with global benchmarks	• Reduce clinical trial approval timelines, harmonise ethics reviews and eliminate duplicate national submissions. • Strengthen the operational capacities of national medicines agencies.
	Expanding early dialogue pathways and regulatory sandboxes	• Expand early dialogue pathways and fast-tracked scientific advice at the European Medicines Agency, including providing adequate resources to the agency. • Facilitate access to regulatory sandboxes.
3 Fragmented health data ecosystem	Incentivising common data standards and operationalising the European Health Data Space (EHDS)	• Promote and incentivise the adoption of internationally recognised machine-readable data standards in Horizon Europe-funded projects to improve interoperability, data quality and reuse. • Integrate data standards through public healthcare procurement and support the upgrade of legacy databases.
	Incentivising sharing of historical clinical control data	• Introduce proportionate regulatory incentives to encourage the voluntary and protected reuse of high-quality historical clinical control data to support innovative clinical trial methodologies (such as synthetic control arms).

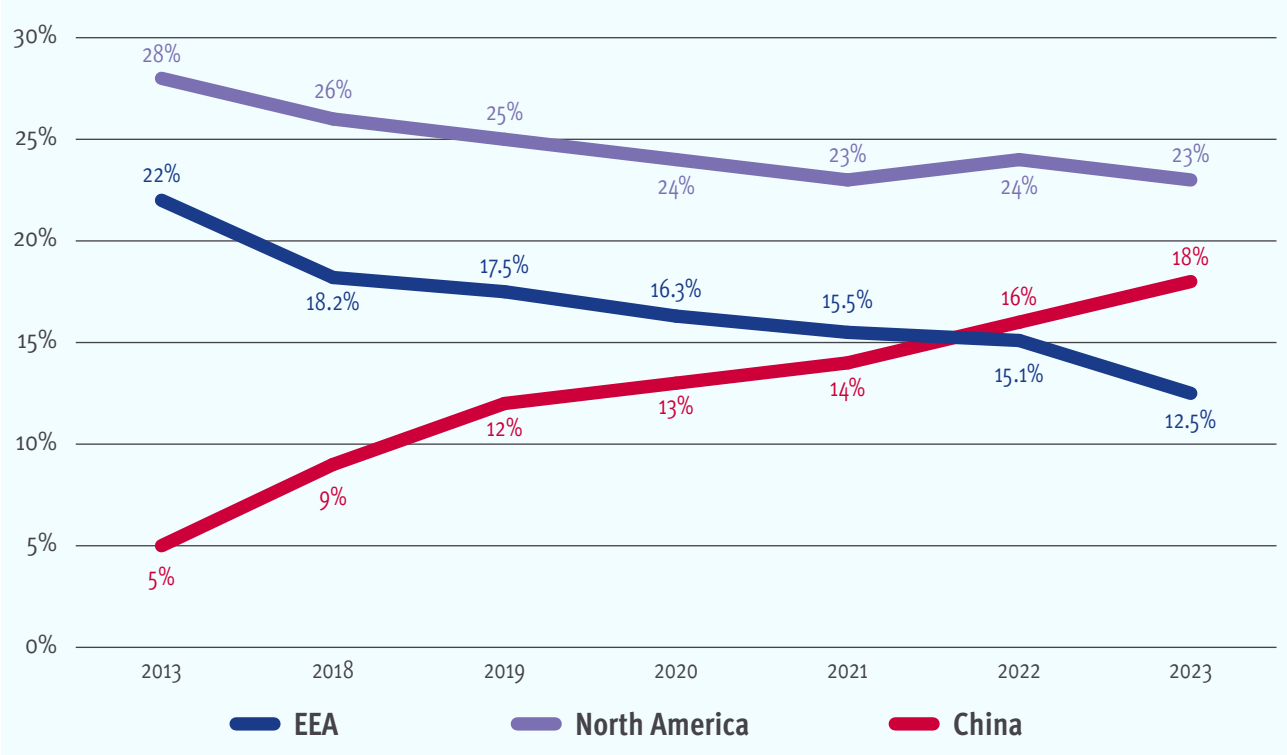
Challenge	Priority	Action
4 Weak connections and lack of critical mass of life sciences hubs	Interlinking regional clusters into a federated network	• Connect regional clusters into a federated European network supported by appropriately coordinated regional physical hubs ("connecting houses").
	Cultivating hybrid skills and standardising technology transfer office licensing	• Develop talent with combined wet-lab and digital/AI skills. • Standardise university licensing templates.
	Deploying cohesion funding to support emerging hubs	• Direct innovation-oriented cohesion funding toward clinical trial capacity in southern, central and eastern Europe. • Shift public grants toward subsidising access for startups rather than just one-off build costs.
5 Market access bottlenecks	Ensuring attractive intellectual property and exclusivity frameworks	• Align European intellectual property (IP) and exclusivity frameworks with global benchmarks to support long-term market predictability.
	Broadening value assessment	• Incorporate broader societal gains into health technology assessment (HTA) appraisals while accounting for immediate payer budget impacts.
	Addressing pricing and reimbursement barriers	• Improve market predictability and reduce access delays by fostering flexible pricing dialogues and outcome-oriented entry models across Member States.
6 Fragmented governance and policy misalignment	Creating a clear vision and end-to-end policy alignment	• Align European and national policy and implementation.
	Transitioning to agile stakeholder dialogues	• Transition to truly collaborative public-private structured dialogues.
	Centralising execution accountability	• Appoint a single, highly accountable individual or entity to drive implementation.

The Global Competitive Context: Policy Lessons from Boston and China

The pharmaceutical sector, biotech's primary market deployment, has long been a juggernaut of Europe's innovation, industry and trade. At first sight, its headline indicators look strong. In Europe, the pharmaceutical sector employs almost twice as many people as in the United States and China combined (950,983 compared to 350,500 in the United States and 202,008 in China), and it is a net exporter by a wide margin (€193.6 billion in 2024). Yet future-looking indicators, such as trend data and venture capital investment, reveal how these impressive achievements are under serious threat from increasing international competition. China is expanding rapidly across several measures, while the United States, despite moderate declines, maintains the leadership in most key indicators.

The share of clinical trials is one indicator of a region's capacity to translate early-stage scientific discovery into commercially viable and human-tested therapeutics while attracting global capital, top talent and clinical infrastructure. China overtook the European Economic Area (EEA) in the share of global commercial clinical trials in 2022, while North America managed to hold on to first place. Europe's decline is particularly steep, from 22% of global commercial clinical trials in 2013 to 12.5% in 2023.

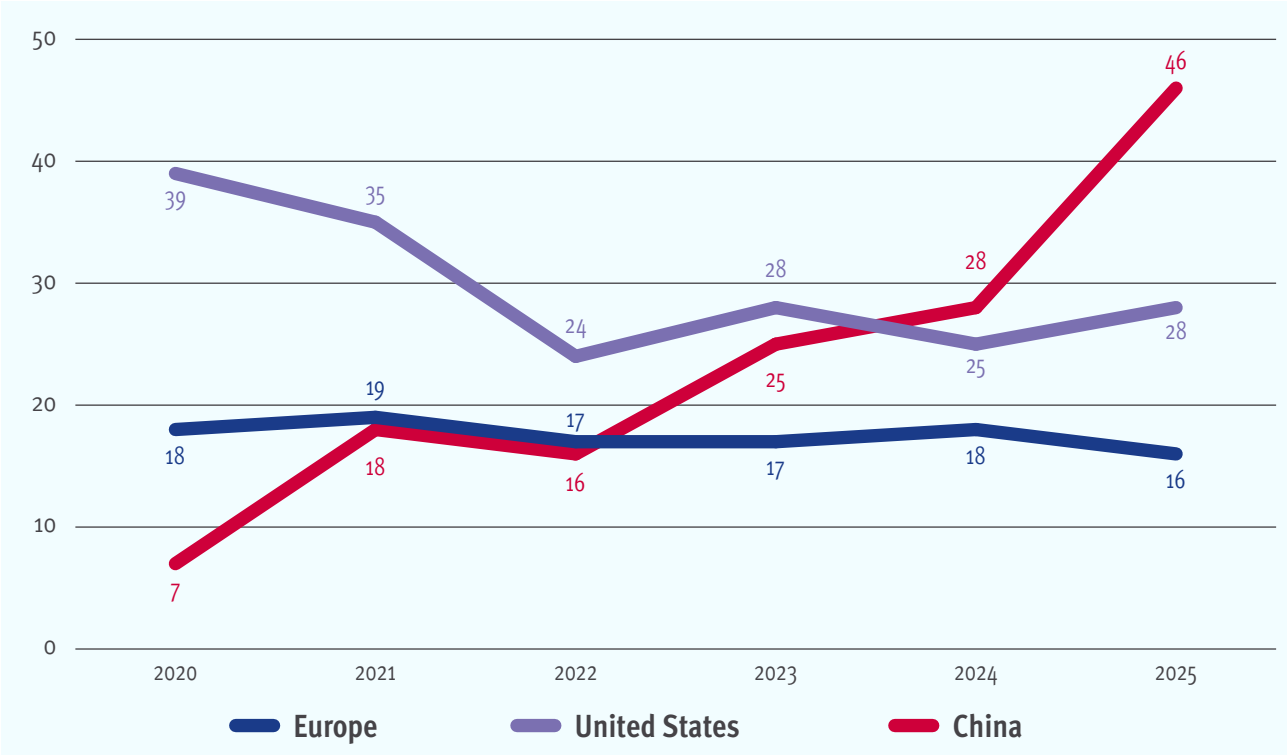
Figure 1. Share of global commercial clinical trial starts by region (phase 1-4), 2013–2023



