

BIOTECH ACT (I) – Medicines for Europe position paper

Biosimilar medicines industry: a strategic pillar for Europe's biotechnological hub that delivers on equitable and timely patient access, industrial competitiveness, economic growth, and health security.

Europe has pioneered the biosimilar sector, with the first-ever approved biosimilar medicine in 2006, and, to date, is the **largest market globally**. The sector today represents an important:

ACCESS CATALYST

- › **Covering 10+ therapeutic areas**, including immunology, dermatology, neurology, oncology, ophthalmology, and rare diseases.
- › **9.2 billion patient treatment days**, since 2011
- › **Expanding access**: in Poland, where access rates are very low, the arrival of the **biosimilar (trastuzumab) increased access by 50% for women with breast cancer**. Similarly, in Bulgaria, France and Norway, the biosimilar entry has doubled access for oncology patients. Looking at other treatment areas, the arrival of anti-TNF biosimilars, used to treat severe inflammatory and autoimmune conditions such as rheumatoid arthritis, has dramatically increased access across Europe; in some countries, such as Austria, by as much as 6x.¹

ECONOMIC ACTOR

- * **81.000 Jobs in Europe**; 40% of direct employees are high-skilled.
- * **€25.6 billion to European GDP in 2024**, 6% of the total pharmaceutical industry contribution.
- * ecosystem of about **100 companies engaged in R&D, manufacturing, and commercialisation**.
- * €75 billion savings, including €13 billion in 2024 alone.

Europe's Biosimilar Ecosystem is at breaking point

1. European biosimilar void with few biosimilar medicines in future pipelines

Biosimilar development is costly, complex and high-risk. Outdated, time-consuming regulatory processes, limited market incentives, and insufficient support discourage investment, leading to a growing biosimilar gap.

BIOSIMILAR VOID



< 30% of biologics losing exclusivity have a biosimilar in development

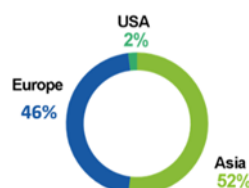
Without urgent action, Europe faces a **biosimilar void**: by 2032, over 100 biologic medicines will lose exclusivity, with 7 out of 10 seeing no competition, putting patient access, affordability and strategic autonomy at risk.

2. Europe's underinvestment undermines both competitiveness and strategic autonomy

Despite significant investment by industry in the European biosimilar industrial footprint over the last two decades, additional investment in manufacturing capacity is needed to remain competitive in next-generation biotechnologies.

Currently, 46% of biosimilar medicines used in Europe are made in Europe, while 54% are sourced from outside, mainly from Asia.

ORIGINS OF BIOSIMILAR MEDICINES USED IN EUROPE



¹ <https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/2026/iqvia-the-impact-of-biosimilar-competition-in-europe-2026-01-26-forweb.pdf>

3. Biosimilar medicines launch delayed by up to 1 year after IP expiry

The European IP system is the longest in the world (15.5 years of effective protection). Biosimilar medicines developed in Europe face several hurdles to reaching the market on Day1 after IP protection expires.

For instance, despite its positive intentions, the current SPC Manufacturing Waiver Regulation continues to create unnecessary barriers to timely biosimilar market entry in Europe. In particular, the **six-month limitation on the stockpiling** waiver is insufficient and commercially unrealistic for complex manufacturing and supply chain planning, undermining the objective of a Day-1 launch after the SPC expiration. In addition, the **unnecessary notification requirements** generate legal uncertainty and frivolous litigation, which have discouraged biosimilar manufacturers from using the waiver to avoid such litigation, thereby *de facto* artificially prolonging IP rights well beyond their lawful expiration or prompting the production of the biosimilar in a non-EU country.

This is exacerbated by cases of dubious or invalid SPCs, especially for combination products, that create legal uncertainty and costly, lengthy litigation that delays competition by several months or even years. Some examples are related to generics used to treat and prevent HIV/AIDS. For instance, the SPC for **emtricitabine/tenofovir** (Truvada) was challenged and invalidated by many EU national courts and ultimately declared illegitimate by the CJEU. This situation delayed the market entry of generics and, in Portugal, led to a **loss of over €109 million** (1.1% of the total healthcare budget for 2018) and affected treatment for over 95,000 patients. Without the invalid SPC being enforced, the Truvada generic version could have been launched on the market as early as February 2017 (when the patent was due to expire), whereas it has been necessary to wait for the CJEU's decision in April 2018.

