



“Hefty price tag for RDP: One additional year of regulatory data protection equals €1bn costs for German healthcare systems, €3bn for EU27”

Statement on the Reform of the EU pharma legislation
12 March 2024

Amidst debates over the EU pharmaceutical reform, the German Social Insurance European Representation (DSV), representing 74 million individuals under statutory health insurance in Germany, calculated the considerable additional costs that the German healthcare system would face if an additional year of regulatory data protection for medicinal products were granted.

Each additional year by which the onset of generic competition is delayed comes at a cost of just over **1 billion euros (€1.005.494.538) for the statutory health insurance system in Germany**. Across the EU, the additional costs for each additional year of regulatory data protection **amount to a staggering 3 billion euros (€3.015.722.966)**.

Therefore, the DSV strongly opposes an extension of the regulatory protection and market exclusivity periods. Generic competition is a key factor for affordable access to medicines and ensures the financial stability of healthcare systems. The later generic competition starts, the greater the burden on the healthcare and social systems, the faster the contributions increase and thus the burden on employees and employers, who finance the health insurance contributions in Germany on a parity basis.

Ilka Wölfle, DSV Director *“With these calculations at hand, we would like to emphasise once again our demands to shorten regulatory data protection to 6 years, to limit cumulative protection to 11 years and to introduce alternative push and pull incentives instead of vouchers.”*

These figures illustrate the need for a balanced position in the European Parliament regarding the length of the protection periods with a view to safeguarding affordability and long-term sustainability of healthcare systems. The already financially strained German healthcare system would be massively affected by this. It is therefore paramount that the European Parliament agrees on a balanced text that promotes



affordable access to healthcare for all patients and shields healthcare systems from massive cost burdens.

The assumptions for the calculations can be consulted [here](#).

Read the DSV's position in brief on the pharmaceutical reform [here](#).

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.