Source: IQVIA, EFPIA and Vaccines Europe, *Assessing the Clinical Trial Ecosystem in Europe – Final Report* (2024).

The number of new chemical and biological entities developed serves as the ultimate measure of true upstream research and development (R&D) productivity. It signals an ecosystem's capacity to generate original, high-value intellectual property, rather than relying on minor reformulations or generic drugs. Of the 104 new chemical and biological entities launched globally in 2025, 90 originated in the European Union, the United States and China; Europe accounted for 16 new entities, while China, with 46 new entities (up from 7 new entities in 2020), beat the U.S. output of 28 to become the leading source.

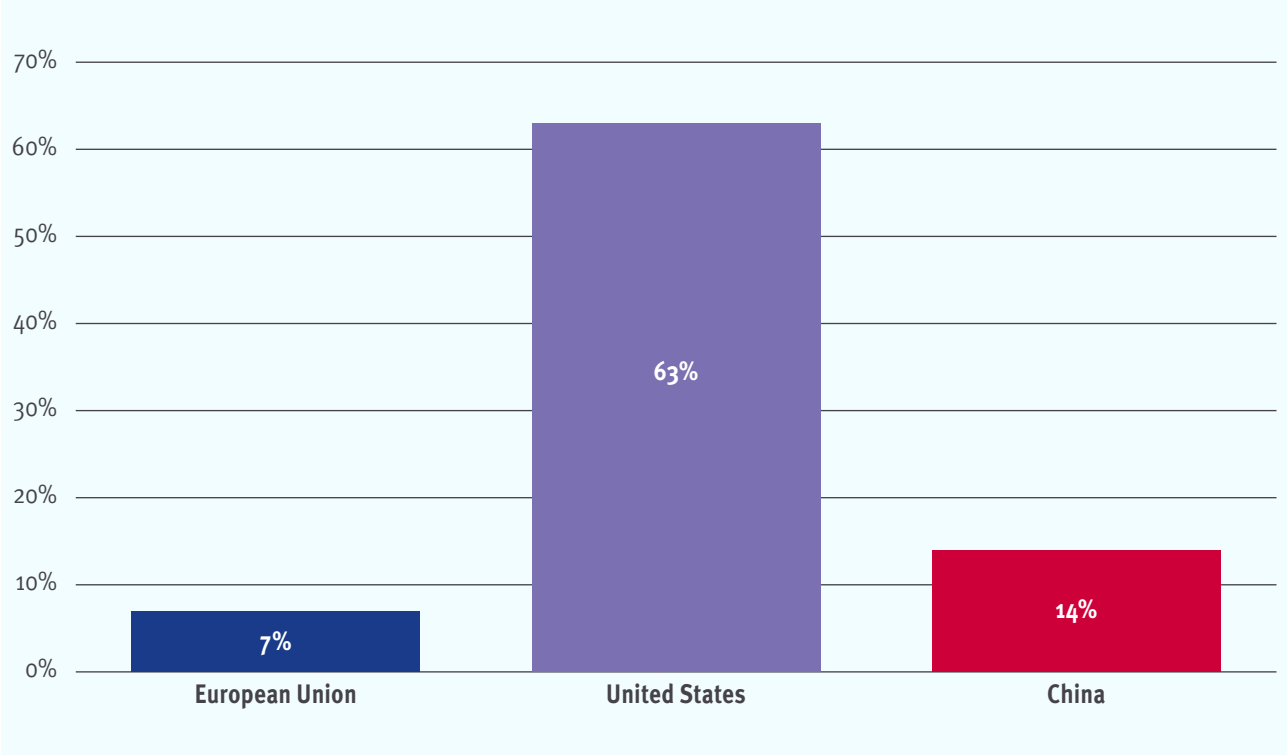
Figure 2. New chemical and biological entities, 2020–2025



Source: EFPIA, *The Pharmaceutical Industry in Figures 2026* (Brussels: EFPIA, 2026).

Venture capital investment provides a further important proxy of innovation performance. It reflects private market confidence in early-stage scientific breakthroughs, finances high-risk multi-year R&D pipelines and acts as a leading bellwether for future clinical progress, initial public offering (IPO) activity and big pharma acquisitions. The European Union's 7% share of global health biotech venture capital highlights the severe growth capital deficit facing European scale-ups.

Figure 3. Share of global health biotech venture capital



Source: European Commission, Directorate-General for Health and Food Safety, *Health Biotechnology in the EU – Figures,* n.d.

To better understand the reasons behind this lacklustre European performance, this section examines two of the world's leading biotechnology ecosystems: the Boston cluster in the United States and China's rapidly evolving national innovation model.

The Boston Model: Local High Density Paired with Federal Framework Conditions

The Boston life sciences cluster operates as an integrated innovation model combining concentrated public funding, close physical proximity and deep private capital. At the start of the value chain, the model is sustained by a concentration of federal public capital. Of the $48 billion annual budget of the U.S. National Institutes of Health (NIH), 9.4% (approximately $4.5 billion) flows directly to the state of Massachusetts (2% of the national population).[5] By comparison, the public annual R&D spending of all Member States on health research was €8.7bn in 2025 while the European Union's Horizon Europe programme allocates €8.2 billion for health research across its seven-year cycle (2021–2027).[6]

Public investment is complemented by downstream private venture capital funding (see Figure 3) and university spin-off mechanisms. In 2025, Massachusetts-headquartered biopharma firms secured $6.85 billion in venture capital across 197 investment rounds, representing over 25% of all U.S. venture funding. The average investment size in the state

5 National Institutes of Health, *Budget,* 13 June 2025.

6 Eurostat, GBARD by socioeconomic objectives 2025, European Commission, Directorate-General for Research and Innovation, *Horizon Europe: Investing to Shape Our Future* (Brussels: European Commission, 2021) p. 22.

was $34.8 million. Corporate R&D intensity among U.S. biopharma firms averages 23.6%, compared to a European Union average of 16.9%.[7] Companies in the Boston life sciences cluster account for 16.1% of the entire U.S. drug development pipeline and roughly 6.4% of the global total.[8]

'Academic laboratories, teaching hospitals, venture capital firms and commercial laboratory facilities operate within walking distance, reducing transaction costs and driving rapid knowledge-sharing for early-stage spin-offs.'

Physically, these dynamics are concentrated in places like Kendall Square, a hyper-dense innovation district engineered by the Massachusetts Institute of Technology (MIT) through long-term institutional land use.[9] Kendall Square hosts more than 120 companies within 2.6 km^2.[10] Academic laboratories, teaching hospitals, venture capital firms and commercial laboratory facilities operate within walking distance, reducing transaction costs and driving rapid knowledge-sharing for early-stage spin-offs.

