From Science to Scale: Completing Europe's Health Innovation Market

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I. Abstract

Europe possesses world-class scientific capabilities, strong regulatory institutions, and publicly financed health systems with stable demand. Yet, it persistently underperforms in translating research excellence into scalable, commercially viable health innovation. This paper argues that the core challenge is not scientific capacity but market fragmentation. Across the health innovation continuum, from clinical trials and regulatory approval to health technology assessment, pricing, reimbursement, procurement, and financing, Europe lacks the scale, speed, and predictability required to function as an integrated innovation ecosystem. The result is delayed patient access, compressed revenues, weakened investment incentives, and the externalisation of value creation to more coherent markets such as the United States and, increasingly, China.

Building on the Letta Report's call for a "Fifth Freedom" of knowledge, data, and innovation, the paper proposes completing a genuine European Health Innovation Market. It identifies three strategic levers: (1) establishing the European Health Data Space as core market-making infrastructure; (2) reducing time-to-market through closer alignment of regulatory and reimbursement pathways while preserving national competencies; and (3) restoring investment credibility through EU-level de-risking instruments, targeted demand guarantees, and deeper capital market integration. Rather than framing health expenditure solely as a fiscal cost, the paper advances a growth-oriented perspective in which predictable access, sustainable profitability, and public–private risk sharing become conditions for resilience, competitiveness, and equitable patient access.
Completing the Health Innovation Single Market is presented not as sectoral reform but as a strategic imperative for Europe's economic sovereignty. By aligning regulatory coordination, pooled demand, data infrastructure, and capital mobilisation, Europe can transform its latent strengths into a durable comparative advantage, ensuring that innovation discovered in Europe is developed, scaled, and retained within it.

II. Rationale

Despite its strong scientific foundations, Europe continues to underperform in the commercialisation and deployment of health innovations. According to the latest EFPIA–IQVIA Patient WAIT Indicator, only 46% of medicines approved by the European Medicines Agency (EMA) between 2020 and 2023 are available to patients across Member States, with an average delay of 578 days from central authorisation to patient access. While the EMA has established high regulatory standards and the EU has progressively expanded its role in health, the structural conditions required for a more coherent and predictable European market for pharmaceuticals and health technologies remain incomplete. As emphasised in the Letta Report (2024), Europe lacks integrated mechanisms across the entire health innovation continuum: from early-stage research and clinical trials to evidence generation, pricing and reimbursement, procurement, workforce capacity, and investment conditions. This fragmentation undermines both competitiveness and equality of access.

This paper argues that Europe's health innovation challenge is dual and deeply interconnected, spanning both upstream and downstream segments of the continuum. Upstream, Europe retains a world-class scientific base but faces intensifying competition from the United States and China, which increasingly outperform the EU in scale, speed, translational efficiency, and R&D investment. Downstream, Europe struggles to convert scientific advances into timely patient access, competitive industrial performance, and sustainable returns on investment. Crucially, these weaknesses reinforce one another: fragmented downstream markets weaken incentives for upstream R&D and private investment, while uneven research infrastructures and translational gaps exacerbate downstream inefficiencies.

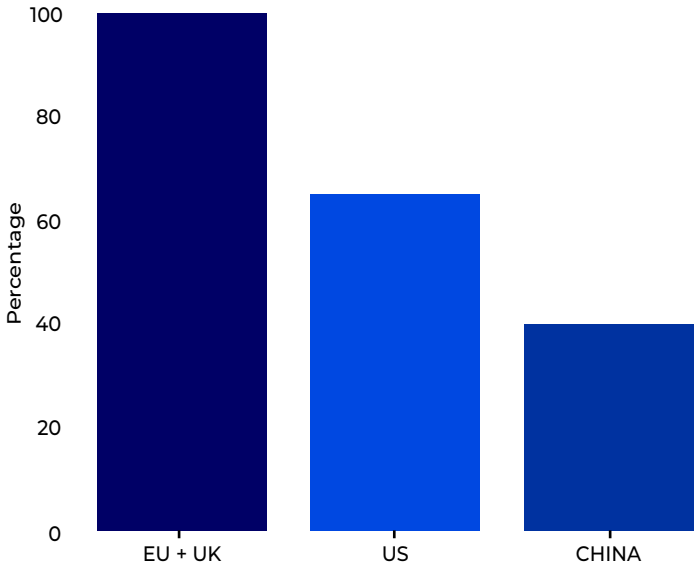
Fragmented regulatory and clinical trial environments, divergent evidence, and Health Technology Assessment (HTA) requirements, heterogeneous pricing and reimbursement practices, limited procurement coordination, fiscal constraints on health systems, and inconsistent incentive structures collectively prevent Europe from operating as an integrated innovation and commercialisation space. At the same time, skills shortages, uneven research capacity, and insufficient support for translational science hinder the transfer of discoveries from the laboratory to the clinic. Addressing Europe's competitiveness gap, therefore, requires a holistic approach, one that simultaneously strengthens upstream capabilities, reforms downstream market structures, and restores the economic conditions under which innovation can be financed, scaled, and sustained within the Single Market.

III. Health Innovation in a Multipolar World

For much of the past century, the discovery, development, and commercialisation of new medicines were dominated by Europe and the United States. That era is coming to an end. Today, China has become the world's largest developer of new medicines, running nearly one-third of global clinical trials, up from just 5% a decade ago, and advancing rapidly in critical therapeutic areas such as oncology. Investor confidence has followed: Chinese biotech stocks rose by more than 110% in 2024, outperforming their American peers by more than three times. This transformation is not accidental. Over the past decade, China has systematically aligned regulation, finance, clinical infrastructure, and industrial policy across the health innovation continuum, compressing development timelines, expanding regulatory capacity, and mobilising capital at scale.

The timing could not be more consequential. Europe and the United States face some of the steepest patent cliffs in pharmaceutical history, with drugs generating over $300 billion in cumulative revenues set to lose exclusivity by 2030. For companies, this represents a significant commercial challenge, with implications for investment, employment, and R&D capacity. For public payers, however, patent expiry also creates an opportunity: once exclusivity ends, many medicines become substantially cheaper, generating fiscal savings for national health systems. The strategic question is how these

Graph 1. Number of citations in top pharma journals as a percentage of "leader"



Source: ING, Pharma Outlook 2026, p. 12

savings are used. If reinvested into pharmaceutical budgets and earmarked for innovative therapies, clinical research, and adoption of high-value technologies, the patent cliff could create fiscal headroom for the next generation of innovation. If diverted elsewhere, Europe risks weakening the very ecosystem it seeks to strengthen. At the same time, geopolitical tensions are reshaping supply chains and innovation strategies. While the United States seeks to reduce strategic dependencies, its pharmaceutical firms are becoming increasingly reliant on Chinese innovation pipelines to replenish their portfolios. Europe, meanwhile, finds itself in a more precarious position: rich in scientific excellence (Graph 1), yet increasingly marginal in the downstream stages where value is captured, scaled, and reinvested.

