MEMO

A competitiveness strategy for the European healthcare sector

This MEMO note outlines a proposal for a competitiveness strategy for EU healthcare industries. It reacts to the global challenges: Trump Administration MFN and tariff policy; competition with Asian countries; internal EU policies that harm medicines supply.

1. **Response to Trump Administration policy**: Agree access mechanism for markets where originators do not launch in EU; support generic and biosimilar uptake strategy to create financial leverage for investment in healthcare; engage with US on health security cooperation.
2. **Competitive industrial ecosystem:** Allocate Competitiveness Fund resources to off-patent manufacturing investment for technology (to compete on cost), for greener production processes and for health security responsiveness. This will make Europe an attractive location for investment.
3. **Amend EU policies that harm competitiveness**: While continuing to work with our industry to improve the environment, for example our manufacturing footprint, adapt legislations that clearly represent a major threat to medicines availability like UWWTD or ensuring a thorough assessment of the sector before applying PFAS restrictions.

Context

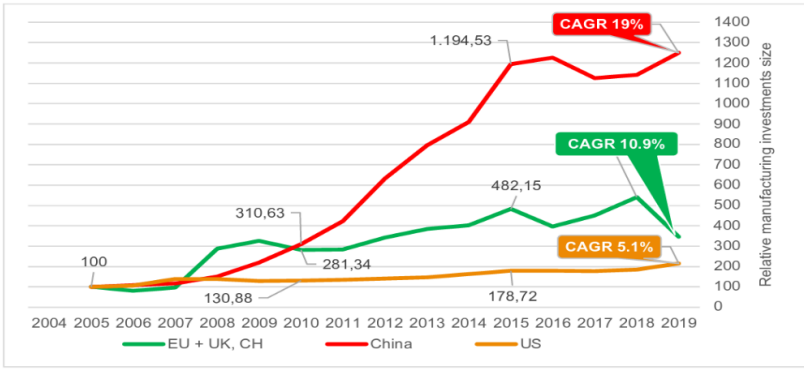
Europe has reached a strategic turning point in pharmaceutical policy. The reform of EU pharmaceutical legislation, the Critical Medicines Act and the Biotech Act, together with the reform of the Medical Devices Regulation, signal a broader shift: medicines policy can no longer be separated from industrial policy, resilience, competitiveness and health security. At the same time, measures such as the Urban Wastewater Treatment Directive and PFAS-related restrictions show the need to better align environmental and pharmaceutical policy to avoid unintended consequences for medicines availability and production in Europe.

The sector also faces external pressure. In the United States, most-favoured-nation pricing policies are reshaping global pricing dynamics and could worsen launch delays or non-launch in lower-price markets**. As the recent UK-US MFN agreement is expected to raise UK pharmaceutical spending by 10%, or £1 to 1.7 billion per year, a similar effect could follow in the EU.[1] This could mean a 5-10% increase in Member State pharmaceutical spending, or roughly €15-30 billion per year**.

China is also emerging rapidly as a pharmaceutical and biotechnology competitor, backed by scale, industrial strategy and growing innovation capacity. Within Europe, budgetary pressure on healthcare systems continues to rise.

[1] https://commonslibrary.parliament.uk/research-briefings/cbp-10850/

Figure 6: Relative growth in pharmaceutical manufacturing (including APIs and generics) is greatest in China[55]



2 Source: CRA analysis of various sources [56] *CAGR (compound annual growth rate) is the average rate of growth between two given years

The EU's own policies also present major challenges for the future. The ill-conceived Urban Waste Water Treatment Directive (UWWTD) and the clumsy review process for the restriction of PFAS chemicals represent the biggest threats to EU manufacturing and supply security. The EU must now address these fundamental threats to its industry.

