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A European Innovation Fund for Transformative Health Technologies; Advancing patient access and competitiveness

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Executive Summary

The European Union (EU) has a strong biomedical research base, extensive clinical expertise and channels significant amounts of public investment into innovation in the health sector. However, these strengths do not consistently translate into timely patient access or into an attractive market in which innovators can launch and scale up transformative technologies. Fragmented national processes for the assessment of health technologies, pricing, reimbursement and procurement weaken the connection between research, adoption and patient access. Ultimately, this has a negative impact on Europe's competitiveness in the life sciences sector.

This problem is particularly acute for advanced therapies, personalised cancer treatments, advanced diagnostics and digital or AI-enabled technologies. These types of innovation often entail high upfront costs, specialised infrastructure and uncertainty at launch. However, the real-world evidence needed to address that uncertainty can frequently be generated only after patients receive access to treatments. Health system readiness, including diagnostic capacity, digital infrastructure and specialised skills, is therefore as important as financing.

National initiatives in the United Kingdom, France and Italy demonstrate the value of managed access, evidence generation, strategic investment and public-private de-risking. However, national initiatives cannot overcome EU Single Market fragmentation alone. The next Multiannual Financial Framework provides an opportunity to establish a European Innovation Fund for Transformative Health Technologies that connects these functions without replacing Member States' responsibilities for pricing and reimbursement. released when products are used or disposed of.

This discussion paper sets out five recommendations:

Recommendation 1: Establish a European Innovation Fund for Transformative Health Technologies under the next MFF

How the next MFF is designed will be a key test for patient access. A European Innovation Fund presents an impactful opportunity for Europe to remain competitive in health innovation, acting as a market completion instrument, bridging research and development, evidence generation and patient access for selected transformative technologies. Such a Fund, as part of the next MFF, should target innovations with clear European added value, including advanced therapies, personalised cancer therapies, advanced diagnostics, selected medical technologies and digital or AI-enabled health solutions, and provide structured, time-limited bridge access pending national reimbursement.

Recommendation 2: Make evidence generation key to the take-up of technologies in a European Innovation Fund

Technologies supported by a European Innovation Fund should be required to generate real-world evidence, apply common outcome measures, undergo appropriate validation (including specific validation for AI-enabled technologies) and be periodically reassessed as evidence develops. The evidence needed to reduce uncertainty can often be generated only if patients receive access and outcomes are tracked in real-world settings. This creates an evidence-access dilemma: uncertainty delays reimbursement, while delayed reimbursement limits the possibility of generating the evidence needed to resolve that uncertainty.

Recommendation 3: Invest in health system readiness and timely take-up to improve the EU's competitiveness

European support for innovation should be accompanied by investment in specialised centres, digital infrastructure, diagnostic capacity, trained professionals and cross-border care pathways. This would help health systems adopt transformative technologies promptly and ensure that patients can benefit from them across the EU. If the European access environment is too slow or uncertain, the risk is not simply that launch strategies are redirected elsewhere. There is also a risk that the entire economic and scientific value attached to innovation (jobs, knowhow, intellectual property, manufacturing potential, future growth, clinical trials, medical education etc.) is weakened or lost in Europe. In this sense, delayed access is not only a consequence of weak competitiveness, but is also one of its causes.

Recommendation 4: Address the separation between the 'push' and 'pull' side of innovation

The EU has been more successful in creating 'push' incentives for research and development than 'pull' incentives that reward innovation once products reach the market. This matters because companies need confidence not only that the EU can support discovery, but also that successful innovation will be valued, made available to patients within predictable timelines and ultimately integrated into healthcare.

Delayed access is not only a consequence of weak competitiveness; it is one of its causes.

Without a stronger link between innovation policy and access policy, clinical research, development and scale-up may increasingly shift towards regions that offer both stronger market opportunities and clearer routes to patient access.

Recommendation 5: Move the European Union from fragmented take-up towards a more complete single market for transformative health technologies

The broader purpose of a European Innovation Fund is to move the EU from fragmented take-up towards a more complete single market for transformative health technologies. It will strengthen Europe's technological sovereignty and ensure that innovations can be scaled up and adopted in Europe rather than migrating to the USA and China. It would also give practical meaning to the idea that health innovation is part of the Single Market. This is not only because pharmaceutical products circulate across borders, but because Europe's ability to attract, develop and scale up innovation depends on whether the Single Market can function as a credible space for adoption. In this sense, the Fund is not an exception to the logic of the Single Market. Rather, it is one of the instruments needed to complete it in a sector where scientific excellence, public health, technological sovereignty and industrial competitiveness are increasingly interconnected.

Introduction

The topic of health innovation has never been more political for the European Union. In an increasingly geopolitical world, the EU is losing ground to the US and China when it comes to the attractiveness of its biopharmaceutical sector.[1] The Trump Administration's Most-Favoured-Nation (MFN) drug pricing policy framework and the recent US trade investigation into Germany's spending on new medicines are key examples.[2] This highlights the fact that the sector is far from immune to political dynamics, in an area where EU Member States have traditionally held significant competence. Moreover, China is moving rapidly from manufacturing strength towards biomedical innovation, supported by growing clinical trial capacity, industrial coordination and strategic investment. It is also emerging as one of the strongest drivers of artificial intelligence in the field of life sciences.[3]

This creates a more competitive global environment in which Europe can no longer rely on scientific excellence alone. To remain competitive, Europe must also become a leading region for the adoption and implementation of innovation. Faster take-up generates valuable real-world knowledge, accelerates future innovation, attracts private investment and strengthens an ecosystem capable of competing globally.

