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"Safe and affordable medicines for Europe"

Statement on the Reform of the EU pharma legislation
22 January 2024

The German Social Insurance (DSV) welcomes the reform of the EU pharmaceutical legislation in order to ensure the accessibility, availability and affordability of medicinal products in the European Union in the future. It is important for the healthcare systems of the Member States, and therefore also for the German social insurance system, that medicines which are of great benefit for the care of citizens are available and that therapeutic gaps are closed. With regard to the ongoing legislative process and in particular the discussions in the European Parliament on important proposals and compromises, we would like to highlight five points:

We welcome

_ that many Members of the European Parliament are in favour of greater **transparency in the financing of pharmaceutical innovations**. In future, pharmaceutical manufacturers should not only disclose in databases whether and how much financial support they have received from public authorities, but also make it clear how much money they spend on research and development of new medicinal products. This desired transparency is urgently needed in order to negotiate fair prices for pharmaceuticals between payers and the industry in Member States' pricing and reimbursement procedures.

We appreciate

_ that many Members of the European Parliament share our belief that the **deadlines for regulatory protection and patent protection must be publicly available**. This would be a significant improvement on the status quo, as there is currently no transparency regarding the expiry of a medicinal product's exclusivity protection. This makes it difficult for generic and biosimilar manufacturers to enter the market at an early stage. However, it is precisely this competition that is important and essential for ensuring that necessary medicinal products are available in healthcare systems and that an affordable supply of medicinal products is made possible.

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We are pleased

_ that the idea of expanding the **European Medicines Verification System (EMVS) and using it to establish a comprehensive medicines monitoring system** has been taken up in the Parliament. We share the view that monitoring the safety features of medicinal products and the resulting data transparency is the best way to identify potential delivery and supply bottlenecks at an early stage. Real-time monitoring provides an overview of the current supply and demand situation for medicinal products and opens up new possibilities for an early warning system that is not dependent on the active provision of information.

We are concerned

_ about the voices in favour of **longer exclusivity periods for new medicinal products** during the consultations. Some of the proposed extensions will have a massive impact on pharmaceutical prices, as they extend the monopolies for blockbuster medicines far beyond the current legal framework and will have a significant impact on the cost burden on healthcare systems, to the expense of affordable healthcare for citizens. It would also be unfortunate to miss the opportunity not to link exclusivity periods to policy objectives such as supplying all 27 Member States or closing therapeutic gaps. Pharmaceutical manufacturers' investment funds should be used to develop medicines that are needed, of high benefit and that are available where there is a need.

We warn against

_ authorising more and more **medicinal products for the market via accelerated procedures**. Faster access to the market is not an advantage in terms of care if risks are shifted to patients through medicinal products that have not been adequately tested in clinical trials. It should be standard practice for all necessary data on the efficacy, safety and quality of a medicinal product to be collected in controlled clinical trials and not only after market entry when patients are treated. We believe that accelerated authorisation procedures are justified only in exceptional cases, such as public health emergencies. They should not become the rule.

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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 74 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.