The structural foundation of this life sciences cluster is also tied to local regulatory policy. Following national debates over the safety of recombinant DNA in the 1970s, the City of Cambridge instituted strict municipal oversight and high-containment requirements through its 1977 recombinant DNA ordinance. By establishing clear, predictable and publicly vetted safety rules, Cambridge gave early biopharma firms the legal certainty needed when investing in specialised local laboratory infrastructure.[11]

These local dynamics are further reinforced by national federal framework conditions. Enforceable patent rights lower investment uncertainty during high-risk discovery, with the U.S. system consistently leading the U.S. Chamber of Commerce's International Intellectual Property Index.[12] At the same time, the U.S. Food and Drug Administration (FDA) establishes clinical trial standards and expedited approval pathways that set global commercialisation benchmarks. It also plays an active role in facilitating innovation through extensive dialogue with innovators, which is essential for helping emerging enterprises understand the data that will be required to meet regulatory standards. The size of the U.S. medicines market provides a further advantage. Despite representing 4% of the global population, the United States accounts for approximately 60% of global pharmaceutical revenues compared to 13% of volume utilisation.[13]

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7 Elisabeth Nindl and others, *2025 EU Industrial R&D Investment Scoreboard* (Luxembourg: Publications Office of the European Union, 2025).

8 MassBio, *2025 Massachusetts Biopharma Funding & Pipeline Report* (Cambridge, MA: MassBio, 2026).

9 Massachusetts Institute of Technology (MIT), *Kendall Square Initiative,* n.d.

10 City of Cambridge Community Development Department, *Kendall Square – Cambridge Commercial District Assessment* (Cambridge, MA: City of Cambridge, 2024).

11 Robin Wolfe Scheffler, "Asilomar Goes Underground: The Long Legacy of Recombinant DNA Hazard Debates for the Greater Boston Area Biotechnology Industry," *Journal of the History of Biology,* 58.1, 2025, pp. 67–93.

12 U.S. Chamber of Commerce Global Innovation Policy Center, *International IP Index – 2026 Fourteenth Edition* (Washington, DC: U.S. Chamber of Commerce, 2026).

13 Sonal Parasrampuria and Stephen Murphy, *Comparing U.S. and International Market Size and Average Pricing for Prescription Drugs, 2017–2022* (Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, 2024). The data in this report do not include rebates, which play an important role in U.S. medicines, as well as in other regions. The evidence is broadly consistent with the 2018 finding that the United States is responsible for 64–78% of pharmaceutical profits, on the basis of 27% of global income. See also Dana Goldman and Darius Lakdawalla, *The Global Burden of Medical Innovation* (Los Angeles: Schaeffer Center for Health Policy & Economics, University of Southern California, 2018).

Despite its high output, the Boston ecosystem faces structural constraints and cost pressures that are reshaping its geographic and funding landscape. High commercial laboratory lease rates in central Cambridge are increasing operational overheads and encouraging companies to expand into surrounding areas. Over 50% of recent regional biopharma venture funding has flowed to expanding sub-clusters outside the traditional core, and while this creates additional space for growth, it potentially weakens the networking capacity and knowledge-sharing that underpin the ecosystem's success.[14] The broader U.S. venture capital market is also changing, with increasing selectivity towards late-stage assets. Following a peak in investment during the pandemic, the number of active biopharma firms fell from 977 in 2021 to approximately 750 in 2025.[15] This funding recalibration has created a sharp division between late-stage, clinical-ready assets, which continue to attract substantial capital, and early-stage preclinical startups. Early-stage ventures across the United States need to navigate these capital constraints alongside macroeconomic uncertainties, including federal drug pricing policies under the inflation reduction act, most-favored nation reference pricing measures and federal research budget adjustments. In addition, strict immigration policies like wage-weighted lotteries can also turn global talent away.

Finally, the ecosystem operates under broader macroeconomic pressures defined by Eroom's Law, a phenomenon where drug discovery efficiency halves roughly every nine years.[16] Average development costs in 2025 were $2.7 billion per asset (up from $2.2 billion in 2024), contributing to a contraction in novel chemical and biological entity approvals.[17] This efficiency gap is exacerbated when venture capital models apply short-term, software-style iteration timelines to biological systems that inherently require a 15-year therapeutic development lifecycle. In Boston, short investment horizons and rapid corporate exits foster an exceptionally fluid labour market. While high labour mobility allows companies to quickly move experienced talent to new ventures, this often fractures research teams prematurely. As a result, uncodified tacit knowledge accumulated through multi-year experimental failures is regularly lost, forcing companies to repeatedly rebuild research baselines at significant expense.

14 MassBio, *2025 Massachusetts Biopharma Funding & Pipeline Report* (Cambridge, MA: MassBio, 2026).

15 Ernst & Young, *2026 Biotech Beyond Borders Report* (Ernst & Young, 2026).

16 Scannell, Jack W. and others. "Diagnosing the Decline in Pharmaceutical R&D Efficiency," *Nature Reviews Drug Discovery,* 11.3, 2012, pp. 191–200 [accessed 20 September 2026].

17 Deloitte Centre for Health Solutions, *Measuring the Return from Pharmaceutical Innovation,* 04 May 2026.

The Chinese Model: Top-Down Industrial Policy and Cost-Efficient Delivery

The main global alternative to the market-driven, hyper-dense hub is an industrial architecture defined by long-term macro-planning and centralised coordination. Under the *Made in China 2025* blueprint and the *Healthy China 2030* initiative, the Chinese state explicitly frames the life sciences sector as a critical strategic asset to be leveraged for economic growth and national resilience. This clarity of intent has driven corporate business R&D expenditure (BERD) to €15.6 billion in 2024, supported by an impressive 19% annual growth rate since 2000. Physically, this top-down model concentrates infrastructure within three primary mega-regions centred on the Beijing-Tianjin-Hebei area, the Yangtze River Delta in Shanghai and the Pearl River Delta spanning Guangzhou and Shenzhen.

'The Chinese state explicitly frames the life sciences sector as a critical strategic asset to be leveraged for economic growth and national resilience.'

The defining structural innovation of the Chinese value chain is its approach to early-stage financial risk. While European startups face a severe capital blockage after seed rounds, Chinese municipalities deploy state-supported government guidance funds to co-invest directly alongside private venture capitalists.[18] In premier innovation parks like the Shanghai Zhangjiang Hi-Tech Park and the Suzhou Industrial Park (BioBAY) (which alone hosts over 3,800 biopharmaceutical companies), these funds actively absorb early-stage scientific risk. While state-directed guidance funds may carry risks – such as capital misallocation and bureaucratic inefficiency – this use of public funds to absorb early-stage scientific risk remains highly effective. Europe can adopt such a de-risking mechanism through market-driven European Union co-investment vehicles without replicating the top-down distortions of state-managed funds.

China has also developed mechanisms to improve exit opportunities and connect domestic companies with global pharmaceutical markets. When global public equity markets tightened, listing reforms such as HKEX Chapter 18A and the SSE STAR Market made it easier for biotechnology companies to access public equity markets. At the same time, cross-border licensing and partnerships with multinational corporations provide additional routes to capital and global market access. Commercial indicators from the first half of 2026 reveal global alliances born from this policy, including the Bristol Myers Squibb/Hengrui Pharma alliance valued at up to $15.2 billion and the Pfizer/Innovent Biologics partnership valued at $10.5 billion.[19,20]

18 Yifan Wei, Yuen Yuen Ang and Nan Jia, "The Promise and Pitfalls of Government Guidance Funds in China," *The China Quarterly,* 256, 2023, pp. 939–959.

19 Bristol Myers Squibb, "Bristol Myers Squibb and Hengrui Pharma Announce Strategic Agreements to Advance Innovative Medicines Across Oncology, Hematology, and Immunology," press release, 12 May 2026.

20 Rajasik Mukherjee and Sherin Sunny, "Innovent Biologics, Pfizer Strike $10.5 Billion Cancer Drug Deal Amid China Biotech Boom," *Reuters,* 29 May 2026.

