ESIP-MEDEV Position

On the Proposal for a European Biotech Act

European Social Insurance Platform (ESIP)
Medicine Evaluation Committee (MEDEV)

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Executive summary

The European Social Insurance Platform (ESIP) and the Medicine Evaluation Committee (MEDEV) acknowledge and welcome the objective of strengthening Europe's biotechnology ecosystem through the proposed EU Biotech Act, by supporting the research, development and manufacturing of health biotechnologies and biosimilar products within the EU.

The EU Biotech Act has the potential to significantly shape the framework for the development, launch and protection of innovative biotechnology products in the EU. Its measures target incentives, including extended exclusivity periods, investment decisions, as well as the speed and regulatory pathways through which products progress from development to authorisation. Such provisions may ultimately influence the nature, maturity and timing of the clinical evidence available at the point of market launch. The proposal therefore merits careful scrutiny, not only in terms of its capacity to achieve its industrial objectives, but also with regard to its longer-term implications for evidence standards and value-based health technology assessment (HTA) and pricing and reimbursement (P&R).

Strengthening Europe's biotech sector should be regarded as equally important as safeguarding the long-term sustainability of public healthcare financing and timely patient access. Thus, access and affordability should be pursued as explicit goals along with competitiveness and innovation.

In this context, ESIP and MEDEV consider the following as key priority areas to better frame the EU Biotech Act in the upcoming negotiations:

- Reject further extensions of intellectual property rights through longer supplementary protection certificates (SPCs);
- Reinforce provisions supporting the development of biosimilar products, notably through strategic projects and a more streamlined, yet evidence-based, approach to clinical data requirements;
- While simplifying the legislative framework on clinical trials, preserve standards and ensure that evidence remains clinically relevant for decision-makers including healthcare payers;
- Limit the scope of regulatory sandboxes to exceptional cases when it is duly demonstrated that the standard regulatory pathways are not practicable;
- Ensure adequate representation of HTA bodies, P&R authorities and public healthcare payers in the Foresight Panel for Emerging Health Innovation;
- Optimise conditions attached to the designation of strategic projects, including appropriate corrective measures in case the related requirements are not met;
- Overall, ensure that national social security budgets remain dedicated to need-based, high-quality and affordable healthcare, without diverting already stretched funds to the pursue of industrial policy and economic objectives.

Reject extended intellectual property protection

The European Commission's proposal prolongs intellectual property (IP) protection for products developed by means of biotechnological processes through an extended supplementary protection certificate (SPC). The 12-month SPC extension proposed under Article 27 is a central concern for ESIP and MEDEV Members, as it undermines budget predictability and the long-term sustainability of healthcare systems. The absence of an ex-ante impact assessment by the European Commission specific to the new SPC extension makes it difficult to assess the scale of budget impact if high-selling biologicals receive another year of protection. According to ESIP Members' calculations, the measure could lead to additional costs of around €1.7 billion per year across the European Union.[1]

The Union already provides long effective protection for originator products: the combined period of patent and SPC protection can reach roughly 15 years in the EU, compared with around 14 years in the US and Japan. The new extension would apply to products developed by biotechnological processes if certain conditions are met, including novelty, distinct mechanism of action, multi-country clinical trials in more than two Member States and at least one manufacturing step in the Union. Yet, these conditions may often reflect existing business practices rather than new, additional investment in Europe.[2] The proposed incentive is therefore poorly targeted, as it relies on delayed competition rather than direct support for innovation.

This concern is further amplified by the broad definition of eligible products, which are identified as products developed by means of biotechnological processes. As drafted, this definition could extend the scope to medicinal products that should not fall under the Biotech Act. For instance, medicines that are primarily produced synthetically could still be captured, even if biotechnological methods were used only marginally during their development.

The underlying originator narrative that biotechnology products necessarily require longer development timelines, and that SPC are therefore a necessary compensation instrument, should be treated with caution. Looking ahead, technological progress and particularly artificial intelligence (AI) applied to pharmaceutical and biotech innovation may shorten the research and development (R&D) phase, making longer exclusivity harder to justify over time.

Furthermore, the related 2020 European Commission's evaluation[3] 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". In parallel, the study led by the Technopolis Group on the effects of SPC

[1] DSV Statement on the SPC Extension under the European Biotech Act

[2] Medicines for Europe. Biotech Act – Factsheet on the Proposed 12-month Extension of the Supplementary Patent Protection (SPC). https://www.medicinesforeurope.com/wp-content/uploads/2026/03/SPC-Biotech-Act-factsheet.pdf

[3] COMMISSION STAFF WORKING DOCUMENT EVALUATION of the Regulation (EC) No 469/2009 of the European Parliament and of the Council concerning the supplementary protection certificate for medicinal products, and Regulation (EC) No 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products.

mechanisms for pharmaceutical products revealed that financial benefits of extended SPC protection fall mostly outside of the EU.[4] Europe must not end up paying, through delayed competition, for investments made primarily outside the Union.

