Brussels, 6 October 2026

A competitive EU biotech sector should not rely on longer monopolies to attract research, development and production

Joint multi-stakeholder statement on the proposed extension of the Supplementary Protection Certificate (SPC) in the European Biotech Act

We, the undersigned stakeholders, call on the co-legislators to reject the additional 12-month Supplementary Protection Certificate (SPC) extension in Article 27 of the proposal for a European Biotech Act.

While encouraging the development in Europe of medicines that address patients' needs is an important public health objective, extending existing monopoly rights is a poorly targeted and potentially very costly measure whose added value for patients, healthcare systems and European research and production has not been demonstrated. Instead, the Biotech Act should strengthen the conditions for healthy competition and timely access to innovative products that provide added value for patients, alongside targeted instruments that directly support research, clinical development and manufacturing in Europe.

Longer exclusivity generates disproportionate costs while benefits remain uncertain.

An additional SPC year would delay the market entry of biosimilar products at the point when competition can substantially reduce expenditure and expand patient access. Extending protection for already expensive products risks locking health systems into an additional year of monopoly prices. The German association of statutory health insurance funds estimates that the proposal could increase pharmaceutical expenditure by approximately €1.7 billion per year across the EU.[1]

European healthcare budgets already face strong expenditure pressures from innovative medicines, while also responding to other major challenges, including the growing healthcare needs of an ageing population, workforce shortages and the need to adapt public health services to looming health threats. At a time of significant budget constraints, additional pharmaceutical expenditure means reduced investment in other healthcare services and infrastructure that patients need.

Furthermore, the assumption that another year of exclusivity would influence where companies locate R&D or manufacturing is not substantiated by the available evidence. The proposal was initially published without an impact assessment and, although the European Commission subsequently published a Staff Working Document, significant uncertainties remain regarding the effectiveness and proportionality of the proposed SPC extension. Besides, previous Commission analysis also found only a very limited effect of SPCs on attracting R&D to Europe.[2] As a rule, measures carrying potentially significant costs for healthcare systems and patients should be based on robust, transparent and evidence-based analysis, clearly demonstrating not only their potential industrial benefits, but also how they would translate into meaningful benefits for patients and public health.

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

[2] 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 (25 November 2020).

The EU should consider other ways of strengthening its competitiveness and its health outcomes.

Europe has already taken steps to address the real barriers to biotech competitiveness, including a streamlined regulatory framework in the pharmaceutical legislation, proposals for improved access to financing, a revised framework for clinical trials that safeguards patient safety and high clinical standards, and greater regulatory predictability. The implementation of the Health Technology Assessment Regulation, as well as expanded opportunities for voluntary joint procurement, also have the potential to decrease duplication and provide simpler market access procedures that can help accelerate patient access.

At the same time, Europe should also reinforce one of its existing competitive strengths: its biosimilar industry. With important losses of exclusivity approaching, it is essential to avoid a growing biosimilar void[3] and create the right market conditions for sustainable competition. This would also generate significant savings for healthcare systems that can be reinvested in meaningful improvements in patient care. Options to strengthen the conditions for timely biosimilar competition should be explored, including whether the existing SPC manufacturing waiver could be expanded to better support EU manufacturing and preparedness for the timely market entry of biosimilars.

Greater attention should also be given to measures enabling small and medium-sized enterprises, public research institutions and universities to play a meaningful role throughout the full lifecycle of medicines development. Rather than concentrating incentives at the end of the innovation cycle, targeted support should be available at different stages of development, enabling smaller actors to initiate, advance and sustain promising R&D activities.

In conclusion, a competitive European biotech ecosystem requires a regulatory environment that stimulates meaningful innovation, healthy competition, and delivers clear added value for patients and healthcare systems. Extending exclusivity periods without clear and demonstrable returns for public health does not serve this objective.

Our calls

- Delete Article 27 and reject the proposed SPC extension.
- Use direct, targeted industrial-policy instruments and regulatory measures that support investment, innovation and sustainable competition throughout the biotech ecosystem, rather than relying on delayed competition to finance competitiveness. Any targeted instruments must deliver clear added value for patients, including improved access, affordability and better health outcomes.

[3] IQVIA. The Impact of Biosimilar Competition in Europe. January 2026.

Signatories

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