China's highly regulated domestic market also creates incentives for local high-level innovation. While a centralised volume-based procurement system drives down the prices of generic medicines, China offers a counter-incentive for innovative medicines: fast-tracked, streamlined entry onto the national reimbursement drug list (NRDL) for original therapies that reflect high R&D risk.[21] The recent drug pricing reforms, in April 2026, mark a shift toward a value- and evidence-based ecosystem that balances patient affordability with the financial viability and global competitiveness of China's domestic biotech and pharmaceutical R&D, with measures including a new formal launch mechanism based on corporate self-assessments of clinical value.[22] These reforms are expected to evolve towards a more dynamic pricing approach supported by real-world evidence through a trusted evaluation network of 79 major medical institutions.[23,24] This serves as a powerful lever to conduct localised clinical trials and China-bound launches. Together, these measures strengthen the incentives for companies to develop and commercialise innovative medicines in China. This is already reflected in China's growing contribution to global drug innovation: Chinese-headquartered companies, including those based in Hong Kong, launched 46 new molecules on the world market in 2025 (see Figure 2).[25]

China has also strengthened intellectual property protection for innovative medicines. Amendments to its patent law have established a patent term extension structurally modelled on the U.S. baselines, offering a five-year extension and a 14-year post-market exclusivity cap. However, China treats its intellectual property framework as an explicit instrument of top-down industrial policy. This coordinated mechanism, reinforced by a 12-month market exclusivity incentive for successful local patent challengers, incentivises international developers to onshore primary clinical trials and sequence China as a first-tier market destination.[26]

Still, China's state-directed, hyper-accelerated model has run into some geopolitical, regulatory and structural barriers that are causing global innovators to rethink their strategies. To protect proprietary discoveries from a fast-following domestic ecosystem that uses published data to rapidly build superior within-class molecules, western biotech firms are increasingly moving from early patenting to prolonged trade secrecy.[27]

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21 The State Council of the People's Republic of China, "China to Further Reform Investment Approval System to Boost Efficiency," *English.gov.cn,* 15 April 2026.

22 – –, "China to Further Open Up Telecom, Biotechnology and Healthcare Sectors," *English.gov.cn,* 16 April 2026.

23 Fineline Cube, *"National Healthcare Security Administration Announces Nationwide Pilot for Real-World Medical-Insurance Value Evaluation," Fineline,* 23 September 2025.

24 VCBeat, "79 Medical Institutions Launch the First Batch of Real-World Comprehensive Value Evaluation for National Medical Insurance Trusted Evaluation Initiative," *vcbeathealth.com,* 19 January 2026.

25 EFPIA, *The Pharmaceutical Industry in Figures* (Brussels: EFPIA, 2026).

26 Aden Chen and Zheng Lu, "China's Pharmaceutical Patent Term Extension Cases Reveal New Landscape for Innovative Drug Protection," *Bird & Bird Insights,* 17 September 2025.

27 Tim Bodicoat, "Minding the Gap. What Does China's Biotech Boom Mean for the UK?" *Cancer Research Horizon,* 02 March 2026; Xavier Martinez, "U.S. Biotechs Are Keeping More Secrets to Beat Copycats in China," *Wall Street Journal,* 10 July 2024.

At the same time, the global regulatory landscape is shifting decisively with the enactment of the U.S. biosecure act under the national defense authorization act for fiscal year 2026, which strictly prohibits federally funded entities from partnering with specific Chinese biotechnology providers. Because an estimated 79% of global biopharma companies currently maintain contracts with China-based contract development and manufacturing organisations, this restriction may force a massive, systemic re-shoring of activities to friendly jurisdictions, possibly opening a short window for Europe.[28] Finally, Beijing's strict statutory bans on the cross-border export of human genetic material and multi-omic datasets have legally constructed an asymmetric digital data silo, making open international scientific cooperation more difficult.

Comparing the Boston and Chinese models

While neither the U.S. nor the Chinese model can be replicated in Europe, both offer important lessons. China's long-term value-chain upgrading and recent market reforms prove that even cost-conscious, highly managed systems are shifting to explicitly reward and differentiate high-level innovation. In the United States, highly capitalised, fast-moving clusters combined with its attractive and increasingly protected market, act as a catalyst exposing the collapse of Europe's traditional, slow "second-wave" launch model.

Ultimately, these contrasting market dynamics both show that biotechnology leadership requires an integrated ecosystem combining investment, regulatory agility, market attractiveness and industrial strategy. Europe has a unique opportunity to build on its scientific excellence by addressing the structural barriers that continue to limit companies' ability to scale, commercialise and manufacture innovation within the European Union. These barriers are explored in the following section.

'These contrasting market dynamics both show that biotechnology leadership requires an integrated ecosystem combining investment, regulatory agility, market attractiveness and industrial strategy.'

28 Biotechnology Innovation Organization, "BIO Survey Reveals Dependence on Chinese Biomanufacturing," 09 May 2024.

Table 1. Lessons learnt from the case studies

Challenge	The Boston Model	The Chinese Model
Capital & scaling	Driven by concentrated federal R&D public funding (NIH) paired with deep private venture capital. Characterised by high labour and real estate overheads, as well as capital pull toward late-stage clinical assets.	Underwritten by municipal guidance funds to systematically absorb early-stage scientific risk. Scaling and liquidity driven by targeted listing reforms and cross-border out-licensing.
Regulatory velocity	Governed by a statutory 30-day implicit approval system for clinical trials, supported by early FDA dialogues and accelerated pathways for prioritised assets.	Uses an agile 60-day implicit approval track for clinical starts, paired with the rapid integration of real-world evidence to speed up reimbursement timelines.
Data	Fragmented across proprietary private hospital networks and academic hospital systems, limiting large-scale and centralised clinical dataset aggregation.	Integrates real-world evidence from across institutions to support reimbursement decisions but enforces rigid statutory bans on cross-border data export, creating a digital silo.
Life sciences hubs	Anchored by hyper-dense urban clusters such as Kendall Square that provide walking-distance co-location and municipal regulatory certainty. Expanding geographically due to space scarcity and rent pressures, while high labour mobility risks losing uncodified tacit knowledge.	Consolidated within three state-directed, regionally supported infrastructure-heavy regions.
Market access and attractiveness	Powered by commercial market scale, single regulator access, facilitating innovation through regulatory dialogues and strong intellectual property protections. Constrained by rising drug discovery costs, federal drug pricing uncertainties and restrictive immigration policies.	Guided by long-term top-down macro planning. Uses volume-based procurement to reduce the cost of generic medicines while offering fast-tracked and stable pricing for original innovative therapies.

Strengthening the European Model by Addressing the Core Challenges

Europe's primary competitive failure is a systematic inability to scale frontier science into globally competitive, commercially viable, locally developed and launched innovations. Based on interviews with experts and data analysis (see the list of interviewees in Annex 1 and biotech competitiveness indicators in Annex 2), this brief argues that Europe faces five structural challenges across its biotech value chain: access to capital, regulatory velocity, data, life sciences hubs, and market access and attractiveness.

Access to Capital

When emerging European startups attempt to scale past initial seed and series A rounds, they are faced with a severe capital shortage. Early-stage funding in the European Union remains structurally over-dependent on public subsidies and non-dilutive grants, as local private investors often lack the specialised expertise needed to back pre-clinical assets. For firms trying to scale, the "series B cliff" is particularly acute.[29] In the United States, the series B threshold represents a stage of greater investor selectivity within a large growth-capital pool. In Europe, however, the problem is more fundamental: there is a scarcity of large, specialised growth funds capable of leading the major multi-million-euro rounds needed to finance clinical development and scaling. As a result, even scientifically validated European ventures that successfully secure clinical milestones lack access to local venture capital. This often forces them to seek capital elsewhere, accept lower valuations or pursue early sale rather than scaling independently. Between 2013 and 2023, European venture capital funds raised just $130 billion, compared to $924 billion raised by U.S. counterparts.[30]

At the same time, Europe has a large, underutilised pension and institutional asset pool. In 2024, European pension funds allocated just 0.01% of their total assets to venture capital, compared to 0.03% among U.S. public pension funds.[31] Tripling European allocations to match U.S. levels would inject nearly €1 billion in new venture capital annually into European tech, helping scale deep-tech and life-science startups while serving as a critical first step toward closing the broader €15 billion funding gap in European biotechnology.[32] Currently, this lack of deep domestic pools of patient capital stifles growth and forces European entrepreneurs to relocate to the U.S. or list on exchanges outside the European Union. Unlocking funding would also generate higher returns for pension funds from local innovation, ultimately strengthening investment yields for European pensioners.

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29 Seed funding is typically the first official institutional fundraising round. Series A funding is the first venture capital round after the seed stage. Companies that have gone through seed and series A funding rounds have already proven to investors that they are prepared for success on a larger scale. Series B funding is used to grow the company. Series B rounds often involve venture capital investors focused on scaling and may include a broader set of investors. The "series B cliff" denotes the sharp reduction in available follow-on capital as companies transition from early-stage proof-of-concept to capital-intensive clinical development and commercial scaling.

