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Deutsche Sozialversicherung
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Proposal for a Regulation on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)

With the Regulation proposed on 16 December 2025 for a European Biotech Act, the European Commission seeks to strengthen the biotechnology and biomanufacturing sector in the EU and to position Europe as a globally competitive biotech location. A Union-wide framework is envisaged that creates favourable conditions for health biotechnology along the entire value chain — from research and development through market access to manufacturing — while at the same time safeguarding high standards for health protection, patient safety, the environment, ethics, quality and biosafety.

The German Social Insurance (DSV) expressly welcomes this overarching objective, as biotechnological innovations can open up considerable therapeutic potential for patients, particularly in the case of serious diseases.

In order to achieve these objectives, the proposal primarily relies on industrial policy instruments and investments. These include financial and administrative support through Health Biotechnology Strategic Projects, Biotechnology Development Accelerators and new financing instruments such as the EU Health Biotechnology Investment Pilot. From the DSV's perspective, this approach is appropriate in principle, provided that economic promotion is clearly separated from the financing of statutory healthcare. Contributions of statutory health insurance serve to ensure needs-based, high-quality and affordable healthcare and must not be used to finance industrial policy objectives.

The DSV positively assesses the envisaged promotion of biosimilars within the framework of strategic health biotechnology projects, as they make an essential contribution to competition, security of supply and affordability. However, this objective is undermined by the simultaneously proposed extension of the supplementary protection certificate (SPC). An extension of patent protection would further delay the market entry of biosimilars and have negative effects on competition, affordability and the safeguarding of supply.

From the DSV's perspective, it is furthermore crucial that the promotion of innovation - for example through the use of artificial intelligence or administrative simplifications in clinical trials - must not lead to a lowering of standards of evidence, data protection or safety. Patient safety, scientific evidence and regulatory reliability must remain guiding principles in clinical trials.

Biotechnological medicinal products, including gene and cell therapies, open up new therapeutic perspectives but are at the same time often associated with considerable financial and supply-related challenges. Germany is among the countries with particularly rapid access to innovative medicinal products, which is reflected in correspondingly high expenditure of statutory health insurance. Cost drivers are in

particular patent-protected, high-priced medicinal products, including numerous biotechnologically manufactured products. Their use is frequently associated with uncertainties regarding efficacy and long-term safety.

In particular, exorbitantly high prices are regularly demanded for gene therapies. At the same time, the financial risk lies unilaterally with payers, as robust long-term evidence often only emerges in routine care. In view of rapidly rising expenditure for patent-protected medicinal products, industrial and innovation policy decisions at EU level have direct effects on competition, affordability and the financial sustainability of solidarity-based healthcare systems. From the DSV's perspective, they must be carefully balanced so as not to endanger the long-term stability of healthcare systems as a whole.

Against this background, the following core demands are central from the DSV's perspective:

Clearly position the Biotech Act as an instrument of economic promotion

The Biotech Act should consistently be designed as an industrial and innovation policy instrument. The promotion of strategic health biotechnology projects, access to public and private sources of financing and investment instruments such as the EU Health Biotechnology Investment Pilot are in principle suitable approaches, provided that they are primarily financed through tax-based public funds and private investment. Contributions of statutory health insurance are intended for the provision of healthcare to insured persons and must not be used to finance industrial policy objectives.

The DSV therefore calls for:

_ **A strict separation between funding for economic promotion and the financing of statutory healthcare.**

Safeguard competition and enable access

The Biotech Act should promote the development of innovative, market-ready therapies without weakening competition. The DSV rejects an extension of monopoly rights of the pharmaceutical industry, in particular the envisaged extension of the supplementary protection certificate (SPC). Such extensions delay the market entry of biosimilars and increase expenditure for high-priced medicinal products. Blanket extensions of patent protection do not lead to a targeted relocation of research, development or production activities to Europe. Competition itself is a central driver of

innovation and investment and makes a substantial contribution to ensuring affordability and sustainable market access for innovative therapies in Europe.

Moreover, a comprehensive protection framework already exists: under current Union law, patent protection may be extended through an SPC by up to five years and, in the case of an agreed paediatric investigation plan, even up to five and a half years. This already grants a monopoly period of up to 15.5 years. A further blanket extension of protection is therefore neither necessary nor proportionate.

The targeted promotion of biosimilars as strategic health biotechnology projects provided for in the proposal is expressly to be welcomed and should not be undermined by parallel extensions of monopoly rights.

The DSV therefore calls for:

_ **Deletion of the envisaged 12-month extension of the supplementary protection certificate.**

Consistently uphold evidence and safety standards

The promotion of innovation within the framework of the Biotech Act must not be accompanied by a lowering of regulatory requirements through so-called “regulatory sandboxes”. The objective of clinical research must continue to be randomised controlled trials as the gold standard, under strict observance of patient safety, ethical standards and regulatory oversight.

The DSV therefore calls for:

_ **Maintaining the applicable safety and evidence standards and restricting the use of regulatory sandboxes.**

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 for statutory health and long-term care insurance funds at the federal level and the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have joined forces to form the "German Social Insurance - Working Group Europe" (Deutsche Sozialversicherung Arbeitsgemeinschaft Europa e. V.) 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 (EU) as well as other European institutions and advises the relevant stakeholders in the context of current legislative projects and initiatives. As part of the statutory insurance system in Germany, 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 effective protection against the consequences of major risks of life.