Health innovation is therefore an area where competitiveness, economic security, preparedness and the sustainability of Europe's social model increasingly converge. Innovative medicines, advanced therapies, advanced diagnostics, medical devices and digital health technologies improve patient outcomes and strengthen health system resilience at a time when the EU's population is ageing. They also support high-skilled employment, advanced manufacturing, research-intensive industries and Europe's capacity to compete in high-value global markets.

The European Union has significant strengths on which to build. Its biomedical research base remains strong and its publicly financed health systems provide broad population coverage, clinical expertise and large volumes of health data. However, these assets do not automatically translate into timely patient access or into a sufficiently attractive environment for innovators. The central problem is not simply whether Europe can generate scientific discoveries, but whether it can turn them into technologies that are assessed, financed, adopted and scaled up within European health systems.

This question is becoming more urgent not only because of geopolitical dynamics but also in the context of the ongoing negotiations on the EU's next Multiannual Financial Framework (MFF). The EU is entering a budgetary cycle in which strategic choices will have to be made about which capacities the Europe Union wants to build for the next decade. Health innovation should be part of that debate. If treated only as a cost and not as an investment, it will remain fragmented across programmes, instruments and national systems. If treated as a strategic investment, it can become a lever for competitiveness, societal resilience and more equitable patient access. The next MFF is therefore a relevant entry point for this debate. The Commission has proposed a 2028-2034 EU budget worth €2 trillion, structured around priorities including competitiveness, research and innovation, preparedness and resilience. Within this framework, the proposed Horizon Europe budget would rise to €175 billion, linking research and innovation more explicitly to productivity, competitiveness and solutions to real-world challenges.[4]

The risk is not that Europe lacks initiatives to support innovation. In recent years, the EU has sought to strengthen its health innovation ecosystem through instruments such as the Clinical Trials Regulation, Europe's Beating Cancer Plan, the Pharmaceutical Package, the Life Sciences Strategy and the proposed Biotech Act. These efforts have improved the environment for clinical research, R&D and scientific excellence. However, the EU continues to lag behind regions such as the United States in terms of timely patient access and attractiveness as a launch market. In other words, the Europe Union has been more successful in creating 'push' incentives for research and development than 'pull' incentives that reward innovation once products reach the market. This matters because companies need confidence not only that the EU can support discovery, but also that successful innovation will be valued, made available to patients within predictable timelines and ultimately integrated into healthcare systems. Without a stronger link between innovation policy and access policy, clinical research, development and scale-up may increasingly shift towards other regions in the world that offer both stronger market opportunities and clearer routes to patient access.

To remain competitive, Europe must also become a leading region for the adoption and implementation of innovation.

Box 1 seeks to summarise this competitive landscape by comparing the European Union, the United States and China across two key dimensions: pharmaceutical R&D investment and clinical trial activity.

Box 1. Health innovation competition

The EU between US scale and China's acceleration

Indicator	United States/ North America	China	EU
Pharmaceutical R&D expenditure 2010 → 2022 (€bn)	€30.7bn → €71.5bn	€1.7bn → €14.8bn	€27.8bn → €46.2bn
Pharmaceutical R&D intensity 2022 (approx. % of GDP)	0.29%	0.08%	0.23%
R&D CAGR, 2010–2022	+5.5%	+20.7% *(from a low base)*	+4.4%
Share of global commercial clinical trials, 2023	23% North America	18%	12% EEA
Clinical trial trend	26% → 23% 2018–2023	Commercial trials roughly doubled since 2018	22% → 12% 2013–2023
Strategic reading	Scale, capital depth and faster route to revenue	Rapid R&D and trial acceleration, from a lower base	Strong science, but weaker translation into scale and uptake.

Source: EPC elaboration based on PwC/EFPIA (2024), Figure 13, and IQVIA/EFPIA (2024), p. 15.

Note: R&D expenditure values are reported in €bn at annual exchange rates, following PwC/EFPIA. The US values refer to the United States, while the clinical-trial rows refer to North America. In the EU column, R&D rows use the broader 'Europe' scope from the source (EU27 + UK, Switzerland and Norway), while clinical-trial rows refer to the EEA. The R&D-intensity figures are approximate, calculated as a share of 2022 GDP. Trial figures cover commercial Phase I–IV trial starts; device and suspended/terminated trials are excluded, and multi-region trials are counted once in each region.

This paper argues that the EU should explore whether a dedicated European Innovation Fund could help address the gap between transformative innovations in health and patient access. Such an instrument should not replace Member States' general responsibilities for pricing, reimbursement or health system financing. Rather, it should act as a market completion instrument for a limited and clearly defined set of transformative innovations, operating upstream of national pricing and reimbursement decisions and within existing EU funding frameworks. Its role would be to address cross-border fragmentation by bridging the gap between R&D and patient access, supporting selected innovations where EU-level coordination and investment can help create a more predictable route from development to take-up. A European Innovation Fund would help align public investment, patient access and competitiveness in a way that existing instruments do not yet achieve. Ultimately, the market completion increases Europe's competitiveness overall as explained above.

That argument is developed in this paper in three steps: first, by examining Europe's innovation and access gap; second, by drawing lessons from national models and existing funding mechanisms; and third, by outlining the possible design principles of a European-level instrument for transformative health innovation.

A European Innovation Fund would help align public investment, patient access and competitiveness in a way that existing instruments do not yet achieve.

Europe's innovation and access gap in a geopolitical world

In many areas of biomedical science, Europe generates high-quality knowledge, clinical expertise and early-stage innovation. The persistent weakness is the EU's limited capacity to organise these assets into a coherent pathway from development to take-up. Research funding, clinical trial infrastructure, regulatory science, assessments of health technologies, reimbursement decisions, procurement systems and health system readiness remain insufficiently connected and coordinated.