As Europe seeks to restore competitiveness and growth, it should prioritise the pharmaceutical sector, which is a strategic industry and major contributor to the EU economy. It accounts for 5% of manufacturing value added and nearly 11% of EU exports (Draghi report). Without a more strategic response, these pressures will weaken access to medicines, undermine security of supply, and reduce investment, manufacturing and high-quality employment across the pharmaceutical value chain.

The Challenges

These developments create three strategic dilemmas Europe must now address more coherently:

1. How can **Europe respond to most-favoured-nation pricing pressure without worsening access inequalities across Member States**, especially if lower-price markets face higher risks of delayed launch or non-launch?
2. How can **Europe invest in health security**, **strategic capacity** and **preparedness** to strengthen resilience without adding unnecessary regulatory or financial burdens?
3. How can **Europe align environmental ambition with pharmaceutical policy** to ensure medicines availability, supply security or industrial competitiveness?

EU responses

1. EU response to US Policy

The Trump administration is pushing pharmaceutical manufacturing from Europe to the US while using external reference pricing to align US prices with those in Europe. This could shift investment to the US and delay or prevent launches in lower-price EU markets. Europe should respond with three actions:

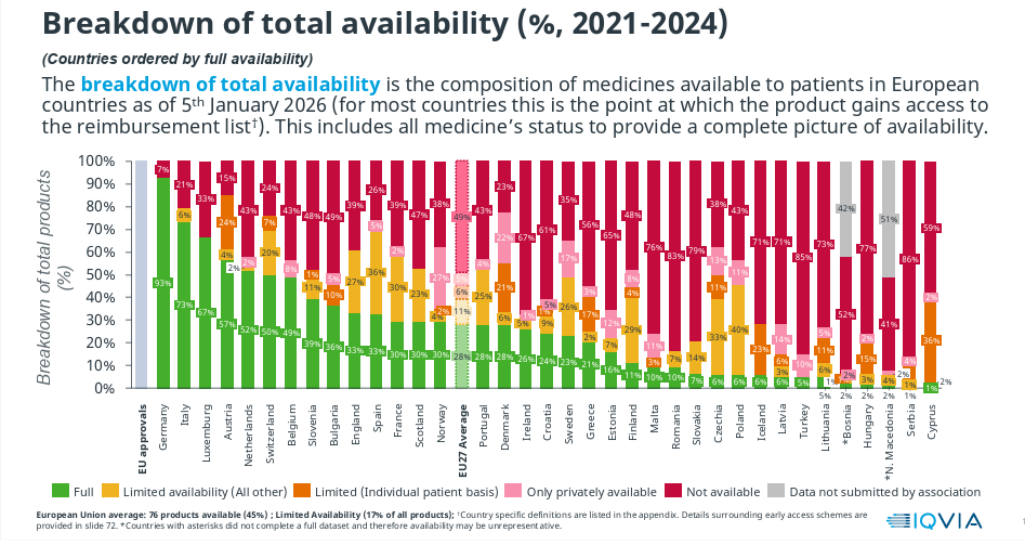
a. How to fund MFN costs? **Create €10 billion a year of fiscal headroom**

[2] https://www.efpia.eu/media/676753/cra-efpia-investment-location-final-report.pdf

Accelerating biosimilar uptake and competition could create €10 billion a year in fiscal headroom for wider investment in medicines. The Commission's Biotech Act staff working document highlights a "biosimilar void": by 2032, 100 biologics will lose exclusivity, but 70% have no biosimilar in the pipeline. Closing this gap could generate savings equal to around 5% of pharmaceutical spending, partially matching the impact of MFN. This will require stronger demand-side incentives, uptake pathways, and procurement and prescribing frameworks that support sustainable competition. Uptake remains weak in many areas, especially retail markets: while Norway, the UK, Germany and Denmark reach 80–90% penetration in some cases, the average is only 35–38%[2]. Faster uptake would create further savings and headroom for innovation.

b. How to protect access equity under MFN? **Create an access mechanism for unserved Member State markets**

