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European Federation of Pharmaceutical Industries and Associations

No delay, no divide: Innovation for European patients from day 1
Position Paper

Growing geopolitical tensions between key pharmaceutical markets with diverging approaches to health and medicines spending, could have a negative impact on access to medicines for European patients. This creates new challenges that European governments and the European research-based pharmaceutical industry must respond to in concert if they want to maintain the capacity to innovate in Europe, regain Europe's competitive edge in a globally challenging environment and ensure that innovative medicines are available for European patients. This will require change on multiple fronts, particularly the amount Europe's healthcare systems invest in pharmaceutical spending, but also the changes in rules and processes that prevent patients from having access to medicines from day one following regulatory approval by EMA.

Europe's research-based pharmaceutical industry is one of the largest and most strategic export sectors, generating over €225 billion in gross value added (GVA) and employing around 730,000 people directly.[1] It drives medical progress by researching, developing and bringing innovative medicines that improve health and quality of life for patients around the world. Yet, without action, the currently evolving global pricing and access environment creates a mounting threat affecting European patients and industrial competitiveness. This highlights the need for a pricing framework across Europe that adequately values and rewards innovation and ensures equitable contributions from Member States based on their economic and epidemiological profiles. Unless urgent action is taken, Europe risks slower and restricted patient access to innovative medicines, leading to poorer health outcomes, loss of high-quality and skilled jobs, reduced investment in innovation, and a weakened position in global health technology.

To address the potential implications of the US referencing prices of some European markets and safeguard future availability of medicines in Europe, EFPIA calls for an amendment to countries' pricing legislations to give companies the discretion to set launch prices and offer patient access to innovation on day 1 in European markets after marketing authorisation approval (avoiding access being delayed by the national pricing and reimbursement process which will subsequently determine conditions affecting availably in the publicly reimbursed market).

Access and availability
In this paper, we use the term availability to refer to the inclusion of a centrally approved medicine on the public reimbursement list in a country. A medicine is available on the market if patients can receive the medicine under a reimbursement scheme. We use access more generally to mean if patients can use medicines within the country's healthcare system.

A strategic imperative: Addressing delayed access and weakening competitiveness

Action is urgently needed to improve access and availability of innovative medicines in Europe in a constantly changing geopolitical environment and to secure Europe's strategic position in global markets.

European patients are waiting longer than previously for new medicines, and the region's role as a leader in pharmaceutical innovation is weakening. IQVIA report notes that 110 (40%) new active substances (NAS) launched in the United States since 2020 are not yet available in Europe. In contrast,

[1] PwC (2024) Economic footprint of the pharmaceutical industry in Europe https://efpia.eu/media/3dqjpl3x/economic-footprint-of-the-pharmaceutical-industry-in-europe-report.pdf

only 14 European launches are not yet available in the United States.[2] Access remains fragmented: on average, only 46% of centrally approved medicines are available to patients in an EU country, and just 29% are fully reimbursed through public systems. [3] According to EFPIA's Patients W.A.I.T. 2024-2025 survey, availability varies dramatically between Member States: 90% of all EU-approved medicines are available on the German market, whilst only 39% are available in Poland or 19% in Romania. It now takes an average of 578 days for a new medicine to reach patients in Europe after regulatory approval, this is more than a year and a half.[4] In comparison, new medicines are typically filed earlier with the US FDA, and approval timelines are shorter, by an average of 3 to 4 months, resulting in significantly faster and broader access for US patients. This regulatory gap, combined with country-level delays linked to pricing and reimbursement processes in Europe, is reinforcing the growing access divide between the EU and the US.[5]

From a broader industrial perspective, the region's share of global pharmaceutical R&D investment has fallen from 41% in 2001 to 31% today, while the US and Asia attract an increasing share of both capital and clinical development. This means access to innovation through clinical trials is also a diminishing opportunity for Europeans.[6] Between 2019 and 2023, two-thirds of new medicine sales were generated in the US, compared with only 16% across Europe's five largest markets.[7]

A significant part of this challenge lies in Europe's current pricing and reimbursement environment. Nearly all EU countries require an approved price before launching in the publicly reimbursed market, creating delays even after regulatory authorisation. Many apply external reference pricing (ERP), which ties a country's price to those of other countries, often to the lowest price in the basket. **These mechanisms, intended to control costs, have instead created a system of interdependence that may further delay and discourage early launches, ultimately slowing down patient access, particularly in smaller markets.** The pressure could be significantly amplified by new international pricing comparisons emerging outside Europe, in particular, the implementation of the Most Favoured Nation (MFN) principle for pricing new medicines on both the public and private US market.

