

EU pharmaceutical reform: The cost of one more year of regulatory data protection

Every year that generic competition is delayed costs the Statutory Health Insurance system in Germany more than **1 billion euros**.

Across the EU, the additional costs for each additional year of regulatory document protection amount to more than **3 billion euros**.

The calculation is based on the following figures and assumptions:

German Statutory Health Insurance (SHI) sales of non-generic drugs 2023 (extrapolation) ¹ :	29.1 billion euros
Average effective protection period ² :	13 years
Lifecycle factor ³ :	1,4
Proportion of medicinal products benefiting from the extension of regulatory data protection ⁴ :	46.5 per cent
Factor for the average extension of the effective protection period ⁵ :	Factor 0.92
Average price reduction due to generics competition in Germany ⁶ :	75 per cent
Germany's share of sales in the EU pharmaceutical market ⁷ :	25 per cent

¹ Non-generic medicinal products are products that are still subject to patent protection (incl. SPC) or regulatory protection under pharmaceutical legislation. Basis for calculation: [GAmSi Federal Report 2023-09 \(gkv-gamsi.de\)](#)

² Includes regulatory protection through data protection (8 years) and market exclusivity protection (2 years), 1 year for a new indication and 2 years that patent protection exceeds the regulatory protection period on average. Source: [Final Report \(copenhageneconomics.com\)](#), p. 72.

³ The lifecycle factor takes into account the fact that, on average, the sales of a medicinal products are higher at the end of the effective protection period than at the beginning and is applied to the average annual sales during the protection period. Source: [Grabowski and Vernon 2000 \(duke.edu\)](#), p. 23.

⁴ Included are the medicinal products that are affected by an extension of regulatory protection, i.e. the medicinal products for which patent protection no longer exists when regulatory protection expires (39 per cent), as well as the medicinal products that are to be included in this group if regulatory protection is extended by one year (7.5 per cent). See: [Final Report \(copenhageneconomics.com\)](#), p. 262 and 74.

⁵ The factor takes account of the fact that for the 7.5 per cent share of the relevant medicinal products (46.5 per cent in total), it must be considered that an extension of regulatory protection can mean only one day of additional protection for some medicinal products, depending on market entry, while for another part the additional protection can mean 364 days. Equal distribution has been assumed here.

⁶ Price reduction for list prices (50 per cent) plus price reduction through discount agreements (25 per cent). Source: [Vondeling et al. 2018 \(nih.gov\)](#), p. 657.

⁷ The ratio of pharmaceutical sales in the EU to pharmaceutical sales in Germany was used to calculate the additional sales at EU level. Source: [Pharm. Industry in Figures 2023 \(efpia.eu\)](#), p. 15. Price reductions through discount agreements were not taken into account for the other member states.