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EU Pharmaceutical Reform: Affordable Access Is Decisive

Statement on the Trilogue Agreement between the EU Institutions on the Pharmaceutical Reform, 16 December 2025

After more than two decades, the EU pharmaceutical reform marks the first comprehensive revision of European pharmaceutical legislation. The compromise reached in the trilogue between the European Parliament, the Council and the European Commission is both politically and technically demanding and sends an important signal: the European Union is, in principle, capable of modernising key structural elements of pharmaceutical law and responding to current challenges related to security of supply and competition.

The German Social Insurance (DSV) welcomes the objectives pursued by the European Commission through the reform proposals and has repeatedly contributed its position to the legislative process. The now negotiated agreement of the pharmaceutical reform addresses numerous well-known weaknesses of the existing system and has the potential to strengthen transparency, coordination and legal certainty at EU level. At the same time, it falls short of expectations in key areas – particularly where a more consistent strengthening of affordability, access and the financial sustainability of solidarity-based health systems would have been required. Whether the repeatedly emphasised ambition of putting patients at the centre will actually be realised will depend to a large extent on practical implementation.

Against this background, the DSV assesses the agreement as follows:

We welcome

- that the maximum regulatory protection period of 11 years agreed in the trilogue clearly limits the overall duration of monopolistic protection rights and thus, in principle, enables earlier market entry of generics and biosimilars – an important signal for competition and long-term affordability;

- the strengthening and clarification of the Bolar exemption, which creates legal certainty and ensures that preparatory activities for marketing authorisation, HTA, pricing and reimbursement procedures as well as procurement procedures can already take place during the protection period. This prevents strategic market delays and strengthens competition from day one after patent expiry;

_ the new rules to prevent and manage medicine shortages, in particular binding prevention plans, clearer reporting obligations and a stronger coordinating role for the EMA;

_ the introduction of a voluntary subscription model for antimicrobials, which from the DSV's perspective represents a sound and important approach to addressing structural market failures in the antibiotics sector. Remuneration models that are fully or partially decoupled from sales volumes provide more appropriate incentives for the development of urgently needed substances than purely volume-based mechanisms.

We note with concern

_ the continued maintenance of an eight-year data protection period for medicinal products, leaving a key reform potential unused. The agreement thus falls well short of the Commission proposal, which had envisaged a reduction of data protection to six years, and fails to significantly facilitate earlier market entry of generics and biosimilars;

_ the persistently high exclusivity periods for orphan medicines. The newly introduced approach for "breakthrough orphan medicines" is more targeted than previous concepts. However, it remains structurally limited, as it does not address the underlying problem of excessively long exclusivity periods, although such a limitation would have been desirable from the perspective of healthcare provision and payers;

_ the continued inclusion of a transferable exclusivity voucher for priority antimicrobials as an incentive instrument, which, despite the limitations achieved in the trilogue, continues to pose significant risks of misaligned incentives and additional costs. Extending protection periods shifts financial risks to solidarity-based health systems, while the actual added value for innovation and patient care remains uncertain, making particularly strict implementation, monitoring and evaluation necessary.

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.