30 Nathaniel G. Arnold, Guillaume Claveres and Jan Frie, "Stepping Up Venture Capital to Finance Innovation in Europe," *IMF Working Papers*, 2024.146, 2024.

31 Atomico, *State of European Tech 2025* (Atomico, 2025), chapter: "Unlocking Capital and Liquidity."

32 Amsterdam Data Collective and Danish Bio, *Bridging the Gap – Transforming EU Biotech Policy: Challenges and Opportunities in EU Biotech,* commissioned by the Novo Nordisk Foundation (2025).

The financing gap is further compounded by tax environments across member states that fail to incentivise corporate venture capital reinvestment. At the same time, rigid national immigration procedures make it harder for European hubs to attract foreign biotech founders and displaced international research talent.

Regulatory Velocity

Europe is also facing a crisis in clinical trial competitiveness. Industry-led clinical research represents the vital engine through which scientific concepts are transformed into verified proofs of concept for growth investors. Yet, over the past decade, the European Economic Area's share of global clinical starts has plummeted from 22% to 12%. One reason is the administrative complexity of conducting trials across multiple European countries. Duplicated information requests and misaligned ethics committee reviews mean that multinational clinical trials within the European Union currently take an average of 113 days to secure regulatory and ethical approvals. While reviews in the United States and China are not readily comparable, 30 and 60 days respectively, initial regulatory-only reviews by way of implicit approval pathways allow for a quicker head start, although processing of ethical reviews is more fragmented in these jurisdictions and administered in a separate process.

'While medicines might be described as being of 'strategic' importance, fully realising this vision depends on closer alignment between European and national regulatory frameworks.'

Europe is also relatively slower to approve products than the United States: the median approval time in the European Union is 430 days, with just 9% of filings successfully using fast-track procedures, while in the United States, the median approval time is 356 days, with 59% using fast-track procedures.[33] These timeline challenges are closely linked to capacity constraints. During recent negotiations on reforming the European Union's general pharmaceutical legislation, many national regulatory agencies opposed faster approval timelines on the basis that national governments would not deliver the additional resources needed. While medicines might be described as being of 'strategic' importance, fully realising this vision depends on closer alignment between European and national regulatory frameworks.

The European Union is starting to use regulatory sandboxes through the revised general pharmaceutical legislation and the proposed biotech act. However, their impact will be limited if emerging biotechnologies – such as point-of-care decentralised biomanufacturing, multi-modal therapies combining artificial intelligence with bio-hybrid devices and custom "N-of-1" personalised genetic treatments for a single patient – continue to fall outside established regulatory pathways and face lengthy consultations, burdensome application procedures and stringent eligibility requirements. While existing initiatives such as the European Medicines Agency's priority medicines (PRIME) scheme should provide valuable early scientific and regulatory guidance for promising medicines, the European Union could

33 Juan Lara and others, *R&D Briefing 101: New Drug Approvals in Six Major Authorities 2015–2024: Trends in an Evolving Regulatory Landscape* (London: Centre for Innovation in Regulatory Science, 2025).

benefit from a broader and more systematic deployment of regulatory sandboxes. This would help de-risk innovation, support faster clinical development and improve regulatory predictability.

Additionally, while the rollout of the unitary patent provided a singular base layer, post-patent extension management remains fractured across individual national patent offices, requiring innovators to bear tracking costs, administrative friction and legal uncertainty. This can be simplified through the centralised supplementary protection certificate (SPC) reform package alongside the 12-month SPC extension for advanced therapy medicinal products proposed under the new European biotech act.

Europe nevertheless retains a major competitive strength in capital-intensive, high-precision manufacturing, even as this is being explicitly targeted by U.S. policy. The average gross value added (GVA) of European pharmaceutical manufacturing reached approximately €137.5 billion in 2024, accounting for 5.3% of total manufacturing GVA, driven by exceptional structural efficiency.[34] The pharmaceutical sector yields €124.03 in GVA per hour worked, vastly outstripping the baseline average of €51.28 across manufacturing as a whole. This sophisticated, high-yielding manufacturing base has taken on heightened geopolitical significance due to profound shifts in international trade policy.

Data

As artificial intelligence transitions from a speculative research tool into an operational necessity for advanced molecular design, the European Health Data Space (EHDS) could enable predictive AI models to be trained locally across federated, decentralised national repositories without the need to transfer the underlying raw files. This preserves patient privacy while offering a secure, unified dataset for computational biology. Yet vast repositories of historical clinical trial control data remain locked inside isolated corporate and academic silos governed by divergent national interpretations of general data protection regulation (GDPR) for secondary research. European Commission assessments indicate that electronic health record (EHR) systems across member states suffer from a "patchwork of incompatible exchange formats" that severely restricts cross-border data portability and secondary research.[35]

'Europe holds the world's largest repository of longitudinal public health data.'

Europe also holds the world's largest repository of longitudinal public health data. Fully operationalising cross-border health data access through the European Health Data Space (EHDS) is projected to unlock €11 billion in economic value over a decade, with €5.6 billion in direct healthcare savings and €5.4 billion in research and innovation efficiency gains.[36] Without structured incentives to aggregate this data, European clinical trials cannot

34 Eurostat, *Gross Value Added and Income by Detailed Industry* (NACE Rev. 2) [nama_10_a64]. The 2024 European Union average is estimated using the latest available data for the member states (2023: Cyprus, Germany, Latvia, Poland, Portugal and Spain; no data: Ireland, Lithuania, Luxembourg and Sweden).

35 European Commission, *Impact Assessment Report Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space,* SWD(2022) 131 final, 03 May 2022.

36 European Commission, SWD(2022) 131 final.

take full advantage of synthetic control arms to compress trial timelines, suppress rising costs and reduce patient burden. Finally, the success of the EHDS relies on building public trust and establishing transparent, secure and opt-out management systems that preserve data integrity while respecting patient agency.

Life Sciences Hubs

Rather than pooling finite public capabilities into a limited number of world-class centres of excellence, Europe dilutes its resources across overlapping, competing regional initiatives. These initiatives operate under fragmented national regulation, which increases their operating costs and triggers counter-productive internal competition, such as Munich competing against Berlin, or Flanders against Wallonia. This prevents regional clusters from collaborating to achieve global critical mass. Worse, these hubs fail to integrate capabilities across the wider Single Market: 88.8% of health data startups are heavily concentrated in western Europe, leaving eastern Europe with just 11.2% of the ecosystem.[37]

Academic incentives create a further barrier. Traditional academic evaluation metrics emphasise publishing output and peer citations rather than commercial translation or intellectual property development. This institutional misalignment is reinforced by university technology transfer offices (TTOs) that remain locked in slow, transactional negotiation models over patent maintenance fees, rather than fostering flexible licensing models similar to the Danish model.[38]

While Europe has successfully prioritised the capital investment required to build world-class research facilities, its current funding architecture – heavily reliant on the research and innovation framework programme and cohesion funds – is optimised for the initial construction or one-off equipment procurement. It consistently fails to support the essential, ongoing operational costs that allow these assets to function. As a result, many state-of-the-art facilities across the continent are trapped in a cycle of under-utilisation, unable to retain the specialised technical staff or maintain the high-frequency service levels required by biotech innovators.

This gap is most acute in advanced therapy medicinal products (ATMPs). Europe has strengths in foundational cell and gene therapy research, yet clinical development and commercial scale-up move elsewhere. Crucial translational infrastructure like vector manufacturing compliant with Good Manufacturing Practice standards, analytics and fill-finish was built using European Union funds, but facilities now run under capacity without instruments funding ongoing operations. For rare disease ATMPs, this capital-versus-operational gap is decisive. This requires a pragmatic policy evolution that supports operational longevity, ensuring that research infrastructure acts as a permanent, high-velocity engine for discovery.

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37 David Osimo and others, *Story 2 – Data-Driven Innovation and Drug Discovery,* in European DATA Market Study 2024–2026 (Brussels: European Commission, Directorate-General for Communications Networks, Content and Technology, 2024).

38 Annamaria Conti and Patrick Gaule, "Is the US Outperforming Europe in University Technology Licensing? A New Perspective on the European Paradox," *Research Policy,* 40.1, 2011, pp. 123–135; UCPH Lighthouse, *Licence Agreements for Your Spinout,* n.d.