The concept: Moving towards access to innovation for European patients from day 1

Companies want to make their new products available to patients everywhere in Europe upon market authorisation. This is not possible today and requires change. To improve the availability of medicines and ensure Europe can be globally competitive in life sciences, the industry is proposing a straightforward approach – the removal of barriers to companies announcing a public price on the day of marketing authorisation, and the establishment of mechanisms for reimbursed access pending confidential price negotiations.

The 'Innovation Access Day 1' concept would require a clear set of actions:

1. Operational freedom in public pricing, enabling companies to set a visible launch price and access from day 1 the private market and possibly the reimbursed market.

[2] IQVIA, Global Trends in R&D 2025
[3] EFPIA (2025) The root causes of unavailability of innovative medicines and delay in access https://www.efpia.eu/media/er5dshuq/cra-efpia-root-causes-of-unavailability-and-delay-final-2025-report-29-apr-2025-stc.pdf
[4] EFPIA's Patients W.A.I.T. 2024 report https://efpia.eu/media/oeganukm/efpia-patients-wait-indicator-2024-final-110425.pdf
[5] Centre for Innovation in Regulatory Science (2024) R&D Briefing 93: New drug approvals in six major authorities 2014–2023: Changing regulatory landscape and facilitated regulatory pathways. Centre for Innovation in Regulatory Science (CIRS), London, UK.
[6] https://www.efpia.eu/news-events/the-efpia-view/efpia-news/europe-s-share-of-global-medicines-rd-shrinks-by-a-quarter-in-20-years-as-sector-s-declining-trends-continue/
[7] https://www.efpia.eu/media/uj0popel/the-pharmaceutical-industry-in-figures-2025.pdf

2. Allowing companies to maintain the publicly listed price over the life of the product, with or without reimbursement.
3. National systems to provide reimbursed access pending pricing negotiations.
4. A clear, fair and predictable resolution pathway in cases where pricing negotiations are unsuccessful (e.g., this should be determined nationally but could include mediation and structured escalation, and where compatible with national law, arbitration), designed to support timely, good-faith agreement between parties. This determines a confidential, value-based reimbursed price within a defined timeframe, consistent with the requirements of the Transparency Directive (e.g., 180 days from the reimbursement application to resolution).
5. Confidentiality of negotiated net prices.

At all times, the company should retain the right to withdraw its reimbursement application in a way that safeguards continuity of care for patients already initiated on treatment and remains commercially reasonable. This voluntary approach should also ensure that companies are not compelled into unintended public price listings or price reference points that could undermine sustainable access across countries. Where withdrawal from the public reimbursement channel occurs, it should not prevent continued availability through appropriate and nationally recognised early access pathways and non-reimbursed channels (e.g., self-pay) at the company-set launch price. This would apply to all European countries.

The benefits: Faster access, sustainable investment and stronger Europe

A commercial framework, which allows commercial launch right after marketing authorisation at a list price determined by the marketing authorisation holder within national frameworks, can support earlier patient access and more predictable processes for all relevant stakeholders, including public health authorities, patients, and industry. This requires procedural or legislative adaptations to pricing and reimbursement frameworks. However, **the benefits of this will only be realised if undertaken alongside a clear and explicit commitment by Member States to increase pharmaceutical investment and budgets in line with medical innovation and societal need**.

This would result in sustained and equitable patient access to innovative medicines:

- **Faster patient access:** It would remove an unnecessary and time-consuming barrier to direct patient access by granting companies the right to set a price at launch within national frameworks. This is an essential step to allow medicines to reach patients as soon as they are approved, while safeguarding the government's ability to review medicines and determine reimbursement.