MFN spillovers could distort launch sequencing and discourage entry in lower-price Member States. Europe should implement the new pharmaceutical legislation access provisions (5a, 56a) in a way that supports timely availability across the Union, including through a clearly defined **access mechanism** allowing generic or biosimilar companies to supply markets where originators do not launch, subject to safeguards for markets where they do. This would require legal clarity: originator IP rights need to be protected in some countries while relaxed in others but without spillover effects; competition law guidance would be needed for originator and off-patent companies; external reference pricing should not apply at molecule level; and medicines under the mechanism should be exempt from parallel trade activity.



c. How to reduce US tariff risk? **Negotiate a health security agreement with the US**

MFN may draw more manufacturing investment to the US, but the country still depends heavily on imports of critical medicines and vaccines. The EU's continued strength in critical APIs, medicines and vaccines could help secure stronger US access or volume guarantees. A health security agreement would also lower the risk of future tariffs.

2. **Strengthen the manufacturing ecosystem**

The US, China, India and Japan all use interventionist industrial policies to support pharmaceutical manufacturing. The US relies on tariffs; others use subsidies. The EU should use its own legal framework to strengthen manufacturing competitiveness.

a. How to implement Pharma legislation? **Focus on measures that strengthen supply and efficiency**

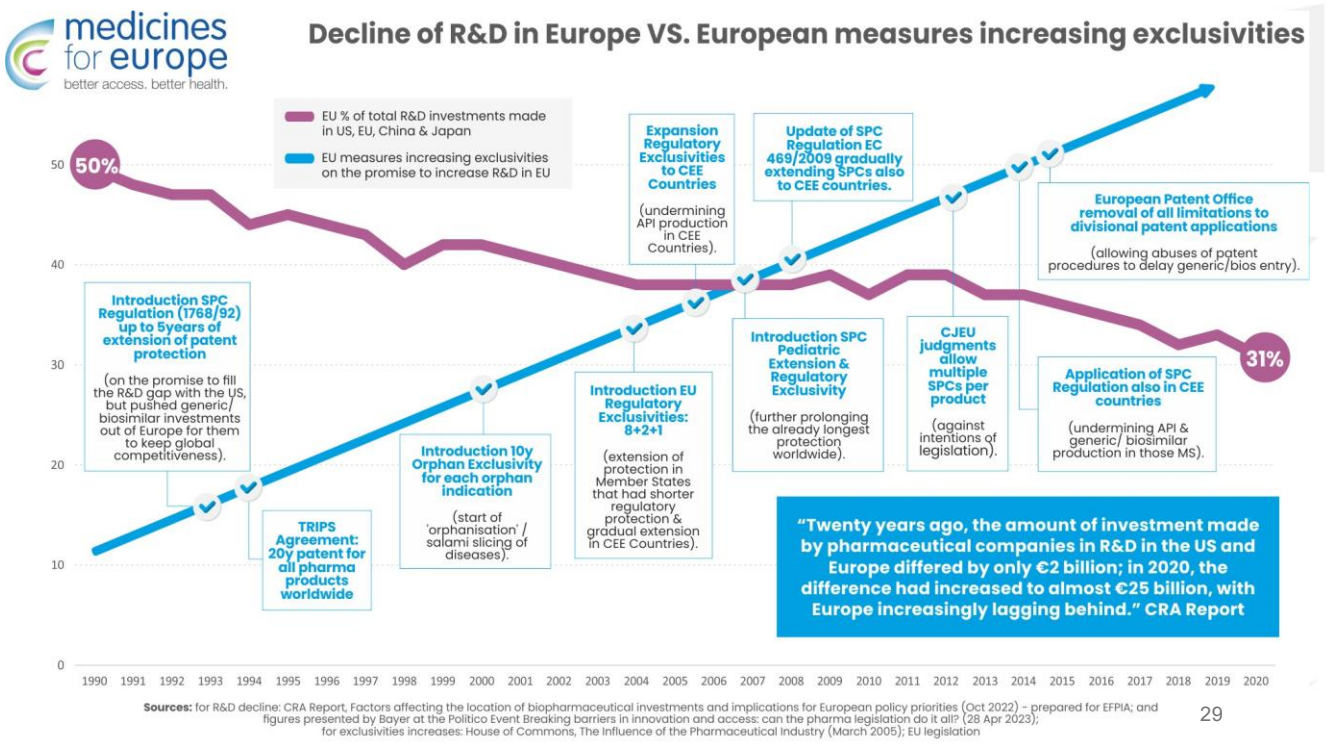
The EU Pharma legislation can be implemented in a pro-competitive way by focusing shortage-prevention requirements on the most critical products and accelerating packaging harmonisation, including wider use of electronic product information. This should build on regional and national initiatives that have already improved availability and cross-border supply efficiency.