Europe's life sciences hubs are nevertheless based on significant talent pools characterised by deep structural stability. Driven by a cultural valuation of long-term professional longevity and social market security, European teams demonstrate far greater retention over multi-year, complex development horizons. This low churn is a distinct macroeconomic asset: it renders Europe's R&D workforce structurally more cost-effective, predictable and resilient.[39] Despite upstream bottlenecks, this stable foundation contributes to European Union pharmaceutical manufacturing employment expanding at 3.4% annually since 2015 (versus a compound growth rate of 2.7% in total pharma employment), capturing a pool of 950,000 highly skilled professionals.[40] However, European and national policy measures should encourage science-industry flexibility to allow scientists and applied researchers to flow between academia and industry. Europe does not need to choose between team stability and career mobility: the goal is to make that stable baseline more permeable. By instituting standard dual-affiliation options and sabbatical frameworks, researchers can step into early-stage biotechs to transfer critical tacit knowledge without having to permanently leave academic tenure or long-term employment security.

'Europe does not need to choose between team stability and career mobility.'

Market Access and Attractiveness

To be "the world's most attractive place for life sciences," Europe must also be an attractive place to sell the products developed here. As previously noted, the United States provides around 60% of global pharmaceutical revenues from around 13% of volume utilisation. China has a rapidly evolving upstream biotech ecosystem and a "single" market of 1.4 billion people. Europe may offer a single regulatory zone for product approvals, but it is ultimately a collection of small-to-micro markets, with global market share ranging from ~4% in Germany to ~0.01% for Malta.[41] In this context, the appetite from the biotech sector for major reforms to Europe's market structure is increasing. This was demonstrated recently, for example, by over 200 commercial biotech ecosystem players calling for "a more competitive end-user market, which would allow European companies to grow sustainably, support the uptake of innovation and contribute to economic resilience."[42]

Europe's intellectual property framework for medicines provides protection broadly comparable to the United States and China, but the effectiveness of that protection is undermined by market reality. The 20-year standard patent life, which applies across all sectors, is supplemented by supplementary protection certificates (SPCs) for medicines, which partially offset the time taken between patenting and authorisation, capped at a maximum of 15 years from authorisation. A possible extension is now under discussion in the biotech act. Meanwhile, regulatory data protection also currently provides exclusivity for a medicine for 10 years from authorisation (eight years of regulatory data protection

39 Based on insights from the interviews carried out for the current paper.

40 Eurostat, *Employed Persons by Detailed Economic Activity (NACE Rev. 2 Two-Digit Level) (2008-2026),* [lfsa_egan22d].

41 Les Entreprises du Médicament (LEEM), *The Pharmaceutical Market Analysis in 2025: Analysis and Outlook* (LEEM, 2026).

42 European Life Sciences Coalition, *"Health Is Wealth": Why Europe Must Act Now to Strengthen Its Life Sciences Industry,"* joint open letter to European leaders (Naarden: European Life Sciences Coalition in association with Invest Europe, 26 June 2026).

followed by two years of market protection) rather than from the moment of patent filing, with a possible additional year for a qualifying new therapeutic indication. This means that it can still be worth investing in development of medicines with limited remaining patent life. However, baseline protection will be reduced from 10 to nine years when the new general pharmaceutical legislation enters into force.

Certainty is further reduced by fragmented, member state-specific reductions in case of product unavailability nationally. Thus, the European Union's maximum protection periods may be comparable with those of the United States and China, as described earlier. However, unlike those jurisdictions, a substantial portion of a medicine's commercially exploitable period of exclusivity is lost to reimbursement processes and negotiations after authorisation: the EFPIA Patient W.A.I.T. Indicator identified a median time of over 500 days for new medicines across member states.[43] In this context, the additional year of SPC protection (subject to eligibility criteria proposed by the biotech act) still only partially offsets these reimbursement delays. Predictable intellectual property frameworks should be viewed as anchors for industrial retention. In return for predictable exclusivity baselines that allow long-term clinical planning, Europe creates the necessary conditions for companies to invest in advanced manufacturing, clinical trial infrastructure and high-value research jobs within member states.

Of course, Europe's public health systems need to manage their costs. Addressing market bottlenecks does not mean ignoring the immediate fiscal constraints of national healthcare budgets. Rather than forcing member states to bear unmanageable upfront costs, health authorities and industry should expand outcome-based reimbursement models and dynamic pricing models. These approaches can help manage short-term public funds while rewarding genuine long-term societal value. Yet, decision-making on health expenditure is consistently disconnected from decision-making on industrial priorities – hence this brief's horizontal recommendations that emphasise dialogue and the development of clear strategic direction from a cross-government and joint European Union/member state perspective. More directly, this brief identifies two measures that can be seen as particularly constraining the market for life-changing innovation in Europe today.

Firstly, Europe's health systems seek the best (direct) health outcomes within a limited budget, and most are characterised by a strong focus on achieving "value" from therapeutic interventions through health technology assessment. For example, if a therapy can reduce future costly hospitalisations, it can generate savings within the health system, and this contributes to the "value" of the product as seen by the payer. This is a rational approach by the payer to manage limited budgets. However, the benefits for wider society (and wider government, from reduced social care expenditure to increased productivity and thus increased tax revenue) are not fully captured. These spillovers can be difficult to measure and value, but not impossible – and the persistent failure to do so results in lose-lose-lose outcomes for producers, governments and society as a whole.

43 Max Newton and others. *EFPIA Patients W.A.I.T. Indicator 2025 Survey* (Brussels: European Federation of Pharmaceutical Industries and Associations, 2026). https://www.efpia.eu/media/mnfdwzax/efpia-patients-wait-indicator-2025.pdf

Secondly, international reference pricing (IRP) is another tool to manage medicine prices and budgets, used by almost all European member states. However, the current rigid application of IRP can create unintended barriers to access. With the risk of lower prices in less wealthy countries being used as references in wealthier markets, manufacturers may be reluctant to enter less wealthy countries in the first place. Compounding this issue, access in those same member states is being affected by the still-evolving introduction of IRP in the United States. A lower price in a relatively small European market may result in reduced revenues in the dominant U.S. market, creating an additional reason to delay or not launch at all in the referenced European country.[44] China's "industrial policy first" approach, on the other hand, has led to premium, evidence-based pricing explicitly designed to attract early-stage launches and build its domestic ecosystem. The historical model in which Europe secured economic value from medicine exports while constraining domestic prices has run its course.

'The historical model in which Europe secured economic value from medicine exports while constraining domestic prices has run its course.'

This should not lead to a European discussion that focuses only on medicine prices – but rather to strengthening the conditions that make Europe an attractive and predictable environment for biotechnology investment and innovation. This requires making better use of existing resources while ensuring that health, industrial and innovation policies work together to support Europe's long-term competitiveness.

The next section offers a positive reform agenda that improves market predictability, accelerates patient access and strengthens Europe's attractiveness as a place to develop, launch, scale and reinvest in innovative medicines.

44 Maggie Fick, Bhanvi Satija and Dominique Patton, "Drugmakers Delay Some European Launches with a Wary Eye on Trump's Pricing Policies," *Reuters*, 31 March 2026.

Strategic Policy Roadmap

The following recommendations offer an integrated, end-to-end competitiveness agenda organised around the five identified challenges, complemented by horizontal measures. This framework shifts the legislative focus toward structural solutions designed to unlock capital, accelerate regulatory velocity, standardise clinical data and scale regional innovation hubs into a unified global competitor.

1. Lack of Capital to Scale

Europe must look beyond public grants, continue the creation of guarantee frameworks and scale-up funds, and actively forge a deep, liquid financial ecosystem capable of sustaining capital-intensive, 15-year drug development cycles. Resolving the severe series B cliff requires pulling long-term public and private capital into the venture market while simultaneously creating strong fiscal incentives for companies to scale and list domestically.

1.1. Mobilising Significant Long-Term Capital

The European Union must unlock large pools of long-term institutional capital such as pension funds and insurers. This requires completing the ambitious savings and investments union (SIU) that combines European, national and private investment. For the SIU to deliver for life sciences, future financial instruments must explicitly designate biotechnology as a critical technology, placing biotech scale-ups on an equal footing with other strategic sectors in investment prioritisation. Following the recent establishment of the European Union scale-up fund, it is essential that the biotech sector is prioritised as a core focus area.

