



# “Additional SPC year under the Biotech Act: Significant costs for healthcare systems, limited impact on Europe’s biotech competitiveness”

Statement on the Biotech Act I on Health  
7 May 2026

The German Social Insurance (DSV), representing around 75 million people covered by statutory health insurance in Germany, strongly opposes the additional 12-month SPC extension proposed under the European Biotech Act.

**Based on DSV calculations, the measure could lead to additional costs of approximately €585 million annually for the German statutory health insurance system (GKV) and around €1.7 billion per year across the European Union.**

While strengthening Europe’s biotech sector and improving resilience are legitimate political objectives, extending monopoly protection periods is not the right instrument to achieve them. The Biotech Act should promote innovative and market-ready therapies without weakening competition. Delaying biosimilar entry through longer monopoly periods increases expenditure for high-priced medicines and places additional pressure on solidarity-based healthcare systems, while competition itself remains a key driver of innovation, investment and affordable access.

The DSV strongly supports innovation promotion. However, support should focus on unmet medical need, demonstrable patient benefit, targeted industrial policy tools, faster market access and scale-up measures — not blanket exclusivity extensions. While the European biotech sector might face some structural challenges such as higher production costs and limited access to risk capital, insufficient monopoly protection is not one of them. Commission evaluations themselves show that SPCs have only a limited impact on decisions about where to locate R&D. Put simply: no company chooses a research or production location because of one possible additional SPC year alone.

Moreover, the proposed SPC extension is neither sufficiently targeted nor evidence based. The eligibility criteria focus primarily on novelty, manufacturing processes and location requirements rather than on clear clinical added value or public health relevance. It also remains unclear how many products and companies would ultimately



qualify for the additional protection period. Proposals to further broaden or split the criteria into multiple categories should therefore be strictly rejected, as they would further weaken predictability and fail to create targeted incentives for bringing biotech investment and production to Europe.

Rather than extending monopoly periods at the expense of public healthcare budgets, Europe should focus on targeted and transparent support instruments that directly address the structural barriers to biotech innovation and competitiveness.

Read the DSV's position on the biotech act [here](#).

The underlying assumptions of our calculation are as follows:

- \_ Net sales of patent-protected biological medicinal products: **€15.537 billion** (Total net expenditure on biologics in 2024: €21.2 billion, of which €5.663 billion relates to substances eligible for biosimilar competition; WIdO Arzneimittel-Kompass 2025, pp. 294 & 304)
- \_ Average effective protection period (including regulatory data protection, market exclusivity, patents, SPC, etc.): **12.5 years** (Copenhagen Economics, Final Report, p. 73)
- \_ End-of-lifecycle sales factor: **approx. 1.4** (i.e. revenues at the end of a product's lifecycle are about 40% higher than the average annual revenues over the effective protection period; PharmacoEconomics 18 (Suppl. 1): 21–32, 2000, p. 23, Fig. 1)
- \_ Share of medicinal products for which the SPC constitutes the final protection period: **approx. 48%** (Commission Impact Assessment SWD(2022) 281 final, p. 38)
- \_ Average price reduction due to biosimilar competition (post market equilibrium):
  - \_ Germany (GKV): **approx. 70%** (around 50% at list price level (The Impact of Patent Expiry on Drug Prices: A Systematic Literature Review - PubMed) + approx. 20% additional confidential rebates via rebate contracts; consistent with WIdO estimates, Arzneimittel-Kompass 2025, p. 308)



- \_ EU-26 and German private insurance (PKV): approx. **45%** (reflecting the absence of rebate contracts and lower price competition)
- \_ Share of German GKV in the EU pharmaceutical market: **24.6%** (€53.729 billion / €218.374 billion; EFPIA, The Pharmaceutical Industry in Figures, p. 15)

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## About us

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the national associations of statutory health and long-term care insurance funds as well as the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have joined forces to form the "German Social Insurance Working Group Europe" with a view to their common European policy interests. The association represents the interests of its members vis-à-vis the bodies of the European Union and other European institutions and advises the relevant players on current legislative projects and initiatives. As part of a statutory insurance system, health and long-term care insurance with 75 million insured persons, pension insurance with 57 million insured persons and accident insurance with more than 70 million insured persons in 5.2 million member companies offer citizens in Germany effective protection against the consequences of major life risks.