As a result, the European innovation pathway is fragmented: strong research coexists with slow deployment; regulatory authorisation coexists with limited access; and promising technologies struggle to find a predictable route to scale.[5]

A first manifestation of this problem is that new medicines are generally less available and become available more slowly in Europe than in other major markets.

According to IQVIA, a US health information technology and clinical research company, the United States has the highest absolute availability of new active substances, while most EU countries lag behind the US both in the proportion of approved medicines that ultimately become available and in the time required to reach patients.[6] Of the 27 EU Member States, 25 have longer median delays to availability than the US, and in 22 countries the median time from regulatory approval to availability is one year or more.

This European-level gap is compounded by substantial differences within the Single Market. Even when a medicine receives EU-level marketing authorisation, there is no guarantee that patients across Member States will have comparable access to it. After approval, companies and innovators must navigate national and sometimes regional systems for Health Technology Assessment (HTA), pricing, reimbursement, procurement and budget allocation. These systems reflect legitimate differences in health system organisation, fiscal capacity and political accountability, but their combined effect is a highly uneven access environment. The same product can move quickly into clinical use in one Member State while remaining unavailable, narrowly reimbursed or delayed in another. To give an example: in 2025, Germany provided access to 158 medicines approved by the European Medicines Agency (EMA) between 2021 and 2024, compared with just 53 in Ireland.[7] For patients, the value of innovation therefore depends not only on scientific progress or regulatory approval, but on the capacity of national systems to assess, finance health technologies and make them available. Similarly, the access to personalised treatments depends on access to advanced genomic diagnostics and, due to differences between P&R (pricing and reimbursement) procedures and requirements between EU Member States, there are large differences in access to advanced diagnostics across Europe.[8]

This unevenness has become one of Europe's most visible access problems. Recent indicators show that only a proportion of centrally authorised medicines becomes available across Member States, and that average delays between EU approval and patient access remain substantial.[9] The difference between faster and slower countries can be measured not in weeks or months, but in years. This creates a structural equity issue within the Single Market: European authorisation establishes that a product can be placed on the market, but it does not guarantee that patients across Europe will benefit from it in a comparable timeframe.
In practice, the EU has a common scientific and regulatory gateway, but not a common route to patient access. The same delays also detract from Europe's attractiveness as an innovation environment. Market access is not only a health system decision but is also part of the investment case for health technologies. When reimbursement is slow, uncertain or fragmented, the moment at which innovators can expect return on investment is postponed. This shortens the commercial life of a product, increases the cost of capital and reduces predictability for launch planning.
Large companies may respond by prioritising markets where revenue prospects are clearer and earlier. Smaller and mid-sized innovators may face even stronger constraints. Many of these firms are rooted in Europe, have limited exposure to other major markets and depend heavily on credible expectations of European take-up to raise capital, enter partnerships or continue development.

If the European access environment is too slow or uncertain, the risk is not simply that launch strategies are redirected elsewhere, but that the entire economic and scientific value attached to innovation (i.e. jobs, knowhow, intellectual property, manufacturing potential, future growth, clinical trials, medical education etc.) is diluted or lost in Europe. In this sense, delayed access is not only a consequence of weak competitiveness but is one of its causes.

The problem is especially acute for transformative health technologies. Already today, advanced therapy medicinal products, cell and gene therapies, CAR-T (Chimeric antigen receptor T-cell) treatments, individualised therapies, advanced diagnostics, digital tools and AI-enabled technologies do not fit easily into conventional access models, as discussed in a recent paper on individualised therapies.[10] They typically target small patient populations, require highly specialised clinical centres, involve complex manufacturing or logistics, and generate evidence that matures over time. Very often, these therapies have high upfront costs but potential long-term value through durable clinical benefit, avoided hospitalisations, a reduced number of future interventions or improved quality of life. They may also depend on organisational changes, digital infrastructure or new patient pathways before their value can be realised. These key features of transformative technologies make traditional assessment, payment and take-up models hard to apply today and warrant special attention to avoid future inequities across and within healthcare systems.

Dealing with evidence uncertainty at launch is a core difficulty. Conventional assessment systems tend to work best when there are large trials, mature endpoints, established comparators and relatively predictable patterns of use. Many transformative technologies reach the market with more limited evidence, not necessarily because the evidence is weak, but because the relevant patient populations are small, follow-up periods are short, or long-term outcomes cannot yet be observed.

In practice, the EU has a common scientific and regulatory gateway, but not a common route to patient access.

Payers are therefore asked to make decisions before the full value profile is known. At the same time, the evidence needed to reduce uncertainty can often be generated only if patients receive access and outcomes are tracked in real-world settings.

This creates an evidence-access dilemma: uncertainty delays reimbursement while delayed reimbursement limits the possibility of generating the evidence needed to resolve that uncertainty. Current value frameworks are not necessarily well equipped to manage this dilemma. HTA processes focus on relative clinical effectiveness, cost-effectiveness and budget impact.

This creates an evidence-access dilemma: uncertainty delays reimbursement, while delayed reimbursement limits the possibility of generating the evidence needed to resolve that uncertainty.

These criteria are essential, but they do not fully capture the broader value of transformative technologies. Future value frameworks should adopt a broader societal perspective in health economic evaluations (quantifying indirect costs such as patient and caregivers' productivity) and incorporate Multi-Criteria Decision Analysis (MCDA) to ensure that socioeconomic benefits, system efficiency improvements and avoided long-term costs are recognised. Similarly, a diagnostic or digital tool may generate value by improving patient pathways, reducing delays or targeting treatment more effectively.[11] If these effects are not captured, access decisions may underestimate the health, economic and societal contribution of innovation. The question is no longer whether every new technology should be reimbursed at any price, but whether assessment systems are sufficiently capable of recognising value when it is distributed over time and across sectors.