- **Improved equity across countries**: Discretion in setting the company launch price would also narrow the time to access gap between countries, substantially improving health equity in Europe**,** ensuring patient access depends on health needs rather than where a patient happens to live.

- **Building on existing models that deliver for patients:** Countries that already permit companies to determine a price at launch show clear benefits such as immediate access for patients who need medicines where the HTA and reimbursement negotiations can follow in a defined period giving price alignment with value without foregoing a robust process of value and assessment.

- **Maintaining global competitiveness:** Allowing companies to set prices at launch also strengthens Europe's strategic position in global markets. By preserving the discretion to set launch prices, whilst allowing commercial agreements with payers, Europe can avoid falling behind other countries and maintain the value of its innovations and regain its appeal as a priority launch region. However, competitiveness cannot be preserved through pricing mechanics alone. In a

global environment shaped by external reference pricing and cost containment measures, insufficient European investment in innovative medicines risks systematically undervaluing innovation, reducing net sales, and weakening incentives for research, development, and early launch in Europe. A system that focuses on constraining prices, without corresponding growth in pharmaceutical budgets, risks further eroding Europe's attractiveness as a priority launch region and surely as a region to conduct business including R&D. If urgently undertaken, alongside other industry priorities, this would help to address the threat to Europe's competitiveness, securing gains and reinvestments for the longer term.

In essence, Innovation for European patients from Day 1 is a balanced solution: it ensures faster patient access (including fast access to innovative medicines on private markets), preserves public oversight through post-launch review, and helps maintain Europe's relevance as a hub for pharmaceutical innovation. This would be an important step forward, but to deliver meaningful and lasting benefits for patients, it must be complemented by increased pharmaceutical budgets.

What needs to change:

To make Innovation for European patients from Day 1 work in practice, several enablers are required:

1. **Legal and procedural flexibility**: Countries should permit companies to set an initial launch price once a medicine is approved, without being delayed by formal price and reimbursement processes. This should avoid long waiting periods between authorisation and availability and align with the existing timings in the Transparency Directive's access requirements, thereby giving patients faster access to innovation. Where this is currently not possible, national and regional legislation, rules or norms would need to change. Although primarily an issue of national competence, the European Commission clearly has a role in ensuring compliance with the Transparency Directive.

2. **Protection of commercial pricing mechanisms**: Confidential commercial terms by payers should be maintained or improved by strengthening the concepts of value-based pricing and confidentiality of commercially sensitive information, such as reimbursed net prices.

3. **Adjustment of external reference pricing:** Reduce reliance on external reference pricing and prioritise national value-based pricing. Under this proposal, manufacturer-set launch prices should be assessed through national HTA and value frameworks, with confidential net prices used to address affordability, rather than being constrained through cross-country price referencing. This shift is essential to avoid distorted value signals, launch delays, and inequitable access, and to support timely access to innovation.

4. **Eliminate mechanisms that distort net prices:** Now is the time to ensure that healthcare systems and medicines budgets are appropriately financed to meet the population requirements in each Member State, including the elimination of the temporary austerity measures from the financial crisis, such as rebates or clawbacks, which disproportionately impact innovation and therefore limit the reliability and attractiveness of the European market.

Call for action

Europe has a choice: either continue with a fragmented, bureaucratic system that delays patient access and erodes its industrial base, and ignore the risk posed by geopolitical challenges, or act decisively to restore its leadership in health and life sciences innovation.

Establishing a clear **framework for Innovation for European patients from Day 1** is necessary, though not a standalone step in this direction. It would enable Europe to:

- Deliver day 1 access to new treatments for patients across all Member States,
- Maintain affordability and value through post-launch reimbursement assessment, and
- Strengthen its strategic autonomy and global competitiveness in a rapidly shifting geopolitical landscape.

EFPIA and its member associations are committed to this new access and pricing framework and will undertake all needed actions to work with governments to amend national legislations that prevent patient access to innovation day 1. We see this initiative as an urgent and necessary condition to preserve a thriving competitive innovative research-based pharmaceutical industry in Europe.