The European Union health biotech investment pilot (announced in the biotech act) should evolve and expand with the goal of fully closing the investment gap between the European Union and the United States, while the European Commission should ensure that all funding mechanisms remain structurally open to a wide array of actors, including small- and medium-sized enterprises (SMEs), startups, scale-ups and mid-caps.[45]

National funds must coordinate directly with large investors, like pension funds, to co-invest in growing biotech companies. By sharing the financial risk, this collaboration makes it safer for private capital to back mature startups, helping them reach the scale needed to qualify for massive investments at European Union level, similar to the mechanisms outlined in Italy's CDP venture capital industrial plan.[46]

45 The new health biotech investment implemented by the European Commission in partnership with the European Investment Bank provides a toolbox of financial products to support biotech companies, including startups and SMEs. It aims to mobilise private investments, strengthen the availability of long-term risk finance, and anchor growth and manufacturing activities in the European Union. It is established for an initial period of two years, subject to review.

46 CDP Venture Capital, "CDP Venture Capital: Target of 8 Billion Asset Under Management by 2028 Focusing on 7 Strategic Pillars for the Country's Economy," press release, 8 April 2024.

1.2. Anchoring Capital Investment and Listings in Europe

To halt the systemic flight of European innovators seeking liquid public equity markets to non-European exchanges, member states should rapidly develop structural countermeasures that reward domestic independence, European Union listings and corporate risk-taking.

A critical first step in this strategy is driving a greater take-up of targeted corporate venture capital (CVC) incentives, specifically through partial tax exemptions on dividends and capital gains derived from qualified corporate investments. Mirroring successful domestic frameworks in France and Spain, this fiscal mechanism encourages established companies to systematically reinvest corporate liquidity back into Europe's high-growth biotechnology companies.

This initiative must be paired with reflection on the effective design of tax incentives encouraging greater private investment in biotechnology research and innovation across Europe.

1.3. Attracting Global Investment and Founder Talent

To strengthen domain expertise in the developing regional ecosystems and capitalise on global talent, Europe must position itself as a highly predictable, high-yield alternative for displaced international researchers and entrepreneurial talent.

The European Union must do more to make specialised international venture capitalists aware of its inherent structural advantages, specifically its significantly lower R&D overhead and superior workforce longevity and cost-efficient development environment. This must be reinforced by launching a unified *Choose Europe for Biotech* initiative alongside fast-tracked national visa and return schemes tailored for international biotech founders. Similar to the *Choose Europe for Science* campaign, it should aim to actively capture world-class entrepreneurial talent displaced by foreign regulatory restrictions or basic science budget cuts.

2. Slow and Complex Regulation

Europe must establish an innovation-friendly, innovation-anticipatory regulatory framework that positions administrative efficiency and reduced timelines as a core strategic capability. Regulatory capacity directly influences where global clinical trials are conducted and where frontier therapies are commercially scaled.

'Regulatory capacity directly influences where global clinical trials are conducted and where frontier therapies are commercially scaled.'

The biotech act proposes a more targeted intellectual property framework, anchored by the supplementary protection certificate (SPC) extension, to offer long-horizon growth investors greater legal certainty across the single market, provided that eligibility criteria are attainable.

Crucially, to translate this certainty into real-world market access, this legislative anchor must be paired with administrative speed across the broader regulatory architecture.

2.1. Streamlining Clinical Trial Systems to Align with Global Benchmarks

To reverse the decline of Europe's share of global clinical trials, the European Union must prioritise the acceleration of clinical trial authorisation processes across countries. By operationalising the biotech act's proposed timeline reductions, Europe can improve predictability and efficiency while maintaining robust safety standards.

This can be achieved by systematically addressing regulatory bottlenecks, including preventing duplicated national assessment. In addition, encouraging member states to reduce and harmonise national ethics committee timelines will further streamline assessment workflows and reduce overall trial approval delays.

Finally, the European Union and member states must reflect on how to better resource and upgrade national medicines agencies. Ensuring that all member states possess the operational capacity for parallel validation, rapid processing of substantial modifications and emergency procedures will enable Europe to consistently meet the operational speed required by modern multinational trial protocols.

2.2. Expanding Early Dialogue Pathways and Regulatory Sandboxes

The European Medicines Agency (EMA) must expand flexible early dialogue pathways specifically engineered for biotech scale-ups and AI-mediated drug discovery firms. Providing non-traditional innovators with early guidance on clinical data expectations prevents late-stage regulatory hurdles without forcing small teams through overly restrictive compliance hurdles.

Facilitated access to regulatory sandboxes and fast-tracked EMA scientific advice will further compress time-to-market. This integrated sandbox architecture would enable innovators to opt in at any stage of product development, test novel methodologies like AI-driven discovery in a controlled environment and receive iterative regulatory guidance, thereby speeding up therapeutic delivery to patients.

3. Fragmented Health Data Ecosystem

Computational biology and AI discovery and development tools cannot operate effectively within fragmented clinical landscapes. Europe must enforce harmonisation across its health data infrastructures to turn legislative objectives into actual discovery speed.

3.1. Incentivising Common Data Standards and Operationalising the European Health Data Space (EHDS)

The European Union can leverage its significant public innovation funding to enforce data interoperability. While the European Union has laid the groundwork via Horizon Europe's FAIR principles, these remain self-reported guidelines. All European public research grants issued to universities, laboratories and spin-offs should incentivise and promote the adoption of uniform, machine-readable data ontologies. Building on the foundational frameworks

established by ELIXIR and the European Genomic Data Infrastructure (GDI), the European Union can ensure that generated biological data is immediately discoverable, reproducible and structured for cross-border algorithmic training.

To fully unlock the competitive potential of the European Health Data Space secondary-use pillar, member states must work on integrating data standards through public healthcare procurement and support the upgrade of legacy local clinical and hospital databases, replicating the highly navigable, unified registry models successfully operationalised in Norway.[47]

3.2. Incentivising Sharing of Historical Clinical Control Data

The EMA should establish structured protocols designed to incentivise private pharmaceutical enterprises to share verified historical clinical control data on a voluntary basis, while ensuring robust protection of commercially confidential information, intellectual property and patient privacy. By leveraging this shared historical data to validate synthetic control arms, the framework will improve the efficiency of clinical trials.

4. Weak Connections and Lack of Critical Mass of Life Sciences Hubs

To achieve global relevance, the upcoming multiannual financial framework (2028–2034) must deliberately concentrate financial capabilities on supporting a limited number of world-class innovation ecosystems while interlinking them into a European network. In parallel, innovation-oriented cohesion funding should be directed toward strengthening university hospital clinical trial capacities in emerging life-sciences ecosystems.

4.1. Interlinking Regional Clusters into a Federated Network

Policymakers must operationally link specialised local hubs (such as regional centres for advanced therapies, biomanufacturing or computational biology) into a federated European network capable of rivalling the scale of the United States' Boston or the United Kingdom's Golden Triangle. This network macro-strategy could be anchored by physical "connecting houses" established within premier regional hubs. These dedicated spaces will function as regional home bases for specialist experts and visiting innovators, facilitating informal personal connections, licensing negotiations and formal knowledge sharing while providing turnkey "compliance-as-a-service" to manage remaining cross-border legal and privacy discrepancies.

4.2. Cultivating Hybrid Skills and Standardising Technology Transfer Office Licensing

To supply these hubs with a modern workforce, Europe's talent strategy must shift from a volume-based science, technology, engineering and mathematics (STEM) focus to a hybrid-specialisation model. Regional vocational training and higher-learning frameworks must mandate dual literacy in wet-lab laboratory sciences and digital architectures, including AI automation and multi-omic data management.

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47 By focusing on discoverability (metadata management system and specifications), ease of access and high trust, Norway has successfully turned a fragmented collection of registries into a unified, navigable, and high-value database.

This operational modernisation must extend to university technology transfer offices (TTOs). Broadly mandating the adoption of standardised, sector-specific licensing templates could eliminate lengthy, expensive legal negotiations, while clear scientific leave policies would allow academic founders to transition fluidly into startup structures.

4.3. Deploying Cohesion Funding to Support Emerging Hubs

To ensure balanced geographic performance without diluting excellence, innovation-oriented cohesion funding should flow directly toward enhancing the clinical trial capacities of university hospitals across southern, central and eastern Europe. Because clinical research is not bound to physical wet labs, this strategy allows emerging regions to plug directly into the federated network of clusters.