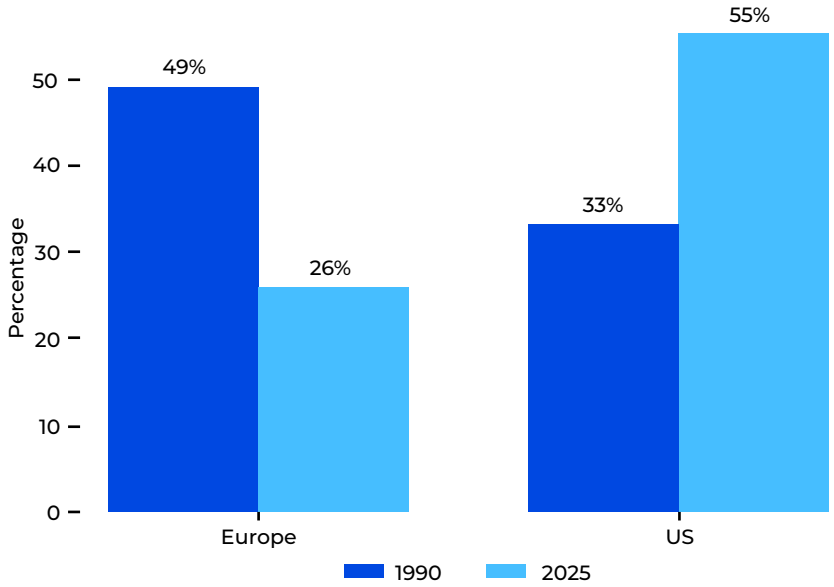
This is paradoxical because health and life sciences remain among the most strategically significant sectors of the European economy. Globally, the sector accounts for approximately €140 billion in annual R&D investment, with Europe historically contributing a substantial share (EFPIA, 2025). The broader biopharmaceutical and medical technology industries support more than 2.8 million jobs across the continent, and the EU remains the second-largest pharmaceutical market worldwide. Health expenditures already account for 10% of EU GDP, a share expected to rise further due to population ageing, the growing burden of chronic disease, and post-pandemic pressures (Eurostat, 2025). Moreover, Europe hosts some of the world's richest repositories of medical and social data through its national health systems. If integrated effectively through the European Health Data Space (EHDS), these assets could form a unique comparative advantage for research, clinical trials, AI-enabled diagnostics, and evidence-based policymaking. In this sense, health innovation is not merely a sectoral concern: it is a high-value test case for the Single Market's capacity to deliver competitiveness, resilience, and equitable access simultaneously (Letta, 2024).

Yet despite this potential, Europe is losing ground to the United States across nearly every downstream indicator of health innovation competitiveness. The US outperforms the EU in R&D intensity (3.6% vs. 2.2% of GDP) (European Commission, 2025), in biopharmaceutical venture capital, where American firms attract four to five times more funding, and in patenting, accounting for 39% of global biotech patent families, compared with less than 20% for Europe (European Commission, 2024b). Development and approval cycles are also faster: the median review time for new medicines at the FDA is approximately 240 days, compared with 420 days or more at the EMA. The US hosts 35–40% of global clinical trials, while Europe's share has declined from 22% in 2012 to just 12% in 2023, despite maintaining a strong scientific publication record. Capital markets amplify these divergences: more than 70% of global health tech unicorns are American, while Europe hosts only about 11%, reflecting a persistent scale-up gap. As a result, even Euro-

pean-origin innovations frequently generate their economic value outside Europe, where faster uptake, higher reimbursement, and deeper capital markets offer more attractive conditions for commercialisation.

China's rise further accentuates this challenge. Its overall R&D spending reached $781 billion in 2023, nearly matching that of the United States and far surpassing the EU (OECD, 2025), while producing 50,000 STEM PhDs annually, compared with 34,000 in the US (FT, 2025). In biopharmaceuticals, Chinese companies move from discovery to early clinical trials two to three

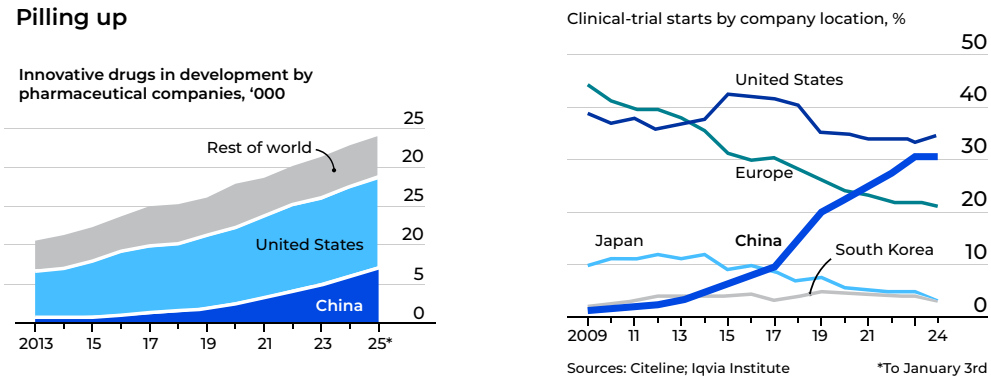
Graph 2. European and American biopharmaceutical companies' R&D spending as a percentage of global spending in 1990 and 2025



Source: ING, Pharma Outlook 2026, p. 11

times faster and recruit patients, dropping it two to five times more quickly, supported by integrated trial networks and large, treatment-naïve populations. Consequently, China's share of innovative drug candidates in clinical development has grown from 8% in 2018 to around 30% in 2025, while Europe's relative position has weakened (FT, 2025). China now accounts for over half of global Phase 1–2 assets in antibody–drug conjugates, compared with roughly 11% for Europe, and has built regulatory and industrial systems capable of approving new biomanufacturing capacity in days rather than months. Combined with scale, speed, and strategic industrial policy, China is evolving from a manufacturing base into a global health innovation powerhouse.

For Europe, this is not merely competitive pressure; it is a systemic warning. The continent's problem is not a lack of ideas, talent, or scientific ambition. It is the failure to complete the health innovation continuum: to design a Single Market in which innovation can be financed, priced, scaled, and



Charts: The Economist, 23rd November, 2025

rewarded. Without deeper market integration, stronger downstream incentives, and new mechanisms to mobilise public and private investment under fiscal constraints, Europe risks becoming a place where innovation is discovered, but not developed, commercialised, or retained. This policy paper argues that completing Europe's Health Innovation Market is therefore not optional. It is a strategic necessity.

