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Feedback from German Social Insurance dated 10 June 2025

The European Commissions call for evidence on an impact assessment regarding a European Biotech Act

I. Preliminary remarks

The European Commission plans to present a Biotech Act during the third quarter of 2026. The German Social Insurance (DSV) welcomes the European Union's (EU) efforts to promote biotechnology in order to improve medical care and ensure supply reliability. In doing so, key principles such as availability, accessibility and affordability as well as a patient-orientated understanding of innovation must take precedence over industrial policy goals.

From the DSV's point of view is that it is essential that the legislative proposal is closely aligned with the EU's objectives and initiatives in the areas of pharmaceutical supply, the EU HTA, and that the provisions of critical medicines.

Biotechnological medicinal products are usually highly complex, which places special demands on the marketing authorisation, evidence generation and reimbursement. A regulatory framework that will enable research, development and market access of biotech companies in the EU, whilst ensuring quality and supply reliability for all patients and safeguarding the financial viability of national healthcare systems is needed for integrating medical progress in Europe through novel therapies used in healthcare.

Challenge: Financing Innovation – But Keeping It Affordable for All

Biotechnological pharmaceuticals, especially gene therapies, offer new perspectives for the treatment of previously incurable diseases. Compared to other European countries, Germany is one of the countries with the fastest and most comprehensive access to new medicinal products. But this comes at a cost: German statutory health insurance funds spend around 55 billion euros annually on outpatient prescription drugs – and this trend is rising. The main cost drivers here are new, patented drugs - especially oncologicals and immunosuppressants, which include many biotechnologically produced compounds such as monoclonal antibodies.

Available gene and cell therapies already cost up to millions of euros per patient. Gene therapies represent a paradigm shift in drug provision. Unlike traditional medicines, they are often designed for single or intermittent use. This single dose usage shifts the entire cost risk to the payers - the statutory health insurance funds in Germany - at a very early stage, when robust data on long-term efficacy, potential late effects and the actual effectiveness of care are often lacking.

II. Opinion

Speed and Streamlining: No Compromises on Safety and Evidence, Strengthen Competition

From the DSV's perspective, the planned Biotech Act must not become a gateway for lowering regulatory standards. The principles of quality, safety, and efficacy of biotechnological medicines must not be compromised, and patients' health must not be put at risk. Blanket demands for regulatory simplifications in the biotech sector are not justifiable for as long as they are not based on a systematic analysis of existing provisions, including possible regulatory gaps and existing regulatory obstacles.

This Biotech Act must align with the principles of evidence-based medicine and the European HTA Regulation. A reliable additional benefit must be proven for high-priced biotechnological medicinal products. A standardised, interoperable database will be essential here, especially for orphan diseases.

Current incentives for rare diseases lead to the development of medicinal products for certain individual rare diseases or even subgroups, while other conditions remain untreated. Numerous therapies are being developed for some orphan diseases, but none are being developed for others. Promising concepts now exist whereby modular gene or RNA therapies—adapted individually—can serve as a therapeutic approach for multiple different rare diseases. This offers hope to patients with conditions for which there are currently no treatment options. It also opens the possibility of combining medical progress with improved economic viability by utilising synergies found during development and application. To bring such therapies into care, existing misaligned incentives for orphan drugs must be corrected. In the future, orphan drug status should not only be tied to disease rarity (prevalence criterion), but also to a profitability criterion: the company must demonstrate that commercialisation would not be viable without the orphan drug designation.

Pharmaceuticals in general, not just those used for treating orphan diseases, need balanced incentive systems that promote innovation but do not hinder market access of generic pharmaceuticals. Functioning competition is crucial for affordable medicines in the EU.

Another key issue here is the lack of transparency regarding existing protection periods. All patent and regulatory exclusivity periods should be made publicly accessible in order to provide planning reliability for manufacturers of biosimilars and enable early market launches. A centralised, publicly accessible database kept at the

EU’s Intellectual Property Office (EUIPO) could make a significant contribution to transparency and fair competition.

Financing: Transparent Public Funding for Biotech

Many biotechnological innovations are based on public research and funding. Research funding must be transparent to ensure that biotech products enabled by public funds are made available to all insured persons at fair prices. Industrial policy measures to diversify the production of biotech products, intermediates, and excipients, as well as investments in European manufacturing capacity, are important elements. Financial incentives and subsidies must be accompanied by sanctions if the subsidised companies fail to provide sufficient quantities of supply-critical biotechnological products. Misappropriation of contribution-based funds intended for healthcare and used for industrial policy purposes must be avoided.

Scope: Promoting Europe as an industrial location – Strengthening security of supply

Promoting biotech production in Europe can contribute to strengthening European innovation. From the DSV’s perspective, building production capacities and clusters is an industrial policy task and must be financed from public funds. The high standards of pharmaceutical safety, quality and usage as well as environmental protection must never be undermined, even under investment-friendly framework conditions.

DSV's view is that the EU must also implement measures to minimise supply bottlenecks and risks. They can have a variety of causes, from geopolitical tensions to operational production disruptions. The reform of EU pharmaceutical law, the Critical Medicines Act, and biotechnology legislation must together provide a consistent foundation for the entire sector. This includes further development of the EU-wide early warning system to increase transparency and prevent supply shortages, obligations for marketing authorisation holders to report impending shortages and prepare mitigation plans, and noticeable sanctions for non-compliance with supply obligations.

Competence: Academic Collaboration as a Foundation for Innovation and Competitiveness

Innovations in the biotech sector are often based on findings from basic research in medicine, pharmacy, biochemistry, and biotechnology. Expanding interdisciplinary exchange between universities at European and international level is therefore key to promoting new biotech developments in the EU. To fully exploit this potential, bureaucratic barriers to academic collaboration should be removed, as this also serves Europe's competitiveness.

Data and AI Use in Biotech: Design Responsibly and for the Common Good

Responsible access to health data and the targeted use of artificial intelligence can significantly contribute to the development of medical care and the innovative capacity of biotechnology in Europe. The European Health Data Space (EHDS) and the use of AI also offer new opportunities in the biotech sector. However, it is crucial that these technologies are used within a clear ethical and legal framework. This applies to accessing AI-supported innovations and healthcare delivery as well as the non-discriminatory design of the data basis and the AI models themselves.

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 longterm 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" (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 and other European institutions and advises the relevant players in the context of current legislative projects and initiatives. As part of a statutory insurance system, health and long-term care insurance with 75 million insured people, pension insurance with 57 million insured people and accident insurance with more than 70 million insured people in 5.2 million member companies, citizens in Germany are provided with effective protection against the consequences of major life risks.