The EU framework for joint clinical assessments and the publication of the first Joint Clinical Assessment report in July 2026[12] is an important step to help address part of this problem by reducing duplication and creating a more coordinated approach to clinical evidence at EU level. However, HTA assessments neither address nor solve the access gap given that decisions on pricing and reimbursement continue to be national. Therefore, a risk is that any better coordination on clinical evidence is followed by continued fragmentation in valuation and decision-making at national level. The effectiveness of joint clinical assessments will depend not only on the quality of the assessment itself, but on whether it creates greater predictability for subsequent national decisions and whether innovators, regulators, HTA bodies and payers can align earlier on evidence expectations.

Real-world evidence is central to this agenda. For transformative technologies, evidence generation cannot stop at authorisation, nor can it be treated as an optional post-launch exercise. It needs to become part of the access model. This requires disease registries, interoperable data systems, agreed outcomes, methodological capacity and clear rules on how new evidence will be used. Adaptive pricing and outcome-based agreements can help manage uncertainty, but only if they are designed with sufficient clarity from the start and built to recognise the value brought by the transformative technology, even retrospectively. Agreements need to specify what outcomes will be measured, when verification will take place, what data infrastructure will be used and what happens if expected outcomes are not achieved, as well as how pricing is adjusted if they are achieved or exceeded. Without that clarity, there is a risk that managed access becomes a way to postpone difficult decisions rather than a mechanism to support earlier access while managing uncertainty for industry and patients.

The access gap is also visible beyond medicines. Medical devices, advanced diagnostics and digital health technologies face their own take-up barriers. Regulatory approval or conformity assessment may allow entry into the market, but adoption can be limited by hospital budgets, procurement practices, outdated positive lists, workforce capacity or insufficient digital readiness. AI-enabled clinical decision support tools cannot be used effectively where patient records are not digitised or interoperable. Complex personalised therapies may depend on specialised centres, manufacturing capacity, transport logistics and long-term follow-up. In these cases, access is not only a reimbursement question but is also a question of health system preparedness.

This points to a broader weakness in the European model: innovation policy remains too focused on the supply side. Europe has significant instruments to fund research, support partnerships and stimulate technology development. It has fewer mechanisms to shape the demand side: predictable take-up, timely and broad access, procurement readiness, outcome measurement and health system absorption. However, demand matters because innovators and investors respond to signals that a technology will find a market if it demonstrates value. Without such signals, Europe may continue to fund discovery while the most attractive conditions for adoption and scale emerge elsewhere in the world, undermining any potential technological sovereignty versus other markets.

The separation between the 'push' and 'pull' side of innovation is therefore a key structural problem. Whether innovation reaches patients depends on a wide range of actors, including research funders, regulators, HTA bodies, payers, procurement authorities, clinicians, patients, public-private partnerships and investors. However, they often operate according to different incentives and timelines. This weakens Europe's ability to prepare for the launch of transformative technologies, anticipate evidence needs and align investment within areas of high unmet need.

Europe's innovation and access gap should therefore be understood as a chain of connected bottlenecks rather than a single missing instrument.

Scientific strength is weakened by fragmented heterogeneous evidence standards, funding processes, uneven clinical research capacity, slow and divergent access procedures, limited demand-side innovation, insufficient real-world evidence infrastructure and variable health system readiness.

Scaling up national models: early access, managed access and de-risking

Several national systems, which are primarily responsible for patient access to innovation, have developed mechanisms that seek to accelerate such access, manage uncertainty, support investment or strengthen the life sciences ecosystem. These models are useful blueprints because they show that the limitations of conventional pricing, reimbursement and funding frameworks are already recognised at national level. At the same time, they also reveal the structural limits of relying on national experience alone. Each model addresses part of the innovation pathway, but none of them can, on its own, overcome the fragmentation of the European market for health innovation.

The United Kingdom offers one of the most developed examples of a dedicated access mechanism. The UK's Cancer Drugs Fund[13] was designed to provide access to selected cancer medicines before a final decision on routine use in the National Health Service (NHS) has been reached. With an annual budget of £340 million, it allows eligible medicines to be made available while additional evidence is generated over a defined period, before reassessment and a final funding decision. The same logic has been extended beyond oncology through the UK's Innovative Medicines Fund, bringing the total ringfenced NHS funding for innovative medicines through these two instruments to £680 million. The UK's Cancer Vaccines Launch Pad adds a further element by linking access policy to clinical research, with the aim of accelerating access to trials for personalised cancer vaccines and other disruptive technologies.[14] However, it does not address patient access.

The strength of these mechanisms lies in the attempt to move beyond a binary access decision. For transformative therapies, the available evidence at launch may be promising but incomplete. A dedicated managed access route allows patients to receive a medicine while the payer retains the possibility of reassessing its value once further evidence has been collected. This is particularly relevant in areas where delaying access until evidence is fully mature may be clinically difficult and politically hard to justify. The UK model therefore shows that access, evidence generation and reassessment can be organised as a single policy sequence rather than as separate steps.[15]

However, the UK experience, summarised in Figure 1, also shows that managed access is not automatically effective. Its success depends on whether the evidence collected during the managed access period is genuinely designed to resolve the uncertainty identified at entry. If the additional evidence collected during the managed access period is not specifically designed to address the uncertainties that prevented routine reimbursement in the first place, the mechanism may simply prolong the assessment process rather than improve the quality of the final decision. Similarly, if price and value are negotiated too early, when uncertainty remains high, the later evidence-generation phase may have limited effect on the final decision. The lesson is therefore not simply that early access funds are useful, but that they require clear eligibility criteria,[16] targeted evidence plans, explicit reassessment points, exit strategies and trust between payers, clinicians, patients and innovators.