In the same way, the SPC on **darunavir** (Prezista) was challenged by generic companies and was invalidated in several EU countries (such as the Netherlands, Spain and Sweden). In this second case, even though there was no final decision because the dispute was settled, generic companies again faced unduly delayed market entry, with consequences for patient access and healthcare budgets (see both cases [here](#)).

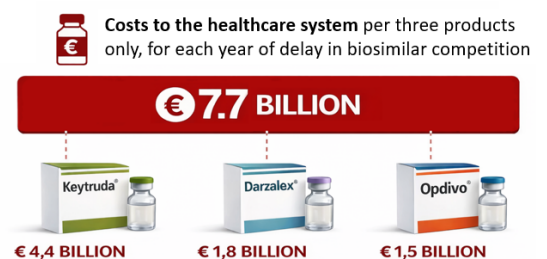
This delays access and competition, and creates costs for national healthcare systems.

[Factsheet on European Biosimilar Medicines Sector: Delivering Impact Beyond Health - Economic, Scientific & Strategic Contribution](#)

Medicines for Europe recommendations to reverse the biosimilar void and boost European strategic autonomy

1. An Intellectual Property System that delivers for patients and for *de facto* production in the EU

The Biotech Act includes a further 1-year delay for biosimilar entry. This would significantly increase costs for national healthcare systems. **Just one year of delayed competition for today's 3 top biologics (Keytruda®, Darzalex®, and Opdivo®, used for oncology treatments) could cost €7.7 billion**, which is more than half of the annual savings generated by all available biosimilar medicines used across Europe in 2024.



The SPC Waiver extension included in the Biotech Act would further delay the entry of biosimilars on the market, postponing the savings they generate for healthcare systems, which are projected to rise from EUR 16-22 billion per year by 2030 to EUR 22-35 billion per year by 2035-2038.

Despite being presented as an explicitly redistributive measure transferring value from biosimilar competitors and healthcare budgets to originators, **the SPC extension is clearly recognised as unlikely to stimulate additional R&D and fundamental manufacturing investments in Europe**. It amounts to the mere hope that sending a positive signal to the industry will influence investment decisions, rather than rewarding actual investments in Europe.

Plus, that measure also fails to address the **real obstacles for the European pharmaceutical industry**, clearly recognised in the 2024 Draghi Report, such as fragmented markets, complex regulatory environments, gaps in financing, and weaknesses in manufacturing.

- › **Reject the extension of the 1-year SPC (Article 27)** that will not boost the competitiveness of the pharmaceutical industry. As an alternative, cooperation with the university and fiscal incentives should be privileged.

In addition, to complement the pharmaceutical legislation provisions - mainly the Bolar clause - the Biotech Act (II) should ensure that existing provisions that boost European production of biosimilar medicines will be functional to deliver equitable and timely access to medicines. This can be done by **improving the SPC manufacturing waiver (new Article in Chapter IX) by:**

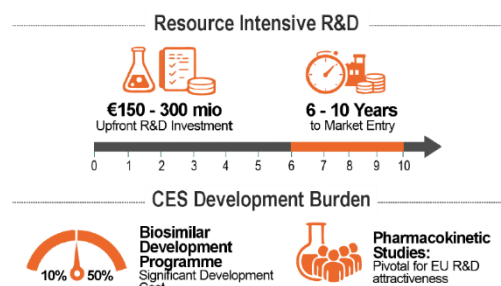
- › Allowing production of biosimilars for EU Day1 launch during the whole protection of the SPC (like for export);
- › Deleting, in line with the recently adopted ban on patent linkage, the unlawful and anticompetitive notification system that is misused for frivolous litigation delaying or making harder the entry of biosimilar medicines into the market.