IV. Diagnosis: Structural Bottlenecks Along the Health Innovation Continuum

Fragmented access and persistent inequalities

Although most innovative medicines obtain EMA authorisation through centralised procedures, market access remains largely national, resulting in highly uneven availability across Member States. Patients in smaller or lower-income countries experience systematically delayed or reduced access[1], while companies face fragmented launch pathways and uncertain uptake. This fragmentation depresses expected revenues and weakens incentives to commercialise innovations across the EU as a whole, reducing the attractiveness of Europe as a primary launch market. Eventually, major pharmaceutical companies prioritise the United States, not because of lower regulatory standards, but because of faster regulatory timelines, clearer development pathways, and the prospect of earlier and more substantial revenues. The U.S. Food and Drug Administration (FDA) combines high evidentiary requirements with comparatively rapid review procedures and earlier reimbursement uptake, extending the effective commercial life of innovative products. Where divergences in evidence expectations exist across jurisdictions, firms rationally align their development strategies with the requirements of the market that offers the strongest and most predictable return. China, for its part, has built capacity for rapid trial initiation and large-scale patient recruitment, enabling accelerated evidence generation, although the global acceptability and transferability of such data may vary. The core competitive issue for Europe is therefore not regulatory stringency, but speed, coordination, and market attractiveness within a high-standard framework.

[1] According to the EFPIA–IQVIA, *Patient WAIT Indicator 2024*, their latest report finds that only 46% of medicines centrally authorised by the European Medicines Agency (EMA) between 2020 and 2023 are available to patients across EU Member States, with an average delay of 578 days between EU-level approval and national availability. Access varies significantly across countries, with smaller and lower-income Member States experiencing systematically longer waiting times and reduced availability. See also EFPIA (2024), "New data shows no shift in access to medicines for millions of Europeans," confirming the persistence of structural disparities in post-authorisation access within the EU.

Regulatory and clinical trial heterogeneity

Fragmentation within Europe's regulatory and clinical trial environment directly constrains the organisation of multi-country clinical trials, which are essential for scale, speed, and global regulatory acceptance. Divergent ethics committee requirements, inconsistent national implementation of EU rules, and heterogeneous approval timelines increase the cost and complexity of conducting cross-border trials. As a result, sponsors often default to single-country or limited-geography studies, which reduces sample diversity, slows patient recruitment, and weakens the international relevance of evidence generated in Europe. This limits Europe's ability to function as a unified development space at precisely the stage of the innovation continuum where coordination needs and capital intensity are highest.

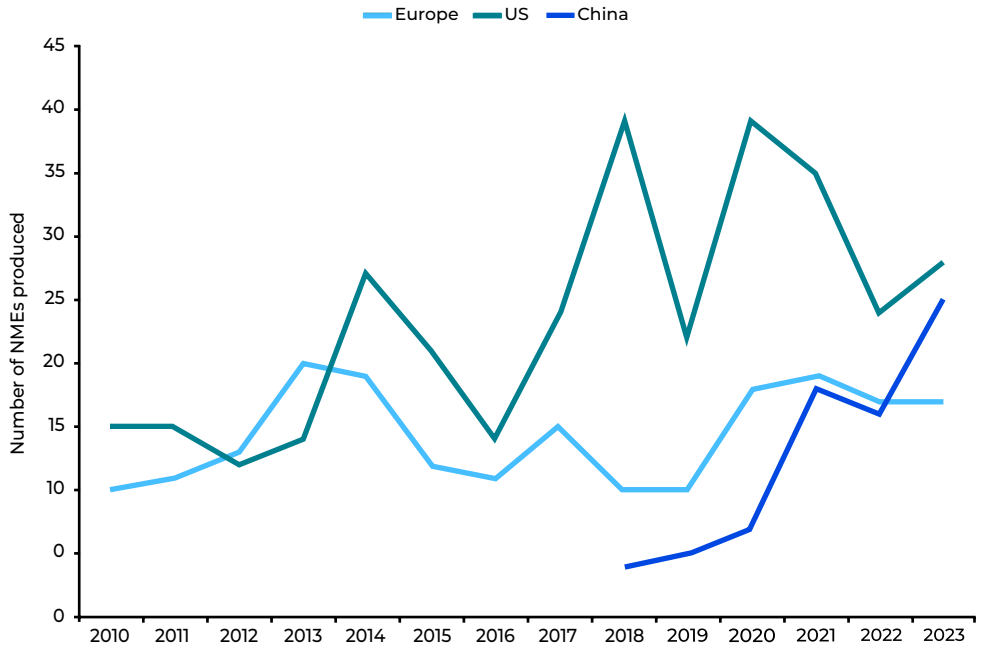
Importantly, this fragmentation is not inevitable. The rapid development of COVID-19 vaccines demonstrated that, when urgency and political coordination align, large-scale, multi-country clinical trials can be organised quickly and effectively across Europe. Emergency regulatory coordination, accelerated ethics reviews, shared protocols, and parallelised approval processes enabled trials enrolling tens of thousands of participants across multiple Member States within compressed timelines. As highlighted in the Letta Report and EMA's Regulatory Science to 2025 (2020), the challenge today is to institutionalise the lessons learned during crisis-driven acceleration and embed them into a stable regulatory architecture. The Commission's proposed Biotech Act (16 December 2025) moves in this direction by introducing additional harmonisation measures and streamlining certain procedures relevant to clinical research and advanced therapies. Yet, important structural gaps remain. Without sustained alignment of ethics standards, interoperable and scalable trial infrastructures, and closer coordination between regulatory and HTA evidence requirements, Europe will continue to underprovide genuinely pan-European trials. The consequence is longer development timelines, higher execution risk, and diminished attractiveness compared with more integrated innovation ecosystems where regulatory, evidence, and market pathways are more closely aligned.

Weak incentives, financing gaps, and investment disincentives

Europe's health innovation ecosystem is increasingly constrained by a deteriorating risk–return environment, driven not only by capital shortages but by structural fiscal pressures on the demand side. Ageing populations, rising prevalence of chronic diseases, and post-pandemic budget consolidation have intensified cost containment in national health systems,

making governments more reluctant to absorb higher-priced innovative therapies, even when the long-term value is plausible[2]. In addition, Europe's security concerns have led to a shift in budget allocation from welfare to defence. During the Great Recession, welfare states, the crown jewel of post-war Europe, were framed as unsustainable fiscal weights to public budgets. During the COVID-19 crisis, this perception changed, and healthcare spending became a priority again. The tide turns against spending, now that increased defence expenses threaten public healthcare. All this translates into a more austere healthcare outlook, aggravated by demographic pressures, with spending restricted across the board. For instance, conservative reimbursement decisions, delayed uptake, narrow eligibility criteria, and frequent post-launch price revisions all depress

Graph 3. Number of NMEs originating in Europe, the US and China, 2010 to 2023[3]



Source: Citeline April 2024 & SCRIP Publications - EFPIA calculations, PwC analysis.