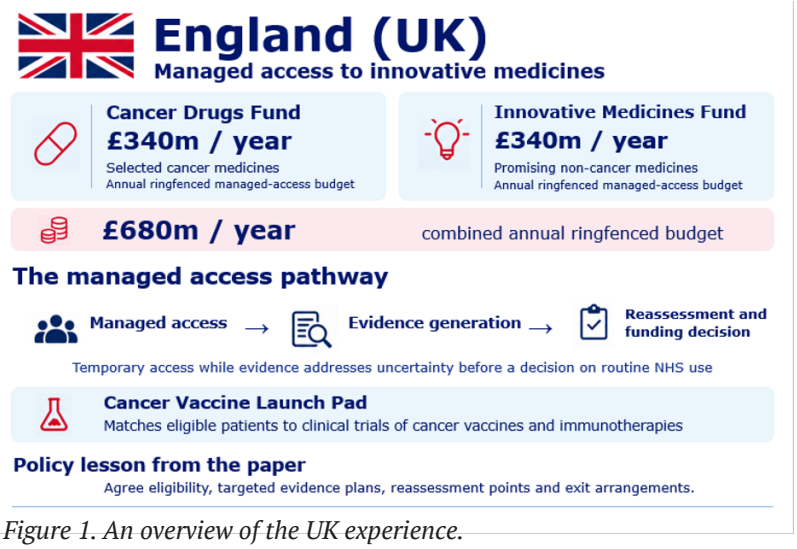

Figure 1. An overview of the UK experience.

The situation in France offers different kinds of examples. Its relevance lies less in a single access mechanism comparable to the UK's Cancer Drugs Fund and more in the combination of industrial policy and access instruments. First, the French Healthcare Innovation 2030 strategy, with a budget of €7.5 billion, reflects a deliberate effort to strengthen the national life sciences ecosystem through support for R&D, industrial capacity, infrastructure, skills and investment. It is therefore primarily a push-side innovation instrument. As such, it strengthens the conditions for developing innovation but does not in itself guarantee reimbursement, adoption or patient access once a technology reaches the market.

The French case is therefore useful because it highlights the importance of directionality. Public resources can do more than finance individual technologies. They can signal that health innovation is a strategic sector, concentrate investment around selected capabilities and support the conditions under which new technologies can be developed, tested and adopted. This matters especially for advanced therapies, genomic technologies, personalised medicine, advanced diagnostics and digital tools, which require specialised infrastructure and coordination across the innovation pathway. A national strategy can help align these elements more effectively than fragmented, project-based funding.[17]

Beyond its industrial strategy, France also offers an important example of early access framework through the Early Access Scheme (AAP, Autorisation d'accès précoce or Accès Précoce). The French model is based on the principle that promising innovations may justify patient access before completion of the pricing and reimbursement standard process, provided that remaining uncertainties are addressed through evidence generation. The French model provides a practical example of an 'access bridge' mechanism that manages uncertainty and seeks to balance timely patient access with collection of real-world data on utilisation, effectiveness and safety.

At the same time, the French example, summarised in Figure 2, also illustrates the limits of national industrial policies in a fragmented European market. A strong national life sciences strategy can strengthen an ecosystem, but it does not guarantee that patients across Europe will access the resulting technologies in a timely or equitable way. Nor does it remove the need for companies to navigate different reimbursement systems, evidence expectations, procurement practices and budgetary constraints across Member States. In other words, while national strategies can strengthen domestic capacity, they cannot by themselves address the cross-border fragmentation that limits the ability of health innovations to scale up across the European market.

