

BIOTECH ACT 4 PILLARS



MANUFACTURING



REGULATORY



IP AND TRADE



SKILLS

Biotech Act proposed 12-month Extension of the Supplementary Patent Protection (SPC)

The European Biotech Act proposal, published on 16 Dec 2025 aims to create an enabling environment for biotechnology products to reduce competitiveness gaps in biotech, despite EU scientific leadership, vis-à-vis other regions.



BACKGROUND

THE PROPOSED BIOTECH ACT I (HEALTH) PURSUES 3 MAIN OBJECTIVES:



Competitiveness & Internal Market

1) To improve the **functioning of the internal market** by establishing a framework to strengthen the competitiveness of the health biotechnology sector, from research to production.



Innovation & Market Access

2) To **create the conditions for the development and timely placing on the EU market**, of biotechnology innovations, products and services.



High Standards & Protection

3) While **safeguarding high standards for the protection of human health**, animal health, patients and consumers, the environment, ethics, quality, food and feed safety, and biosecurity.

PROPOSED ARTICLE 27 OF THE BIOTECH ACT: 12 MONTH-SPC EXTENSION

APPLICANT MUST DEMONSTRATE ALL CONDITIONS ARE MET:



New Active Substance Distinctly Different from Authorized EU Meds

a) The medicinal product contains a **new active substance distinctly different from that of any authorised medicinal product** in the Union.



Different Mechanism of Action with Equivalent Safety and Efficacy

b) The medicinal product has a **mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent** to that of any authorised medicinal product in the Union for the same disease.



Clinical Trials in more than 2 Member States

c) The **clinical trials** evaluating the efficacy of the medicinal product and supporting its marketing authorisation were **conducted in more than two Member States**.



Manufacturing Step in EU Excluding Packaging, Testing and Certification

d) **At least a manufacturing step, excluding packaging, quality testing and certification** is performed in the Union.



EMA ASSESSMENT

Compliance assessed during Marketing Authorisation in statement.



COPY OF STATEMENT

included in the application for an SPC.

The EMA would assess compliance with the conditions as part of the marketing authorisation procedure and where compliance is confirmed, it shall issue a statement to that effect. A copy of the statement shall be included in the application for an SPC.

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WHY THE PROPOSAL IS UNACCEPTABLE FOR EUROPE

Medicines for Europe strongly opposes the proposal to extend the SPC protection that would **provide additional billions € profits to companies** that, despite multiple promises, have been investing in R&D outside Europe for decades now and **have publicly announced 99% of their future R&D investments in the US or China (\$370B in US only).**



CONTRADICTS EU POLICY OBJECTIVES

→ It contradicts broader EU objectives on affordability, access, and competitiveness of the off-patent sector



NO EVIDENCE IT ATTRACTS R&D TO EUROPE

It is inappropriate to propose an SPC extension given that:

- The **SPC itself triggered delocalisation of biosimilar manufacturing out of the EU**: the 2020 Commission SPC evaluation shows that “(t)he lawmakers had not anticipated in 1992 this negative impact of the SPC on the competitiveness of EU-based generics/biosimilars manufacturers”.
- The 2020 Commission’s & the Technopolis’ evaluations of the SPC concluded that the SPC “had a limited effect in tackling the objective of attracting R&D to the EU and preventing delocalisation, as other factors have a significant influence on the geographical location of innovation”, that “**the [SPC] regulation has not achieved its goal**” & “**the financial benefits fall mostly outside of the EU**”.



Costs to the healthcare system for each year of delay in biosimilar competition

€ 7.7 BILLION



€ 4,4 BILLION

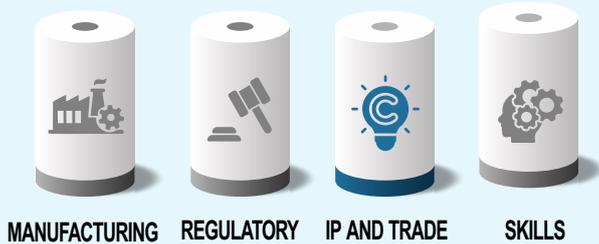


€ 1,8 BILLION



€ 1,5 BILLION

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WHY THE PROPOSAL IS UNACCEPTABLE FOR EUROPE

EUROPE ALREADY HAS THE LONGEST PROTECTION WORLDWIDE

- The EU already has the longest SPC-like protection worldwide. This would lead to up to 16.5 years of effective 'patent + SPC' protection in the EU vs. max. 14 years in the US.
- The Commission is proposing an even further **delayed competition as an industrial policy instrument**, instead of focusing on targeted investment measures.

STRUCTURAL AND LEGAL RISKS

- It creates **legal uncertainty** (with the involvement of a health authority in the granting process) & **administrative complexity** that will **trigger further SPC litigation**.

MASSIVE COST FOR HEALTHCARE SYSTEMS

- The estimated **cost to healthcare systems for each year of delayed competition, only considering 3 molecules** (Keytruda®, Darzalex®, Opdivo®): **€7.7 billion**, ie. more than half of EU annual savings from biosimilar competition (ie. €13 billion, in 2024).
- The **huge costs** of this proposal would be ultimately **financed by patients and healthcare systems**.

WEAKENS EU INDUSTRIAL COMPETITIVENESS

- It **discriminates against biosimilars R&D / production** as this reward applies only to patent/SPC holders.
- It **distorts competition** by favouring big, vertically integrated companies to **the detriment of SMEs**.
Its scope seems to **go beyond only purely biological products** and the conditions **reward already existing practices** rather than stimulating genuine additional investments.

WHAT INCENTIVES SHOULD BE CONSIDERED INSTEAD

- Introduce a **correction of the SPC manufacturing waiver to effectively stimulate development & manufacturing of biosimilar medicines in Europe**. This should be done by
 1. **removing the artificial distinction between export & EU launch** (i.e., deleting the restrictive 6-month period that discourages biosimilar development in Europe as it does not reflect the realities of biotechnological production cycles), and
 2. **removing notification requirements** that are being misused for frivolous litigation to discourage biosimilars manufacturing in Europe. This is key since the SPC itself triggered delocalisation of biosimilar manufacturing out of the EU.
- Very importantly, **other regions of the world (eg. China) are going to introduce an SPC manufacturing waiver to stimulate strategic investments in biosimilar and generic R&D and production**. These regions are certainly going to learn from the European experience and will introduce such waiver without the obstacles to its exploitation that Europe has today in its SPC manufacturing waiver. **Therefore, these corrections have to be made now.**
- **Address evergreening practices** that delay biosimilar medicines market launches by evaluating their impact on the competitiveness of the biologic off-patent sector, competition, patient access, and healthcare budgets, drawing on documented examples — incl. those highlighted in the 2025 IGBA "Gaming the System" report — to inform future policy and enforcement mechanisms.