2. There is substantial empirical evidence that health expenditure can generate medium- to long-term economic returns. OECD estimates suggest that disability and sickness benefits account on average for around 2% of GDP across member countries, indicating the macroeconomic relevance of preventable morbidity (OECD, 2010). Evidence on non-communicable diseases (NCDs) suggests that early detection and treatment can yield positive economic returns, with estimated benefit–cost ratios ranging from €0.30 to €4.90 per euro invested, depending on intervention type and time horizon (EFPIA, 2025, citing multiple modelling studies). Lichtenberg (2019) finds that pharmaceutical launches in 27 countries between 2000 and 2013 were associated with significant reductions in severe morbidity and mortality, implying productivity and welfare gains. In the UK context, analysis by NHS Confederation and Carnall Farrar estimates that each additional £1 per capita invested in the NHS generates approximately £4 in economic return through improved labour-force participation and productivity. While methodologies differ, these studies consistently suggest that health spending, particularly on innovation and early intervention, can produce measurable long-term economic dividends beyond immediate health outcomes.

3. A good proxy indicator to gauge the attractiveness of the Single Market as a destination for R&D investment is the discovery of new drugs. According to EFPIA's report on the Economic footprint of the pharmaceutical industry in Europe (2024, p. 17) "changing growth rates of R&D expenditure are reflected in the pattern of New Molecular Entities (NMEs) discoveries worldwide. NMEs are new drugs with an active ingredient that is marketed for the first time; their discovery is a key product of R&D activity".

expected revenues and weaken Europe's position as an early and attractive launch market (Graph 3).

These pressures are compounded by the widespread use of clawback and rebate mechanisms, which in several Member States have evolved from temporary budget-balancing tools into structural financing instruments. In the United Kingdom, for example, repayment rates under the voluntary pricing scheme reached 26.5% in 2023, and at 24.4% under the statutory scheme, prompting public warnings from industry about launch sequencing and investment decisions. Similar dynamics are visible across the EU. In France, the long-standing clause de sauvegarde, originally designed as a corrective mechanism when pharmaceutical expenditure exceeded predefined thresholds, has been effectively institutionalised as a recurring levy capped at around €1.6 billion. Italy operates multiple payback systems at both national and regional levels, including expenditure caps and ex post rebates that can substantially reduce realised revenues, particularly in hospital and innovative drug segments.

While these instruments serve legitimate fiscal objectives, their scale and unpredictability increasingly shift financial risk from public budgets onto firms after market entry. For capital-intensive, high-risk innovation, especially in areas with uncertain uptake or small patient populations, such ex post revenue compression undermines long-term investment planning and weakens Europe's risk–return profile. In combination with fragmented pricing systems, slow market access, and debates over reductions in regulatory data protection and orphan incentives, these mechanisms contribute to a structurally less investable environment for health innovation.

Antimicrobial resistance (AMR) illustrates the structural misalignment between social value and commercial viability. The World Bank estimates that, by 2050, AMR could cause up to 39 million deaths if new treatments are not developed (World Bank, 2024). Yet because new antibiotics must be used sparingly to preserve their effectiveness, sales volumes remain structurally low.

Even clinically successful products often fail commercially. The problem is therefore not scientific capacity but incentive design. While push incentives support early research, the absence of robust pull mechanisms means that market entry does not guarantee sustainable returns. Subscription models, market-entry rewards, or transferable exclusivity mechanisms have emerged as potential solutions. The broader lesson is clear: where therapies serve a public-good function, innovation policy must reward availability and preparedness, not only volume of sales.

Fragmented procurement and insufficient economies of scale

Public procurement of medicines and health technologies in Europe remains overwhelmingly national or sub-national, reflecting the organisation of healthcare financing and delivery. While this preserves Member State autonomy, it also fragments demand across 27 systems with different tendering rules, contract durations, volumes, and pricing logics. As repeatedly noted by the European Commission, the OECD, and the European Court of Auditors, this fragmentation prevents the Single Market from operating as a credible demand aggregator, particularly for innovative, high-cost, or low-volume products. For firms, the result is a patchwork of small, sequential markets rather than a single, scalable launch environment, which raises transaction costs, delays uptake, and reduces expected returns.

Evidence from recent EU experience underscores both the potential and the limits of procurement coordination. Outside exceptional circumstances, cross-border procurement remains marginal, ad hoc, and limited in scope. By contrast, the COVID-19 joint procurement mechanism demonstrated that when demand is credibly pooled at EU level, Europe can offer manufacturers immediate scale, predictable volumes, and bankable long-term contracts, conditions that accelerated investment, strengthened supply security, and de-risked production capacity. OECD (2024) analyses similarly suggest that pooled procurement can generate efficiency gains, enhance the resilience of medical supply chains, and facilitate information sharing among governments.

However, joint procurement carries important caveats. If aggregated demand is deployed primarily as a cost-containment tool, it risks reinforcing the very underinvestment dynamics that have weakened Europe's attractiveness as a launch market. Historically, constrained health budgets and price-driven procurement practices have posed a more significant structural challenge than fragmentation alone. A future-oriented EU procurement framework should therefore avoid equating scale with downward price pressure. Instead, coordinated procurement should be designed to improve predictability, enhance supply resilience, and reward therapeutic value, especially in innovative or high-risk areas, while preserving commercially viable returns. Efficiency gains should complement, not undermine, the economic conditions necessary for sustained innovation.

The absence of scale is particularly damaging in innovation-intensive markets, where upfront R&D costs are high and economic viability depends on predictable, sufficiently large patient uptake. While price-driven tendering is more typical for mature or off-patent products, innovative therapies face

a different but equally consequential set of barriers. Fragmented market access pathways, heterogeneous HTA methodologies, outdated assessment frameworks, and the use of inappropriate comparators can delay or distort value recognition. In several cases, broader societal benefits, such as productivity gains, reduced caregiver burden, or system-wide efficiency improvements, are insufficiently captured in reimbursement decisions. This limits the effectiveness of value-based and outcomes-linked purchasing models, as they require consistent evidence standards, interoperable data infrastructure, and longer contract horizons across jurisdictions.

Without more systematic coordination of demand, whether through voluntary purchasing alliances, EU-backed framework agreements, harmonised HTA evidence standards, or carefully designed joint procurement mechanisms, the Single Market struggles to provide credible signals of scale and value. The issue is therefore not a lack of aggregate purchasing power, but the fragmentation of how value is assessed and translated into predictable revenues. As long as expected returns remain uncertain and uneven across Member States, Europe will continue to discourage investment in high-risk innovation, not because it lacks the capacity to pay, but because it fails to mobilise its market power coherently.

This fragmentation is not accidental; it is the predictable outcome of how health competencies are distributed politically and administered bureaucratically. First, many of the core levers that shape market access, pricing, reimbursement, procurement, and aspects of clinical governance remain national competencies. Harmonisation is therefore politically sensitive, as it can generate visible domestic winners and losers (for example, through shifts in procurement structures, reference pricing dynamics, relocation of clinical trials, or changes in hospital purchasing patterns). Member States remain reluctant to relinquish sovereign fiscal authority over healthcare expenditure. Second, fragmentation is reinforced by bureaucratic path dependence. National agencies and HTA bodies have developed distinct evidentiary cultures, methodological traditions, and accountability frameworks over the course of decades. These institutional legacies raise switching costs and slow convergence, even when partial legal harmonisation is introduced at EU level.