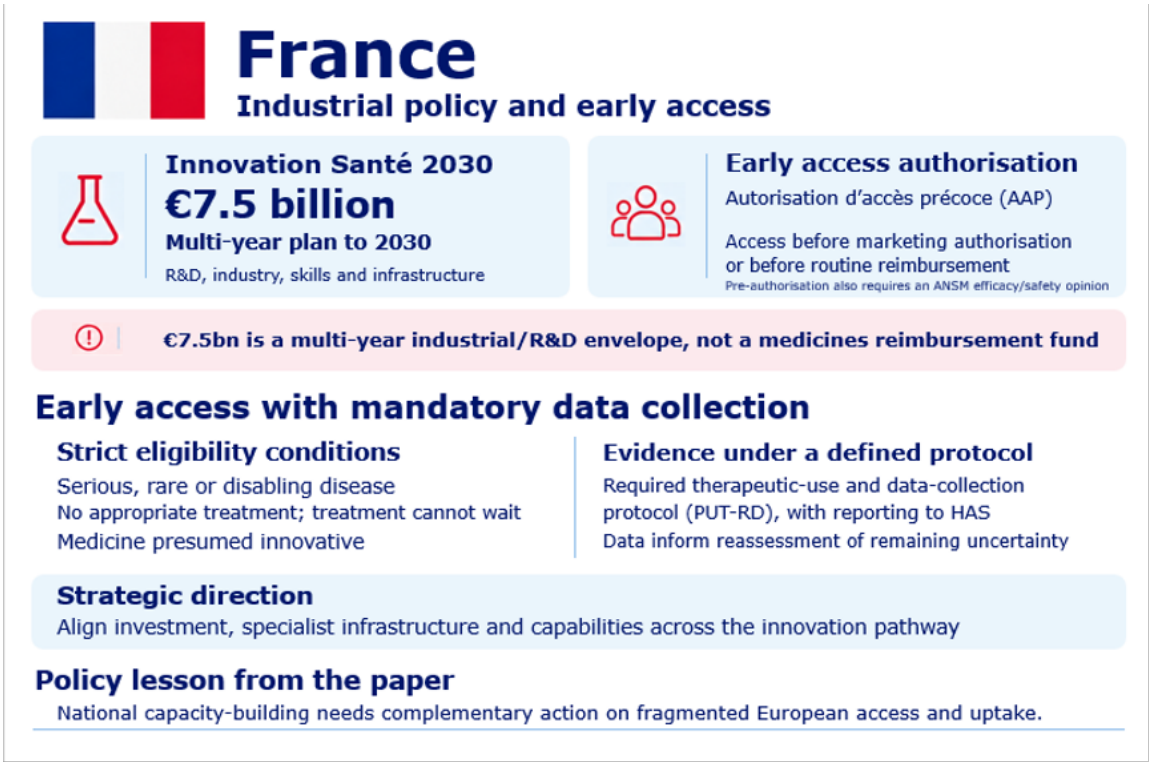

Figure 2. An overview of the French experience

The Italian case provides a particularly relevant example of how dedicated public funding can support timely and equitable access to innovative medicines within a decentralised health system. The Italian Innovative Medicines Fund is a dedicated financing mechanism within the Italian National Health Service. It is designed to ensure access to medicines that are recognised as innovative by the Italian Medicines Agency (AIFA) while limiting the immediate financial burden on regional healthcare budgets. The Fund currently amounts to approximately €1.3 billion.

Eligibility is linked to AIFA's assessment of innovation, based on three main criteria: unmet therapeutic need, added therapeutic value and the quality and robustness of the supporting scientific evidence. Medicines granted innovative status can be financed through the dedicated Fund, while prescriptions and dispensations are monitored through AIFA registries. Resources are then allocated to regions according to actual utilisation. Since 2025, medicines with conditional innovativeness status, as well as selected last resort antibiotics addressing antimicrobial resistance, have also become eligible for Fund coverage.

The model is particularly relevant because it separates, for a defined period, access to selected innovative medicines from the immediate budgetary constraints of individual regions. Medicines included in the Fund benefit from dedicated coverage for three years and are exempt from the clawback mechanism associated with hospital pharmaceutical expenditure overruns. In this way, the Fund acts as a safeguard for patient access while also protecting pharmaceutical innovation from short-term budgetary pressures.

The Italian experience, summarised in Figure 3, therefore illustrates a function that is highly relevant to the proposed European Innovation Fund: a dedicated, criteria-based funding mechanism can provide a temporary bridge between the recognition of innovation and its routine financing within decentralised health systems. At the same time, the Italian model also highlights the importance of eligibility design and implementation. A significant share of available resources has remained unspent in recent years, partly due to increasingly restrictive criteria for the recognition of innovativeness. This suggests that the effectiveness of a dedicated fund depends not only on the size of its budget, but also on whether eligibility rules allow resources to reach innovations for which access support is most needed.

More broadly, and separately from the Innovative Medicines Fund, Italy also has public investment instruments such as CDP Venture Capital and the Italian National Innovation Fund, which support start-ups, scale-ups, technology transfer and growth financing.[18] These instruments serve a different function from access funding, but they illustrate the complementary role that public finance can play across different stages of the innovation pathway.[19]

Taken together, the UK, French and Italian examples show three distinct responses to the same structural problem. The UK model focuses on managed access and evidence generation. the French model focuses on strategic direction and ecosystem building, as well as managing uncertainty through early access and real-world evidence (RWE) generation for innovative medicines. And the Italian model focuses on making medicines that fulfil certain innovativeness criteria available to patients and protecting them, for a period of three years, from the clawback mechanism linked to pharmaceutical expenditure overruns.

While each approach is only a partial solution, each addresses a weakness in the innovation pathway. Early access without targeted evidence generation can become a delayed decision. In a private-sector innovation environment, an industrial strategy focused solely on push incentives may increase R&D activity in the short term. However, without a functioning market that values and adopts innovation, investors lack a predictable return, weakening the business case for future innovation and reducing the sustainability of the system.

These examples also point to a broader lesson for the EU's Single Market. Health innovation does not move through a single market in the same way as ordinary goods and services. Even when regulation is centralised, the conditions that determine take-up remain dispersed across national and regional systems. Pricing and reimbursement, HTA, procurement, workforce readiness, data infrastructure and budgetary priorities all shape whether innovation reaches patients. The Single Market for health innovation is therefore incomplete not because Europe lacks scientific capacity, but because the downstream conditions for adoption and scale remain fragmented.

There are two underlying policy questions. The first is whether there are any learnings to be gained from national solutions. And the second is whether there is value in an integrated European innovation approach, be it by supporting Member States or strengthening Europe's position in health sciences. Completing the Single Market does not mean imposing uniformity, replacing national health systems or centralising pricing and reimbursement decisions. It means reducing avoidable fragmentation where it prevents patients from accessing innovation and prevents innovators from seeing Europe as a credible place to launch, scale up and reinvest. The UK, French and Italian experiences, summarised in Figure 4, do not offer a ready-made blueprint, but they do identify functions that a more coherent European approach would need to connect: managed access, evidence generation, strategic investment, public-private de-risking and implementation capacity.