This perfectly aligns with the Biotech Act's objective of strengthening the competitiveness of the biotech industry in Europe and would have no costs at all for patients or healthcare budgets.

[Factsheet on Optimising Intellectual Property \(IP\) Framework and Trade Partnerships](#)
[Factsheet on the Proposed 12-month Extension of the Supplementary Patent Protection \(SPC\)](#)

2. Streamline clinical trials processes and responsible AI deployment

In the international regulatory network, Comparative Efficacy Studies (CES), part of the clinical programme supporting the comparability demonstration for a biosimilar medicine candidate, are recognised as having limited scientific added value in the regulatory decision-making process. While still required to obtain approval in Europe, they represent the **largest development costs (up to 300€ million)** and can create an absolute barrier to the development of many biosimilar candidates. Considering experience and scientific progress, Europe should also consider:



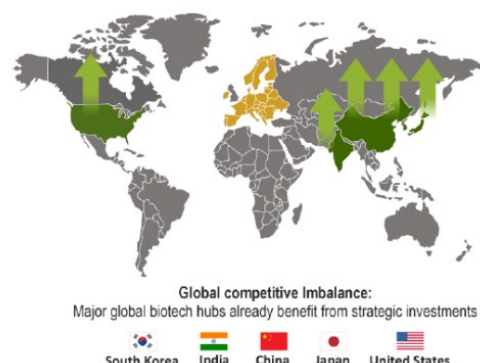
- › **A waiver for comparative efficacy studies (CES) enshrined in official guidelines (Article 28): CES should no longer be required by default due to their limited scientific added value in the regulatory decision-making.**
- › **Acceptance of foreign source comparator via Single Global development (Article 28):** without additional data from a three-way pharmacokinetic study (using the proposed biosimilar, the EU reference product, and non-EU comparator products).
- › **Early guideline development and standard setting for future biosimilar biotechnology platforms** (e.g., ATMPs) should be prioritised and early dialogue with industry encouraged to enhance Europe's attractiveness for biosimilar R&D. EU leadership towards international convergence on these standards is essential.
- › **Artificial intelligence (AI) (Article 58)** can contribute to improving efficiency in both regulatory filings and manufacturing.

[Factsheet on Reforming Regulations, Market Entry and Competition for Biosimilar medicines](#)

3. Strengthen the European Biotech manufacturing ecosystem (Chapter III)

To regain and reinforce its global competitive advantage, it is essential for Europe to strengthen its biotech ecosystem (the full value chain, across the product and technology IP life cycle) and supply resilience. Targeted EU funding for biotech R&D and manufacturing must be expanded and clearly prioritised. The economic viability and sustainability of biosimilar manufacturing will be crucial to ensuring the availability of these essential treatments.

- › MFF and European Competitiveness Fund should earmark budget for biosimilar strategic projects funding.
- › Clear rules on how biosimilar projects labelled 'strategic' can access EU, regional and national funding and the associated dedicated budget.
- › Faster permitting procedures should include regulatory requirements, GxP inspections, and certifications needed for supply.



4. Advance European resilience through ambitious market policy reforms (Chapter V)

Manufacturers in Europe face significant market-entry barriers, including aggressive pricing policies, suboptimal procurement practices, and persistent disparities in access across Member States. These unfit requirements and processes discourage investment in European development, manufacturing and innovation, weaken competition and delay patient access.

A mix of policies is needed to support sustainable market development for biosimilars, stimulate competition to fill further areas of the 'biosimilar void', and ensure that many more patients can benefit from the increased access biosimilars bring. The Biotech Act should encourage:

- › the development of national strategic plans covering patient and physician education, measures to support biosimilar uptake and patient access monitoring
- › pro-competition uptake policies, including sustainable pricing and reimbursement measures that reflect real development and production costs and provide predictable operational margins;
- › reform of procurement frameworks through the development of guidance for pharmaceutical procurement that prioritises non-price criteria and multi-winner models.

[Factsheet on Investing in Biotech R&D and Manufacturing Platforms](#)

[Factsheet on Developing Confidence in Biotech, Attractiveness, Talent and Skills](#)