Third, regulatory and market rules are not shaped by science alone, but also by strategic interaction among organised interests. Safety standards and evidentiary thresholds are essential pillars of public trust, and there is no case for weakening them. However, debates framed as purely technical or scientific can sometimes mask underlying distributive conflicts about market structure, competitive positioning, or cost allocation. Different business models, originators, generics, SMEs, hospital systems, and payers

may favour different procedural designs, comparators, or value assessment criteria. As a result, “science” and “safety” discussions can become arenas of negotiated compromise rather than neutral optimisation. Recognising this political economy dimension is not an argument for deregulation; it is a prerequisite for designing governance mechanisms capable of preserving high standards while reducing unnecessary duplication, strategic blocking, and downstream fragmentation.

V. A Strategic Response: Completing the Health Innovation Market

In line with the Letta Report's call for a renewed and integrated European economy of health, this paper frames health innovation as a prime test case for the Fifth Freedom of the Single Market: the free movement of knowledge, data, innovation, and skills. The four traditional freedoms were designed for an industrial economy centred on goods, capital, and labour. They are no longer sufficient for an innovation-driven economy in which value creation depends on the ability to generate, combine, and scale intangible assets across borders. Health innovation is emblematic of this transformation. It is data-intensive, knowledge-driven, highly regulated, and capital-heavy, and it exposes more clearly than any other sector the economic costs of fragmentation, regulatory misalignment, and insufficient scale within the Single Market.

The Fifth Freedom should therefore be understood not as a declaratory principle, but as a market-making infrastructure that allows research, data, and innovation to circulate at a continental scale with legal certainty, interoperability, and predictable incentives. As argued in the Fifth Freedom framework, European integration advances through concrete mechanisms that create markets rather than through abstract harmonisation alone. In health, this implies moving beyond isolated regulatory reforms towards an integrated innovation continuum that actively pulls discoveries from research to scale-up and adoption. Europe is uniquely well-positioned to do so: healthcare spending is largely publicly financed, politically legitimate, and structurally stable, offering predictable long-term demand. If regulatory alignment, data governance, and financing instruments are properly integrated, Europe can transform its welfare-based health systems from a perceived fiscal constraint into a strategic asset for competitiveness. The strategic response set out below builds on this premise, starting with the European Health Data Space as the foundational infrastructure of the Fifth Freedom in health, and extending to the downstream market and financing conditions required to complete a genuine Health Innovation Single Market.

The European Health Data Space as a critical infrastructure

Building on the necessary conditions for facilitating research and innovation, this paper aligns with the proposal for a European Health Data Space (EHDS).

The EHDS should not be understood merely as a technical, cost-efficiency–oriented data-sharing reform, but as the core infrastructure through which the EU can operationalise a Fifth Freedom: the free movement of health data, knowledge, and digital capabilities across borders. Harmonised data governance, interoperable electronic health records, and robust frameworks for the secondary use of health data, including for research, clinical trials, health technology assessment, and regulatory evidence generation, are essential to enabling research at scale and attracting global pharmaceutical and MedTech investment. In this respect, the treatment of secondary data use is pivotal.

As the Letta Report acknowledges, further clarification and critical examination of the opt-out clause for secondary data use is needed. Without legal certainty, consistent interpretation, and predictable access conditions, the EHDS risks remaining underutilised for innovation purposes. By contrast, a well-functioning secondary data regime, based on high standards of anonymisation, cybersecurity, and public trust, could allow companies and researchers to conduct market research, drug development, and real-world evidence generation using Europe's uniquely rich health datasets. In this sense, the EHDS is a cornerstone of a functioning Health Innovation Market: while estimates suggest it could generate up to €11 billion in efficiency gains through improved data accessibility and healthcare delivery, its true value lies in the unquantifiable R&D and innovation dynamics that a genuinely integrated European health data space could unleash.

Harmonised and predictable access pathways

With a data infrastructure in place and shared ethical standards, many of the upstream challenges of healthcare innovation can be progressively addressed. Regulatory harmonisation remains complex, but the Commission has significant leverage through legislative instruments, coordination mechanisms, and agency cooperation. The more demanding task lies downstream. The decisive difference between developing a drug in the United States and in Europe is not scientific capability, but market access. Beyond pricing levels or market size, time to market is the single most powerful structural advantage of the U.S. system and a central reason why the FDA remains attractive to innovators. Faster regulatory decisions, earlier reimbursement, and clearer development pathways extend the effective patent life and accelerate revenue generation. In Europe, by contrast, EMA authorisation is only the beginning of a prolonged and uncertain sequence of national HTA assessments, pricing negotiations, and reimbursement decisions, often adding years before patients gain access and companies can realise returns.

Aligning EMA procedures more closely with the new EU HTA Regulation provides a concrete opportunity to narrow this gap. Stronger coordination between EMA scientific advice, accelerated pathways such as PRIME, and joint clinical assessments (JCA) under the HTA framework can reduce duplicative evidence requirements and provide earlier clarity on what data will be sufficient for both authorisation and reimbursement. At the same time, both EU-level and national HTA methodologies must remain scientifically adaptive. Biomedical innovation is increasingly characterised by precision therapies, small patient populations, and durable responses that may not generate mature overall survival data within traditional trial timelines. In such cases, rigid reliance on conventional endpoints risks penalising transformative therapies and unnecessarily delaying access. Ensuring that evidence requirements evolve in step with scientific progress, including the appropriate use of validated surrogate endpoints, real-world evidence, and adaptive data collection, would not weaken standards. Rather, it would strengthen the credibility and responsiveness of European regulatory science, while preserving patient safety and methodological rigor.

Crucially, coordination must extend beyond authorisation to reimbursement timelines. While pricing and reimbursement remain national competencies, greater convergence could be achieved through time-bound national decisions, for example, a horizontal EU-wide deadline from EMA authorisation (or joint clinical assessment) to a national reimbursement decision. Such deadlines, as already foreseen in principle by the Transparency Directive, should be triggered upon the company's submission of a complete pricing and reimbursement dossier. It is equally important, however, that competent authorities consistently observe these timelines in practice. Predictability requires reciprocal discipline: timely submissions from industry and timely decisions from payers. Complementary soft mechanisms, such as minimum access guarantees or recommended maximum delays, could further reduce dispersion across Member States. These instruments would not impose uniform prices, nor would they constrain national budgetary sovereignty. Rather, they would significantly reduce uncertainty, shorten time to first revenues, and limit today’s stark inequalities in patient access across Europe. By competing on both speed and safety, and by ensuring that procedural commitments are respected on all sides, Europe could materially improve its risk-return profile for innovation, without lowering regulatory standards or undermining national control over health budgets.