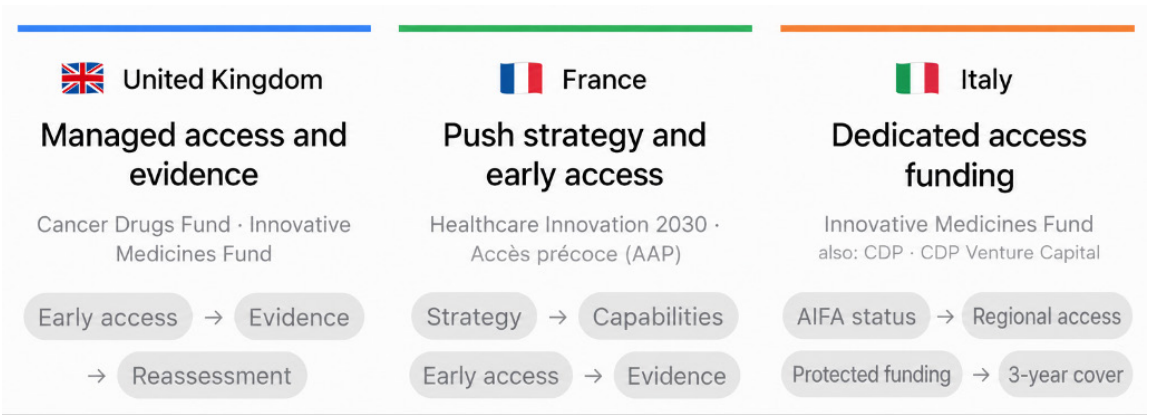

Figure 4. A comparison of the UK, French and Italian experiences

Seizing the political momentum: towards a European Innovation Fund for Health

A market completion instrument

Against this background, the way in which the next MFF is designed will be a key test for patient access. The challenge is not only to provide sufficient funding for R&D, but also to ensure that innovation delivers tangible benefits for patients and strengthens Europe's competitiveness in health innovation. In this context, the creation of a European Innovation Fund for Health can play an important role. Its rationale should be to address market failures and structural and systemic inefficiencies that prevent transformative health innovation from moving from development to assessment, evidence generation and adoption across the European market. Rather than financing the value of medicines themselves, the Fund should finance transitional activities that facilitate their adoption, such as evidence generation, implementation support, infrastructure and other enabling conditions needed before stable national reimbursement is in place.

A European Innovation Fund would help create the conditions under which national reimbursement decisions can be taken more predictably. It would do so on the basis of stronger evidence and within a less fragmented European environment, thereby supporting both patient access and Europe's attractiveness as a place to develop, launch and scale up innovation.

The Fund should be understood as a European market completion instrument for health innovation. Its objective would not be to determine what Member States must pay for a medicine, device or digital technology. Nor would it oblige national health systems to reimburse a given product. Rather, it would support access to a limited and clearly defined set of transformative innovations, across Member States, in the phase before national reimbursement is secured. In doing so, it would not replace national pricing and reimbursement systems as such but would address a specific gap in the current European pathway: the absence of a common mechanism to bridge R&D, evidence generation and patient access for disruptive technologies.

Legal basis and institutional fit

If the fund were framed primarily as a health-financing tool, it would immediately raise political and legal concerns about national competences over pricing, reimbursement and the organisation of healthcare systems. By contrast, framing it as a market-building and competitiveness instrument shifts its purpose and circumvents these concerns. This framing also points to the most plausible legal basis: Article 114 of the Treaty on the Functioning of the European Union (TFEU). This would underpin the market completion dimension of the instrument, particularly where the objective is to reduce fragmentation and improve the functioning of the internal market for transformative health technologies. Such an approach would not require harmonising national pricing or reimbursement decisions. Rather, it would establish a common European framework for functions that are currently fragmented or underprovided.

Depending on its final architecture, the fund could also rely on complementary legal bases. Article 173 TFEU would be relevant if the instrument is designed to support the competitiveness of Europe's life sciences, biopharmaceutical, medtech and digital health industries. Articles 182 and 183 TFEU would be relevant for the research and innovation dimension, particularly where the fund supports clinical research, real-world evidence generation, data infrastructure, demonstration projects or technology deployment. Article 168(5) TFEU could provide an additional health policy basis for incentive measures, coordination and support actions, provided that the fund does not harmonise national rules on health system organisation or financing. The legal architecture would therefore reflect the hybrid nature of the problem. Health innovation sits at the intersection of internal market, industrial policy, research and public health. A European Innovation Fund would need to be built precisely at this intersection. Its purpose would be to make the European market for transformative health technologies more complete, without pretending that the EU can or should take over the core distributive decisions that remain at national level.

Scope, eligibility and core functions

The scope of the European Innovation Fund should be clearly defined, focusing only on transformative health technologies where fragmentation is particularly damaging and where Europe gains a competitiveness edge or maintains it. This could include advanced therapy medicinal products, cell and gene therapies, personalised cancer therapies, individualised neoantigen therapies, advanced diagnostics, selected medical devices, digital and AI-enabled health technologies, and other areas of high unmet need or strategic European relevance.

Firstly, the fund should focus on technologies that raise a European coordination problem: small or dispersed patient populations, evidence uncertainty that cannot be resolved within one national system alone, specialised infrastructure needs, cross-border logistics, high upfront investment costs or a clear risk that technologies developed in Europe will fail to be

adopted and scaled up in Europe. Selectivity would be important both for financial sustainability and for political legitimacy. The fund should support innovation where European added value is demonstrable.
In operational terms, the fund could be structured around a limited number of goals. The first objective would be to facilitate regulatory authorisation and national take-up. This does not mean paying indefinitely for products after approval. It means providing a structured bridge for selected technologies where early access is justified, but where additional evidence is still needed before stable national reimbursement decisions can be made. This bridge would need to be time-limited, conditional and linked to clearly defined evidence requirements.

The second objective would be to strengthen shared evidence generation. For transformative technologies, the problem is often not only that evidence is incomplete at launch but also that there is a mismatch in what is considered to be sufficient evidence. Another challenge is that certain breakthrough technologies function as platforms rather than single products. Their first indication may demonstrate only part of their overall potential. Further indications and additional data may generate evidence for benefits beyond what is originally presented for decision making. This is also the case for advanced diagnostics, when moving away from single-gene tests and hotspot tests to broad testing, such as CGP (Comprehensive Genomic Profiling), which can include 300 genes in a single test. It is not tied to a single product and its value becomes dynamic.[20]

A European fund could support common outcome sets, interoperable registries, cross-country data collection and methodological standards for real-world evidence. This would be particularly useful where patient populations are small, where long-term follow-up is needed or where national datasets alone are insufficient. The fund would therefore help turn access into a source of learning for future decisions.