At the same time, public support for research infrastructure must shift from one-off capital cost grants to long-term operational sustainability. Public authorities should provide public funding for the maintenance of research infrastructures through access subsidies to startups.

5. Market Access Bottlenecks

5.1. Maintaining Globally Competitive Intellectual Property and Exclusivity Frameworks

European intellectual property and market exclusivity protection must remain globally competitive, predictable and resilient. Rather than viewing exclusivity durations in isolation, policy frameworks should account for the real-world timelines of clinical development and market access. The ongoing legislative process on the European biotech act provides a timely opportunity to ensure that Europe’s intellectual property protections continue to incentivise long-term biotech investment and match international standards. To maintain Europe's global competitiveness in clinical development, exclusivity frameworks must offer predictability. Policy design should ensure that incentive structures are operationalised through clear, workable conditions.

5.2. Broadening Value Assessment

Health technology assessment and reimbursement frameworks must better reflect the broader economic and societal benefits of innovative biopharmaceuticals. These benefits can include reduced long-term care burdens, improved workplace participation and higher productivity. While payers must manage immediate budget impacts, recognising these benefits – supported by robust methodologies – provides a more complete assessment of the value generated by innovative therapies.

5.3. Addressing Healthcare Resources and Pricing and Reimbursement Barriers

Increasing the attractiveness and equity of Europe's innovation-driven biotech markets requires balancing budget sustainability with timely patient access. Addressing reimbursement delays requires strengthening health technology assessment operational capacity while mitigating market distortions from International Reference Pricing (IRP), which often delays therapy launches in lower-income member states. Payers and innovators should co-design risk-sharing models that protect access in lower-income member states while respecting national fiscal ceilings and maintaining market predictability. In today's complex and fragmented market reality, this will require political will and sincere dialogue – in line with the horizontal enablers below.

6. Fragmented Governance and Policy Misalignment

6.1. Creating a Clear Political Vision and End-to-End Policy Alignment

Executing this roadmap requires the Council of the European Union, the European Parliament and the European Commission to align behind a single, unyielding strategic vision. The aspiration to establish the world's most attractive place for life sciences by 2030 cannot rely on fragmented, siloed action. Europe must learn from the long-term clarity of Chinese macro-planning and the micro-level ambition of Kendall Square, combining them into a uniquely European coordination model that bridges European Union-level aspirations with quantified national activity.

6.2. Transitioning to Agile Stakeholder Dialogues

Formal, high-level dialogue between institutions and stakeholders must move away from the reading of sequential, pre-scripted political statements and towards genuine collaboration to achieve shared goals. For example, the complexity of AI-driven drug discovery demands agile, collaborative co-working sessions where regulators, payers and industry innovators co-design adaptive market frameworks. This renewed spirit of collaboration is also vital to moving beyond narrow, static health technology assessment models and designing pricing mechanisms that properly reward a medicine's wider societal value and productivity improvements.

6.3. Centralising Execution Accountability

The distributed nature of European governance means that responsibility is widely diffused and clear accountability resides with no one. If the European Union truly views biotechnology as a vital pillar of economic security and sovereignty, it must have the political courage to designate clear accountability within a single highly responsible person or entity within the European Commission. This leadership asset will be explicitly charged with managing upstream supply-side measures and influencing national policies, moving past talk to deliver the concrete structural changes necessary to catalyse Europe's biotechnology renaissance.

Conclusion

Europe stands at a strategic crossroads: it can either remain bound to fragmented, static national frameworks that relegate it to a collection of secondary markets, or it can unify its policy architecture to lead the global biotech revolution. Europe has the scientific excellence, industrial base and research and entrepreneurial talent to remain a global leader. However, maintaining that position will require a coordinated policy agenda that strengthens the entire innovation ecosystem: from research and clinical development to manufacturing, market access and scale-up.

'Europe stands at a strategic crossroads: it can either remain bound to fragmented, static national frameworks that relegate it to a collection of secondary markets, or it can unify its policy architecture to lead the global biotech revolution.'

Capitalising on this narrow strategic window requires a rapid pivot away from passive cost-management toward coordinated macro-planning. The world's leading life sciences ecosystems have succeeded by combining long-term strategic vision with coherent policies that attract investment, accelerate innovation and improve patient access. By executing the targeted priorities established across this framework – pension investment mobilisation, rapid implementation of the European Union biotech act, uncompromising data standardisation, creating capitalised networked life sciences hubs, and a market reform – Europe can build a premium, innovation-anticipatory industrial ecosystem.

The reforms proposed in this report represent a positive agenda to stimulate research, mobilise investment, improve predictability and accelerate patient access to elevate Europe as the preferred destination to discover, develop, manufacture and launch innovative medicines. It does not require choosing between health and competitiveness policy but rather ensuring that Europe can continue to deliver on both. By doing so, Europe will also help secure its most precious asset: the health and wellbeing of its citizens.

Annex 1 – List of Interviewees

Max Wegner	Bayer	Head regulatory affairs
Edward van Wezel	Biogeneration Ventures	Managing partner and co-founder
Trine Bartholdy	BioInnovation Institute Copenhagen	Chief business officer
Cathrine Nygaard Christensen	BioInnovation Institute Copenhagen	Senior public affairs manager
Ines Verbaendert	Biovia	Operations and strategy manager
Lucia Martinez Fernandez	European Innovation Council	Policy officer Directorate General for Research and Innovation
Magda Krakowiak	European Innovation Council	Policy officer Directorate General for Research and Innovation
Claudia Louati	European Patients' Forum	Head of policy
Kristina Eskenazi	Health & Life Sciences Cluster Bulgaria	Chairwoman of the management board
Dimitar Dimitrov	Health & Life Sciences Cluster Bulgaria	Chairman of the management board
Ségolène Martin	Kantify	Chief executive officer
Salah Dine Chibout	Novartis	Global head of public private partnerships
Michael Linden	Biotech entrepreneur	

Annex 2 – Biotech Competitiveness Indicators

Key metrics	European Union	United States	China
PERFORMANCE			
Share of world's top 10% most-cited biotech literature *(2024; CAGR 2010-2024)*	**6.56% (-3.9%)**	10.05% (-3.2%)	14.68% (3.6%)
Share of world's top 10% most-cited pharma literature *(2024; CAGR 2010-2024)*	**8.1% (-1.9%)**	11.7% (-0.5%)	13.6% (3.1%)
Biotech patent applications at the European Patent Office *(2025; CAGR 2016-2025)*	**2,617 (1.9%)**	2,779 (5.8%)	666 (23%)
Biotech patent application success rate (2025; CAGR 2016-2025)	**17.7% (-10.3%)**	24.5% (-10.3%)	16.7% (-11.6%)
Venture capital investments in health biotech (% of global share)	**7%**	63%	14%
Average funding for health biotech firms	**Less than €10 million**	$24.3 million (national average) $34.8 million (Boston)	Highly concentrated (guidance funds)
Registered clinical trials (2024, WHO Data; CAGR 2010-2024)	**10,154 (3.7%)**	10,431 (4%)	15,066 (19.2%)
Total employment in pharmaceutical industry (2024; CAGR 2015-2024)	**950,983 (2.7%)**	350,500	202,008
R&D employment in pharmaceutical industry (2024; CAGR 2015-2024)	**130,000 (1.6%)**	*not available*	74,045 (FTE)
Net pharmaceutical trade balance (2024, UN Comtrade; CAGR 2015-2024)	**€193.6 billion (11.8%)**	-€117.5 billion (14.9%)	-€21.5 billion (14.9%)
ENABLERS			
Business R&D expenditure (BERD) (2024; CAGR: 2015-2024)	**€18.8 billion (9.4%)**	€120.3 billion (2023) (10.8%)	€15.6 billion (10.5%)
Average corporate R&D intensity (2024; CAGR 2014-2024)	**16.9% (2.5%)**	23.7% (3.1%)	6.5% (11.1%)
Average time to approve a clinical trial (*5-10 days for Australia for phase 1 trials)	**Over 100 days**	30 days (implicit approval)	60 days (implicit approval)

Notes: The reference year for the values is mentioned in the "Key metric" column, followed by the period covered by the compound annual growth rate (CAGR); the CAGR is added in brackets below the values per region/country.

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