Predictability in access pathways must be complemented by vigilance over the effective duration of intellectual property protection. While formal patent lengths are harmonised at the EU level, firms increasingly argue that the effective period of market exclusivity is being eroded by long development

timelines, sequential regulatory and reimbursement delays, and post-authorisation evidence requirements. In practice, a prolonged time-to-market compresses the window during which innovators can recoup R&D investments, particularly in complex therapeutic areas. Rather than reopening contentious debates on patent length, the EU could establish a light governance and monitoring mechanism to track when cumulative regulatory, HTA, and reimbursement delays materially undermine effective patent life and threaten the commercial viability of strategically important innovation pipelines. Such a mechanism, anchored in the Commission and informed by EMA, HTA bodies, and industry data, would allow early identification of systemic misalignments and enable targeted, timely corrective action (for example through accelerated procedures, transitional access arrangements, or tailored incentives). This approach would preserve the integrity of the EU's IP framework while ensuring that downstream frictions do not unintentionally hollow out Europe's capacity to innovate.
Finally, a complementary governance innovation would be to create an EU Health Innovation Sandbox: a voluntary, time-limited pilot regime in which participating Member States adopt a harmonised, fast-track pathway covering trial authorisation coordination, evidence-generation standards, procurement design, and, where feasible, aligned reimbursement timelines for a defined set of innovations. The sandbox logic is pragmatic: rather than attempting uniform harmonisation across 27 systems at once, it focuses on coordination where it is politically and administratively feasible, delivers demonstrable results (speed, uptake, real-world evidence), and reduces opposition by keeping participation voluntary and scope bounded. If successful, the sandbox can then be scaled through opt-in expansion and replication.

To ensure that the sandbox and EU financial instruments catalyse upstream investment (not only late-stage diffusion), the EU could pair them with an explicit priority-setting mechanism, a transparent process that identifies strategic therapeutic areas and technology platforms (e.g., AMR, neurodegeneration, mental health, high-impact diagnostics) and links them to targeted financing, trial infrastructure, and demand guarantees. This would provide the capital market with clearer signals and reduce coordination failures. The risk, crowding out non-prioritised innovation, can be mitigated by rotating priorities, maintaining an open lane for investigator-driven breakthroughs, and using portfolio approaches rather than single-technology bets.

Health Innovation Meets Capital Markets

Reducing regulatory and reimbursement delays is not an end in itself, but a precondition for restoring investment credibility. Predictable, timely access

decisions determine when revenues begin to flow and, therefore, whether innovation is financeable in the first place. Even without harmonising prices, greater convergence in decision timelines, supported by soft coordination mechanisms such as EU-wide benchmarks or recommended maximum delays following EMA authorisation or joint clinical assessment, would materially improve Europe's risk–return profile. Faster time to first revenues reduces financing costs, lowers capital requirements, and makes Europe more attractive for both industrial and financial investors. In this sense, accelerating access is not only a health policy objective; it is a financial lever that links regulatory reform directly to capital mobilisation and market depth.

In the bigger picture, reconciling innovation with fiscal sustainability requires a shift in how risk is allocated across the public–private boundary. EU-level de-risking instruments, anchored in the EIB, InvestEU, and related facilities, can help absorb part of the early and scale-up-related risks that private investors face. Instruments such as a European Health Innovation Guarantee Facility can advance market commitments and launch-phase financing without replacing market discipline but improving the risk–return profile of innovation, where fragmentation, delayed access, and pricing uncertainty currently deter investment. By targeting clearly defined health challenges that often meet market failures, such as rare diseases, antimicrobial resistance, advanced cancer therapies, and prevention, these tools would enhance predictability while preserving incentives for efficiency and performance.

In addition to guaranteeing facilities and pull incentives, the EU should consider Advanced Market Commitments (AMCs) in carefully selected areas where social value is high, and market incentives are structurally weak (e.g., AMR, priority vaccines, select rare disease platforms). AMCs work by committing ex ante to purchase (or reimburse) a defined volume at a pre-agreed value-based price if a product meeting specified criteria is delivered. The advantage is not only demand certainty, but also earlier-stage signalling: credible commitments can improve the investment case for R&D by reducing uncertainty about downstream uptake and potential revenues for pharmaceutical companies. The limitation is cost and scope: AMCs are best suited to technologies that are viable and measurable. Therefore, they should be deployed selectively, transparently, and with strong conditionality (milestones, performance clauses, and sunset rules).

At the same time, innovation-oriented procurement, and value-based reimbursement models, supported by the European Health Data Space, can transform public spending from a passive cost into an active investment lever. By linking payment more closely to outcomes and long-term system

savings, procurement can generate credible demand signals without imposing unsustainable short-term fiscal burdens. The strategic use of Cohesion Policy funds, particularly for digital infrastructure, screening, prevention, and proximity healthcare in less-developed regions, can further expand absorptive capacity and reduce long-run expenditure pressures, reinforcing both equity and efficiency objectives.

Crucially, these public instruments should be designed to crowd in private capital rather than substitute for it. Europe's capital markets remain comparatively shallow, fragmented, and risk-averse, particularly for late-stage life sciences and scale-up financing. A deeper, more liquid European capital market, long advocated under the Capital Markets Union agenda, represents a decisive lever for health innovation. Instruments such as health innovation revenue bonds, EU-backed co-investment platforms, portfolio-based financing vehicles, and securitised royalty streams could translate regulatory integration into investable assets suitable for pension funds, insurers, and other long-term institutional investors. Yet upstream capital is only half of the equation: the sustainability of Europe's innovation ecosystem ultimately depends on credible downstream demand. Public investment in access to medicines is not merely a fiscal cost but a structural component of the innovation cycle. As the United States increasingly debates price containment and global burden-sharing, sustained price compression across advanced economies could narrow the global financing base for pharmaceutical R&D. Europe therefore faces a strategic choice: either continue to treat pharmaceutical spending primarily as short-term budgetary pressure, or recognise it as a productive investment with medium- and long-term economic returns in workforce participation, reduced disability, avoided hospitalisation, and strengthened industrial capacity. Embedding health expenditure within a broader growth and competitiveness strategy would align capital-market deepening with a credible, investable demand-side foundation for innovation.

In this perspective, mobilising investment under fiscal constraints is not merely a defensive exercise in burden-sharing. It is a strategic reconfiguration of Europe's financial architecture, aligning health innovation with long-term savings pools and transforming fragmented national markets into a credible continental investment proposition. By combining targeted public de-risking with capital markets deepening, Europe can expand the fiscal space for innovation without undermining macroeconomic stability, while making the Single Market a more profitable, predictable, and attractive environment for health innovators to develop, scale, and commercialise within Europe.

VI. The Vision: from Fragmentation to Scale

Europe stands at a strategic crossroads in health and life sciences. The continent possesses all the foundational assets required to lead globally in healthcare innovation: world-class universities and research centres, a highly skilled scientific and clinical workforce, trusted regulatory institutions, and health systems with broad political legitimacy and near-universal coverage. No other major region combines scientific excellence with such extensive public demand for healthcare and a social contract that values health and guarantees constant healthcare expenditure via the welfare state. This combination, scientific excellence, skilled human capital, and collectively financed demand, constitutes a latent comparative advantage that no other global competitor can replicate. Yet despite these advantages, Europe persistently underperforms in translating research leadership into globally competitive innovation, industrial scale-up, and timely patient access.

