Deutsche Sozialversicherung
Europavertretung
Rue d'Arlon 50
1000 Brüssel
Belgien

Tel: +32 2 282 05-50
info@dsv-europa.de
www.dsv-europa.de
Transparenzregister-Nr.:
917393784-81

"Costs are Evident, Benefits Remain Unclear"

Statement on the European Commission's Calculations Regarding the Additional SPC Year under the Biotech Act
8. June 2026

With the Biotech Act, the European Commission proposes extending the duration of Supplementary Protection Certificates (SPCs) for certain biotechnological medicinal products by twelve months. The calculations now published in the accompanying Staff Working Document (SWD) confirm, from the perspective of the German Social Insurance (DSV), several key criticisms of this proposal. The DSV had already presented its own calculations on the financial implications of an SPC extension in April 2026. The Commission itself acknowledges that the measure would delay the market entry of biosimilars, generate additional costs for healthcare systems, and postpone access to more affordable treatment options. At the same time, there is still little evidence that an additional SPC year would actually lead to more research, investment, or production in Europe.

According to the Commission's calculations, one additional SPC year would generate around €70 million in additional costs for public payers and approximately €205 million in total societal costs per medicinal product. Assuming two to three eligible products per year, this would amount to an annual burden of roughly €615 million for payers and patients. By contrast, the positive effects on investment, clinical research, manufacturing, or competitiveness are not quantified in a robust manner. The Commission merely argues that the SPC extension *could* promote investment, create employment effects, and influence companies' behaviour.

Actual Costs Could Be Higher Than Assumed

The calculations themselves are also subject to considerable uncertainty. The Commission relies on a limited number of products, several simplifying assumptions, and a model based on list prices. National discounts, reimbursement agreements, and other competitive mechanisms could not be taken into account.

- **Conservative assumptions regarding biosimilar competition:** From the DSV's perspective, the Commission's assumptions regarding price developments following biosimilar market entry appear particularly conservative. The Commission assumes

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a price reduction of only around 9% resulting from biosimilar competition, yet the analysis does not provide a robust source for this assumption. The DSV's assessment, by contrast, is based on significantly stronger competitive effects. Assuming competitive tendering and a well-functioning market environment, the German statutory health insurance system (GKV) expects price reductions of around 70% in Germany and 45% at the European level. The Commission also notes that the expanded Bolar exemption and simplified marketing authorisation procedures could accelerate biosimilar competition.

- **Potentially more eligible medicinal products than assumed:** The Commission assumes that the SPC extension would be economically relevant for only two to three medicinal products per year. However, its own analysis shows that five to six products annually would have met the basic eligibility criteria in recent years. The Commission further acknowledges that the geographical requirements could be relatively easy to fulfil, potentially increasing the number of eligible products. It identifies an average of ten medicinal products per year that would satisfy the innovation criteria, such as a novel mechanism of action. Assuming that the SPC is the final relevant form of protection for around 40% of these products, approximately four medicinal products per year could benefit from the extension. This would already exceed the Commission's estimate of two to three products annually. Applying the DSV's assumptions regarding biosimilar competition would result in direct additional costs of around €1.5 billion per year. This figure is considerably closer to the DSV's previous estimate of €1.7 billion in annual additional costs than to the Commission's calculations.

New Uncertainties Instead of Greater Predictability

The proposed eligibility criteria for the SPC extension are also partly novel and open to interpretation, particularly regarding innovation, mechanisms of action, and the geographical requirements for research and manufacturing activities. The Commission therefore anticipates additional litigation and administrative burdens. For companies, patent offices, and courts, the new rules could initially create greater uncertainty. This creates a contradiction: a measure intended to promote innovation and competitiveness could simultaneously increase regulatory complexity and reduce predictability for businesses.

Overall, the European Commission's analysis appears to provide stronger arguments for a critical reassessment of the measure than for its political justification.

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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.