For these reasons, the proposed SPC expansion appears unsuitable as an incentive mechanism, while contradicting broader EU objectives on affordability, access and competition. In the context of both the proposed Biotech Act and the Critical Medicines Act, more effective levers are available to strengthen Europe's biologics and biosimilars ecosystem. These include targeted public and private funding to support investment in research, development and manufacturing capacity in Europe for projects identified as valuable for society, thus aligning with the goal of directing health product R&D towards areas of societal need. These incentives could create an attractive environment for start-ups and small companies, regardless of their current commercial success. In contrast, an extended SPC would primarily generate additional revenue for companies that are already successful. The benefits of this for Europe's economy and access to clinical trials remain uncertain.

For these reasons ESIP and MEDEV oppose the proposed SPC extension in Article 27, as it would delay competition and increase costs for payers and patients, without convincing evidence that longer SPC protection attracts R&D or manufacturing to Europe. Rather than introducing an SPC extension, a review clause for the SPC manufacturing waiver could be considered, so that biosimilar manufacturers can produce throughout the entire SPC term, rather than only during the final six months. This rationale is better aligned with the competition approach reflected in the revised EU general pharmaceutical legislation, particularly through the strengthened Bolar exemption supporting day-one competition after patent expiry.

Reinforce biosimilar competition in the EU Biotech Act

Biosimilars are one of Europe's strongest biotech success stories and should be prioritised in the EU Biotech Act. Europe approved the first biosimilar in 2006 and should remain a global leader in this field. Biosimilars deliver high value for health systems despite accounting for a relatively small share of pharmaceutical expenditure, thus creating substantial savings while supporting broader patient access. With important losses of exclusivity approaching, it is essential to avoid a growing biosimilar void[5] and create the right market conditions for sustainable competition.

ESIP and MEDEV welcome the biosimilar-specific provisions set out in Article 28 of the Biotech Act, notably the inclusion of biosimilar products within the scope of strategic projects

[4] Technopolis Group. Effects of supplementary protection mechanisms for pharmaceutical products. Final report, May 2018.
[5] IQVIA. The Impact of Biosimilar Competition in Europe (January 2026).

and the introduction of regulatory pathway that avoids unnecessary duplication, in line with recent EMA guidance on a tailored approach in biosimilar development.[6]

ESIP and MEDEV recognise that the evolving scientific and regulatory experience with biosimilars, including long-term data on interchangeability, may support a more streamlined approach to clinical data requirements. Such approach should continue to be guided by scientific evidence and by the established principles of quality, safety and efficacy that underpin confidence in biosimilar medicines. In parallel, the option to request additional clinical data where justified should be preserved.

Safeguard standards for clinical evidence

The proposal for an EU Biotech Act introduces substantial amendments to Regulation (EU) 536/2014 (Clinical Trials Regulation, CTR), shortening authorisation timelines and enabling more flexible, risk-based requirements for certain categories of clinical trials.

ESIP and MEDEV could support a proportionate simplification of the rules governing genuinely low-risk studies, particularly where this helps reduce unnecessary burden without undermining participants' rights and safety. At the same time, ESIP and MEDEV caution against turning the CTR into a policy tool focused primarily on speed and industrial simplification at the expense of patient protection, ethical oversight, transparency and the robustness of clinical evidence. Faster procedures do not necessarily translate into better care or improved access. For payers and HTA bodies alike, the quality, maturity and clinical relevance of the evidence remain fundamental.

Faster procedures may raise concerns particularly where they are not supported by adequate capacity and resources. For example, the proposal requires the competent authority to review the information in Part 1 of the application dossier within seven days. If this deadline is not met, the study is considered to be a minimal-intervention or low-intervention study, provided that the manufacturer has indicated this in the application. As a result, capacity constraints within the authority could lead to studies being treated as eligible for simplified requirements even where they do not, in fact, meet the relevant criteria.

Furthermore, the proposal does not appear to adequately address the continued need for comparative clinical trials or the inappropriate use of placebo where effective treatments already exist. As a result, while the proposal seeks to accelerate research, **it does not sufficiently consider whether the resulting trials will generate evidence that is clinically relevant for healthcare systems and payers**. More broadly, the implications of shorter clinical trial timelines for HTA and P&R procedures remain uncertain.

[6] European Medicines Agency. Reflection paper on a tailored clinical approach in biosimilar development. (adopted by CHMP on 16 March 2026). https://www.ema.europa.eu/en/documents/other/reflection-paper-tailored-clinical-approach-biosimilar-development_en.pdf-0

Limit derogation mechanisms within the scope of regulatory sandboxes

The proposal also foresees the creation of regulatory sandboxes as a mechanism to support the development of novel biotechnology products. Regulatory sandboxes are intended to serve as controlled and supervised environments in which innovative products, processes or regulatory approaches can be tested where they do not fit within existing legal frameworks.