The central paradox explored in this paper is therefore not one of capability, but of incentives. Europe does not lack science, talent, or regulatory credibility; it lacks a functioning market that rewards innovation across the full continuum from discovery to deployment. Europe's difficulty is not a lack of innovation inputs, but the absence of an integrated market capable of transforming discovery into scale and profitable products. Fragmentation across regulatory procedures, pricing systems, reimbursement timelines, procurement practices, and financing channels prevents the EU from functioning as a coherent innovation space. As a result, health innovations either occur in the US and are then brought to Europe, or, worse, are developed in Europe and commercialised elsewhere, while European health systems face delayed access and rising long-term costs.

Profitability as a Necessary Condition, Not a Policy Taboo

A functioning Health Innovation Single Market requires credible, predictable pricing conditions that enable innovation to be financed, scaled, and reinvested. In Europe, fragmented and often restrictive pricing and reimbursement systems compress expected revenues and delay uptake, weakening the ability to develop and launch innovative therapies in the EU. Even after centralised EMA approval, companies face multiple, sequential national negotiations, heterogeneous and often rigid HTA methodologies, and downward price convergence. This leads firms, particularly in high-risk, capital-intensive areas such as oncology, rare diseases, and advanced

therapies, to prioritise non-European markets for early commercialisation. This paper has argued that profitability is not a by-product of innovation policy, but a necessary condition for sustaining a competitive and high-quality health innovation ecosystem. Without predictable post-approval revenues, private capital will not finance high-quality multinational trials, advanced manufacturing capacity, or late-stage scale-up. The consequence is a self-reinforcing cycle: weak revenue expectations reduce investment, reduced investment lowers innovation density, and lower innovation density further erodes Europe's attractiveness as a launch and development market. This is not an argument for unbounded pricing or for abandoning public value. Rather, it is a recognition that value creation must precede value redistribution. Europe's current model places disproportionate emphasis on ex-post cost containment, through restrictive HTA practices, clawbacks, and delayed access, without adequately addressing how innovation is financed ex-ante. Over time, this undermines both industrial competitiveness and patient access.

Time to Market: Europe's Most Underused Competitive Lever

If the FDA's greatest advantage is often perceived to be regulatory speed, its true strength lies in speed to revenue. In the United States, regulatory approval, reimbursement, and market uptake are closely aligned, allowing innovators to generate early cash flows that validate business models, attract capital, and finance further innovation. Europe, by contrast, systematically delays this transition from approval to revenue.

Reducing time-to-market is therefore one of the most powerful and least inflationary ways for Europe to improve its risk–return profile. Aligning EMA procedures with the EU HTA Regulation, strengthening early dialogue mechanisms such as PRIME, and coordinating regulatory and reimbursement timelines would materially reduce uncertainty and duplication. Crucially, coordination must extend beyond authorisation to reimbursement decisions. Under the Transparency Directive, pricing and reimbursement timelines are triggered by the company's formal application following EMA approval, and Member States are expected to conclude procedures within 180 days. In practice, however, this statutory deadline is not always respected, and additional administrative steps can further delay access. While pricing and reimbursement remain national competencies, greater convergence could be achieved by ensuring systematic compliance with the 180-day rule, limiting post-deadline procedural extensions, and complementing this framework with soft mechanisms such as minimum access guarantees or recommended maximum delays. Such measures would not harmonise prices, but they would significantly shorten the time to first revenues and

improve predictability across the Union.

These instruments would not impose uniform prices, but they would significantly shorten the time to first revenues, improve capital efficiency, and limit today's stark inequalities in patient access across Member States. By competing on both speed and safety, Europe could materially enhance its attractiveness as a development and launch market, without lowering regulatory standards or undermining national control over health budgets. The COVID-19 vaccine experience demonstrated that, when urgency is recognised, Europe can coordinate multinational trials, accelerate regulatory processes, pool demand, and provide credible revenue guarantees at scale. The lesson is not that emergency powers should become permanent, but that structural coordination is possible when innovation is treated as a strategic priority rather than a residual budget line.

Financing Innovation Under Fiscal Constraints: From Fragmentation to Leverage

Reconciling long-term health innovation with short-term fiscal constraints also requires a more flexible interpretation of the EU's fiscal framework. Within the Stability and Growth Pact, limited and conditional flexibility could be introduced to protect high-value health innovation investments, such as advanced manufacturing capacity, digital health infrastructure, clinical trial networks, or strategic pharmaceutical R&D, from pro-cyclical welfare spending cuts. The use of the Pact's escape clause or targeted investment carve-outs, under clearly defined eligibility criteria, monitoring requirements (via the European Semester), and a predefined return to the adjustment path, would create a protected fiscal space with high long-term returns and without undermining debt sustainability. According to a study by McKinsey (2026), improved population health through sustained healthcare spending on treatment and pharmaceutical innovation can generate fourfold returns on investment. For instance, investing in modern medicines for obesity or chronic obstructive pulmonary disease can generate substantial economic returns in high-income countries where health systems can absorb the high cost of these drugs[4]. By recognising health innovation as a productive investment of high social value rather than a

[4] Scaling access to proven, cost-effective health interventions, particularly preventive measures, could generate substantial long-term economic returns. Global projections suggest that expanded prevention and treatment could create up to $12.5 trillion in annual economic value by 2050 (approximately 7% of projected global GDP), with estimated returns of roughly four dollars for every dollar invested. Nearly two-thirds of these gains derive from preventive interventions, yet most countries currently allocate less than 2% of their health budgets to prevention. Without action, populations may spend significantly more years in ill health despite rising longevity (McKinsey, 2026).

recurrent cost, such flexibility would improve Member States' ability to co-finance innovation, crowd in private capital, and sustain Europe's competitiveness in strategically critical therapeutic areas.

The cost to public budgets can be mitigated by adopting a blended approach. Europe's fiscal constraints are real, but they need not crowd out long-term health investment. Health innovation is uniquely well-suited to public-private risk sharing: it delivers high social returns, benefits from pooled demand, and generates long-term cost savings through prevention, productivity gains, and reduced disease burden. EU-level de-risking instruments can play a catalytic role. A Health Innovation Guarantee Facility, backed by the EU budget and implemented through the EIB or InvestEU, could stabilise revenue expectations in areas characterised by high social value but uncertain commercial returns, such as rare diseases, antimicrobials, pediatric medicines, and breakthrough prevention technologies. Complementary instruments could include EU-backed advance purchase commitments, outcome-linked payment guarantees, and co-investment vehicles that crowd in institutional capital at later development stages.

