

## Press release

### **ESIP reacts to the political agreement on the EU General Pharmaceutical Legislation**

Brussels, 11 December 2025

The European Social Insurance Platform (ESIP), representing statutory social and health insurance institutions in the EU, takes note of the political agreement reached today on the reform of the EU general pharmaceutical legislation.

*‘As statutory social and health insurers, our role is to secure sustainable access to effective medicines. The agreement on the pharmaceutical package contains important safeguards, such as the cap on regulatory protection and a strengthened Bolar exemption that can help preserve competition and protect public budgets. At the same time, some of the new incentive tools, including transferable exclusivity vouchers, will require careful implementation and monitoring.’ Anne-Claire Le Bodic, ESIP President*

ESIP notes positively the combined period of regulatory data and market protection capped at 11 years. At the same time, ESIP remains cautious about modulating market protection based on comparative clinical trials, which should remain the gold standard for robust clinical evidence, not an optional reward for prolonged exclusivity. ESIP therefore calls to ensure that the link between comparative trials and incentive modulation does not erode fundamental requirements for evidence-based decision-making.

ESIP appreciates that the objective of sustainable healthcare systems through timely market entry of generics and biosimilars is supported in the legislative text. We welcome a strong and legally sound Bolar exemption, which allows generic and biosimilar competition from day one after patent expiry. Similar approaches should be pursued in other relevant legislative initiatives, related to supplementary protection certificates and other IP instruments.

ESIP warns against the introduction of Transferable Exclusivity Vouchers (TEVs) for priority antimicrobials, effectively allowing a total of 12 years of protection in certain cases. While recognising the urgent need to stimulate the development of new antimicrobials, and taking note of the “blockbuster clause” that limits use of TEVs for products above a certain turnover, ESIP reaffirms that TEVs are inherently unpredictable and calls for strict governance, transparency and monitoring of TEV use, including systematic assessment of budgetary impact and added therapeutic value.

Finally, while supporting a differentiated approach that considers unmet medical needs and the absence of existing treatments, ESIP views with caution the extension of market exclusivity for certain orphan medicinal products to 11 years, given that pharmaceutical expenditure has been growing exponentially and further prolongations of exclusivity may limit competition and pressure healthcare budgets.



## About the European Social Insurance Platform (ESIP)

The [European Social Insurance Platform \(ESIP\)](#) represents 47 national statutory social insurance organisations in 19 EU Member States and Switzerland, active in the field of health insurance, pensions, occupational disease and accident insurance, disability and rehabilitation, family benefits and unemployment insurance. The aims of ESIP and its members are to preserve high profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European debate and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

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