b. How to encourage manufacturing investment? **Use the Critical Medicines Act and Biotech Act to support the EU Competitiveness Fund**

The Critical Medicines Act and the Biotech Act should be structured to provide legal and policy basis for supporting biosimilar and critical pharmaceutical manufacturing under the next EU Competitiveness Fund, including clearer eligibility pathways for strategically relevant projects. This will require a more permissive and targeted application of the State aid framework, given that existing rules have materially constrained investment in pharmaceutical manufacturing capacity and technology deployment within the Union. These initiatives should facilitate Union-level financial support for manufacturing technologies relevant to API, generic and biosimilar production which are under the highest competitive pressure.

By contrast, the Biotech Act should not be used to justify any extension of supplementary protection certificate (SPC) rights. As show in the graph below, the Union already provides one of the longest and most protective intellectual property frameworks globally, and further extension would not establish a credible basis for additional investment in Europe[3]. As underlined in the 2024 Draghi report, prolonging market exclusivity through additional intellectual property protection is unlikely to enhance the Union's competitive position vis-à-vis third-country producers. It would, however, risk deferring competitive entry and imposing further cost pressure on public health systems already affected by expenditure on high-priced medicines[4].
The European Union should prioritise measures that have a direct and demonstrable effect on production capacity, industrial growth, employment and timely patient access within Europe. A concrete example is the need to revise the SPC manufacturing waiver, whose six-month stockpiling limitation and notification obligations continue to operate as disincentives to biosimilar manufacturing and related investment in the Union[5].

[3] NOTE on Proposals to extend pharmaceutical intellectual property incentives in reaction to US tariffs.
[4] Medicines for Europe factsheet on 1year SPC extension in the Biotech Act.
[5] Medicines for Europe factsheet on 1year SPC extension in the Biotech Act.



c. How to create viable markets for supply security? **Align the Public Procurement Directive with pharmaceutical policy objectives**

The EU Pharmaceutical Legislation, Critical Medicines Act and Biotech Act all prioritise supply security and manufacturing resilience. By contrast, many Member State market policies still focus on cost containment and lowest price. The Commission should address this through targeted guidance in the revision of the **Public Procurement Directive**, aligned with the supply security goals of these acts.

3. Align environmental ambition with pharmaceutical policy

The EU should take a more coordinated approach to environmental rules that affect medicine access, supply security, production and competitiveness.

a. How to deal with policies that undermine availability? **Amend the UWWTD**

The UWWTD should be reformed, as its assumptions on the impact of human medicines in wastewater are contested and its effects on essential and critical medicines could be severe. The directive should therefore be paused and reassessed.

b. How to deal with chemical restrictions? **Assess the pharma sector for PFAS**

The pharmaceutical sector should also be fully assessed by ECHA before any PFAS restrictions apply.

c. How to balance environmental and pharmaceutical regulation? **Apply One Health policy**

In future, cross-sector environmental rules should not automatically apply to pharmaceuticals, which are already tightly regulated for safety, quality and efficacy. Environmental measures should instead be integrated into pharmaceutical legislation, where medicines agencies can assess risk and benefit under a One Health approach.