The third objective would be to support health system readiness. Transformative technologies require specialised centres, trained professionals, diagnostic capacity, digital infrastructure, manufacturing ecosystems or cross-border pathways. Building this up takes sometimes more than two years, which requires substantial upfront investment that is therefore at risk. A European Innovation Fund could help support these enabling conditions, particularly through networks of reference centres or 'lighthouse' sites capable of testing and scaling up new models of care. This would shift part of EU innovation policy from the supply side to the demand side: not only funding the development of technologies, but preparing health systems to use them.

The fourth objective would be investment de-risking. Many European innovators face a difficult financing environment when access routes are slow or uncertain. A European Innovation Fund could help reduce this uncertainty through guarantees, blended finance, co-investment, technical assistance or links with existing European and national investment instruments.

The objective would not be to replace private capital, but to make European health innovation more financially viable where public value, strategic relevance and market fragmentation justify intervention.

The fifth objective would be to strengthen competitiveness through timely take-up. Patient access also contributes to Europe's attractiveness as a place to develop, test and scale up transformative technologies. Earlier take-up helps health systems build clinical experience, generate real-world evidence and develop the skills needed to use new technologies effectively. It also sends a stronger demand signal to innovators and investors. A European Innovation Fund could therefore support competitiveness by helping health systems become early and capable users of selected transformative technologies.

These objectives should be interconnected rather than treated as separate silos. The point of a European Innovation Fund would be to overcome the fragmentation between research funding, industrial support, regulatory science, HTA, reimbursement, implementation and competitiveness.

Governance, financing and safeguards

Governance of the fund would be as important as its financing. To succeed, the fund would require a structure that brings together stakeholders operating across different stages of the innovation pathway, including relevant Commission services, EMA and regulatory experts, HTA bodies, national payers, patient representatives, clinicians, public-private partnerships, innovators, and investors. Its role should be practical: identifying eligible technologies, agreeing evidence expectations, assessing infrastructure needs, coordinating data collection, and ensuring that support from the fund is linked to clear objectives and exit points.

A useful way to define the fund's institutional role is to distinguish between three questions. The first is whether a technology works, a matter primarily for regulatory assessment and clinical evidence. The second is whether it is valuable, which relates to HTA assessments, comparative effectiveness, unmet need, broader health impact and real-world outcomes. The third is how access should be financed and under which payment conditions. This is the most politically sensitive question.

A European fund should not replace national pricing and reimbursement systems, but neither could it avoid this issue altogether. During the fund-supported phase, it would need to establish clear funding terms for the selected technologies that it covers, acting as an initial booster to secure availability and timely access across Member States. Once a product moves beyond the fund, responsibility for continued reimbursement would return to Member States, supported by stronger evidence, greater coordination and a clearer European access signal.

The financial set-up could combine EU resources with national matching contributions, in-kind contributions, European Investment Bank (EIB)-type financial instruments, private capital and targeted support from existing EU programmes. Participation could be introduced in phases, beginning with a limited number of technologies, therapeutic areas, countries or centres, and expanding as the model proves its value. This approach would allow the EU to strengthen coordination without requiring full uniformity from the outset.

Such a phased approach would also help manage political sensitivities. Rather than transferring core reimbursement powers to the EU, Member States would participate in a framework that supports the assessment, financing and implementation of technologies that are difficult to manage individually. Smaller or less affluent Member States could benefit from shared evidence infrastructure and pooled learning, while larger Member States could benefit from more predictable European take-up and better coordination of investment.

The underlying logic is one of mutual capacity building rather than centralisation.

Safeguards would be essential. The fund should have a clear mandate, transparent eligibility criteria and strict exit rules. It should not become a permanent compensation mechanism for national underinvestment, nor a way to reward innovation without credible value. Support should be conditional on companies' participation in evidence generation, data sharing where appropriate, as well as outcome measurement and reassessment. Input from patients and clinicians should be integrated into the process, as value and implementation cannot be assessed solely through financial or administrative criteria. The fund should also be evaluated against measurable outcomes: time to access, evidence generated, number of participating Member States, take-up in clinical practice, investment leveraged, reduction in access inequalities and patient outcomes achieved.

Conclusions

The broader purpose is to move the European Union from fragmented take-up towards a more complete single market for transformative health technologies. National best practices demonstrate that early access, strategic investment and public-private de-risking can address parts of the challenge. However, what is still lacking is a European-level mechanism that links these functions across borders and enables what individual Member States cannot or will not deliver alone. A European Innovation Fund for Transformative Health Technologies could fill this gap by creating a more coherent European pathway from innovation to take-up. This mechanism would help Europe to build and retain strategic capabilities. It would strengthen Europe's technological sovereignty and ensure that innovations could be scaled up and adopted in Europe rather than migrating to the USA and China.

Designed in this way, the fund would not undermine national health competences. Rather, it would help make them work better together in areas where fragmentation currently weakens both patient access and European competitiveness. It would also give practical meaning to the idea that health innovation is part of the Single Market - not only because pharmaceutical products circulate across borders, but because Europe's ability to attract, develop and scale up innovation depends on whether the Single Market can function as a credible space for adoption. In this sense, the fund is not an exception to the logic of the Single Market. Rather, it is one of the instruments needed to complete it in a sector where scientific excellence, public health, technological sovereignty and industrial competitiveness are increasingly interconnected (see Figure 5).

Figure 5. The interconnectedness of the health innovation sector.

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

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