However, pooled demand and joint-negotiation mechanisms must be carefully designed to avoid a race to the bottom in pricing. If aggregation of purchasing power primarily results in further downward price compression, below the weighted-average returns that firms would expect across EU markets, the attractiveness of launching and scaling innovative therapies in Europe could decline significantly. The objective of resource pooling should therefore be to enhance predictability, reduce transaction costs, and stabilise long-term revenues, not to intensify cost containment. Efficiency gains must not come at the expense of sustainable value creation; otherwise, the very instruments intended to strengthen Europe's innovation ecosystem risk undermining its profitability and long-term competitiveness.

Crucially, these instruments should be embedded within a broader effort to deepen European capital markets. A more integrated and liquid capital market, supported by the Savings and Investments Union, can significantly improve Europe's long-term risk–return proposition, but only if it is anchored to credible demand signals. Capital markets amplify incentives; they cannot substitute for them. Without predictable pricing, faster access, and scale, even the most sophisticated financial architecture will struggle to mobilise patient capital for health innovation.

Strengthening Europe's Internal Innovation Capacity

For decades, the global pharmaceutical ecosystem has relied heavily on the scale, pricing dynamics, and capital markets of the United States to

sustain high-risk biomedical innovation. Differences in health spending levels illustrate this asymmetry. In 2024, average health spending across OECD countries reached nearly $6,000 per capita (PPP-adjusted), but disparities remain striking. The United States remains a clear outlier, spending over $14,800 per person, around 2.5 times the OECD average, followed by high-spending European countries such as Switzerland, Norway, and Germany ($9,300-10,000). A broader group of Western European countries, along with Australia and Canada, spends between $7,000 and $8,500 per capita (OECD, 2025). By contrast, spending levels decline sharply across Southern, Central, and Eastern Europe and are substantially lower in Latin American OECD members such as Mexico ($1,590). These divergences highlight both Europe's considerable aggregate purchasing power and the persistent inequalities in health investment capacity within the Union.

However, reliance on external markets as the primary engine for global returns is increasingly fragile. US pricing reforms, fiscal pressures, and geopolitical uncertainty are altering the global distribution of innovation financing. At the same time, China is rapidly expanding its health innovation ecosystem, combining regulatory speed, industrial coordination, and growing scientific capacity. In this evolving environment, depending disproportionately on the commercial dynamics of a single external market carries strategic and economic risks.

This changing landscape presents Europe not only with a challenge, but with an opportunity. Unlike any other region, Europe combines strong scientific capabilities with health systems that enjoy broad political legitimacy and stable public funding. Healthcare spending is largely socialised, reducing financial barriers for individuals and creating a predictable demand base. If properly aligned with capital-market deepening, regulatory coordination, and value-based pricing reforms, this model can underpin a distinctive and resilient innovation ecosystem—one that rewards value, ensures equitable access, and sustains public trust.

The strategic question for Europe is therefore not whether to emulate other systems, but whether to fully mobilise its own internal market. Health innovation should be treated not merely as a budgetary line item, but as a pillar of economic resilience, social cohesion, and strategic capacity. Embedding health innovation within Europe's broader economic governance framework, alongside industrial policy, capital-market integration, and fiscal coordination, would strengthen the Union's ability to finance and scale innovation from within, reducing vulnerability while enhancing competitiveness.

A Call to Action: Completing the Market

The choice facing Europe is not between affordability and innovation, but between managed value creation and unmanaged decline. The path forward is clear. Europe must reduce time-to-market, align pricing, and access through predictable signals, and embed these reforms within a genuinely integrated Single Market framework. Regulatory harmonisation, pooled resources, shared data infrastructures such as the European Health Data Space, and EU-level financing instruments must work together, not in isolation, but as parts of a coherent innovation continuum.

Completing the market will also require institutional design that recognises domestic veto points and bureaucratic path dependence; this is precisely why pilot-based integration, through sandbox regimes, coordinated procurement, and targeted AMCs, can unlock progress where full harmonisation is politically difficult. If Europe succeeds, it can transform its latent strengths into a durable comparative advantage: a Health Innovation Single Market that delivers cutting-edge therapies to patients faster, offers credible returns to innovators, and reinvests value back into public health systems. The potential for Europe's resilience is immense. Rapid vaccine development during the COVID-19 pandemic enabled a swift economic recovery, with millions of lives saved and labour forces shielded from the virus. An efficient single market for pharmaceuticals is not only a high-value-added economic multiplier but also a safeguard against future sanitary crises in which dependencies could be weaponised by competitors. If Europe fails on this front, it risks becoming a discovery hub for others, innovating upstream while value creation, scale-up, and strategic control migrate elsewhere.

The window for action is narrowing, but the foundations are already in place. What is required now is political will, strategic clarity, and the courage to move from cost-containment to value creation.

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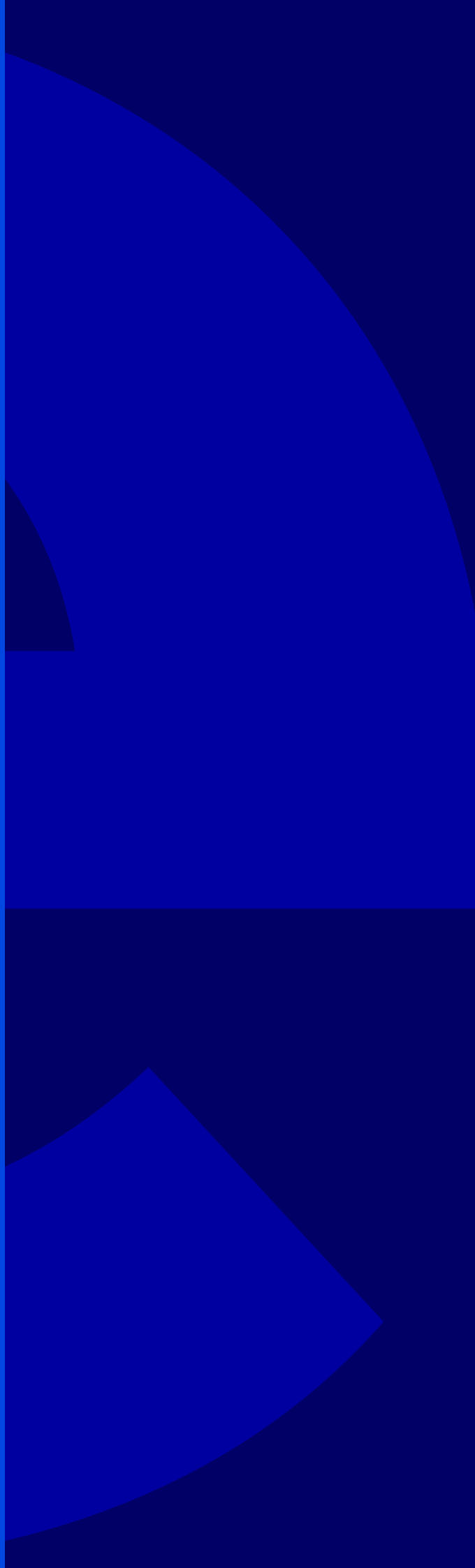

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