The introduction of regulatory sandboxes, alongside this and other pieces of legislation,[7,8] raises important questions about the downstream implications of increased reliance on non-standard development pathways. In particular, there is a risk that such pathways could lower the evidentiary standard for clinical robustness and comparative evidence, placing HTA and P&R decision-makers under pressure to accept greater uncertainty for novel biotechnology products.

ESIP and MEDEV take therefore a cautious view regarding the proposal to establish regulatory sandboxes. The current provisions are broadly formulated and leave the practical consequences of sandboxes insufficiently defined. While adapted pathways may be justified under certain conditions, there are concerns that they could be misused to selectively relax core clinical trial requirements.

A narrower and more clearly defined scope of regulatory sandboxes is therefore essential. In particular, regulatory sandboxes should be **limited to exceptional cases when it is duly demonstrated that the standard regulatory pathways are not practicable**.

Furthermore, there are concerns that the wider use of regulatory sandboxes could reduce the volume of data submitted in support of marketing authorisation. This would create difficulties for follow-on developers, who rely on publicly available regulatory information to understand the underlying evidence base. More broadly, increased reliance on adapted pathways may increase the risk that relevant supporting data remain non-transparent or insufficiently accessible, ultimately weakening predictability, scrutiny and the conditions for effective competition.

Ensure early involvement of public payers

The proposal envisages the creation of a **Foresight Panel for Emerging Health Innovation** to provide scientific, technical and regulatory advice on emerging health biotechnologies. Its

7 Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006

8 Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

tasks would include horizon scanning, support for cross-framework dialogue among EU bodies and Member States and the facilitation of exchanges on regulatory sandboxes.

ESIP and MEDEV support the establishment of such Panel and consider it essential that **HTA bodies, P&R authorities and public healthcare payers are adequately represented**. Given their role in identifying unmet medical and societal needs, assessing potential access and affordability challenges, and anticipating willingness to pay for emerging products, payer involvement would ensure that the Panel's discussions are well-informed from the early stage. ESIP and MEDEV also consider that the panel should be connected to existing international horizon scanning initiatives in order to avoid duplication and promote greater coherence and coordination.

Optimise conditions for strategic projects

The proposal introduces health biotechnology strategic projects as EU-based initiatives with the potential to strengthen the Union's biomanufacturing capacity and enhance supply resilience. These projects would benefit from a dedicated governance and support framework.

ESIP and MEDEV support this approach. At the same time, the Biotech Act should **more clearly define the conditions attached to the designation and support of strategic projects**, to ensure appropriate public return on often substantial public investment. In particular, strategic projects should be required to demonstrate a tangible contribution to further research, improved availability and greater supply security within the EU. Where such commitments are not met, **appropriate corrective measures or penalties should apply**.

Preserve health insurance budgets under pressure

The EU Biotech Act is primarily conceived as an industrial and regulatory initiative to strengthen the EU biotechnology and biomanufacturing ecosystem. In this context, reliance on industrial policy tools and investment instruments appear appropriate, including support for strategic health biotechnology projects and access to public and private financing.

At the same time, it is important to ensure a **clear distinction between industrial policy funding and the financing of statutory healthcare systems**. Statutory health insurance contributions are intended to support need-based, high-quality and affordable healthcare, and should therefore remain dedicated to that purpose. Particularly in light of the financial pressures already facing health insurance systems, resources allocated to social security should not be used to pursue industrial policy objectives, whether at European or national level. National budgets intended to finance social security should not be diverted to fund broader economic policy objectives.

About the European Social Insurance Platform (ESIP)

The European Social Insurance Platform (ESIP) represents 46 national statutory social insurance organisations in 19 EU Member States and Switzerland, active in the field of health insurance, pensions, occupational disease and accident insurance, disability and rehabilitation, family benefits and unemployment insurance. The aims of ESIP and its members are to preserve high profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European debate and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

ESIP members support this position insofar as the subject matter lies within their field of competence.

About the Medicine Evaluation Committee (MEDEV)

The Medicine Evaluation Committee (MEDEV) was established in 1998 by representatives of the social health insurance organisations in Austria, Finland, Germany, Luxembourg, The Netherlands, and Switzerland to facilitate informed discussions and exchanges on pharmaceutical policy developments in the EU. MEDEV is a network of 25 national authorities from 20 Member States and Norway bringing together all the relevant institutions (national HTA agencies and social health insurers-payers) responsible for the assessment, pricing and reimbursement of medicines in Europe. The overarching mission of MEDEV is to further the sustainable provision of medicines to patients who are publicly insured. The European Social Insurance Platform (ESIP) in Brussels was commissioned with the role of coordinating the activities of the Committee.

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