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EU Pharma Reform – We Have A Deal!

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On 11 December 2025, the European Union (EU) institutions reached an agreement on the "Pharma Package". This milestone follows several years of legislative work, beginning with the European Commission's proposal in April 2023, which initiated the most substantial update to EU pharmaceutical legislation in more than two decades. The initiative aims to modernize the regulatory framework, improve the availability and affordability of medicines, and strengthen supply-chain resilience – motivated in part by lessons drawn from the COVID-19 pandemic and persistent concerns around antimicrobial resistance. The European Parliament adopted its position in April 2024, followed by the Council in mid-2025. Trilogue negotiations concluded in the early morning of 11 December with a provisional political agreement between the EU institutions. This agreement represents a decisive step toward rolling out a new legal framework that will influence innovation, market access and regulatory oversight across the EU for years to come.

The agreed legislative texts have not yet been published.

Key features

Regulatory and market exclusivity adjustments: 8+2+1 → 8+1(+1+1)

The agreement maintains the baseline eight-year period of data protection, reduces standard market protection from two years down to **one year** and introduces a structured system of extensions. Products will be eligible for 12-month extensions to market protection if any of the following conditions are met:

- The product addresses an unmet medical need.
- The product contains a new active substance, fulfills a combination of conditions on comparative clinical trials or multi-country clinical trials, and introduces a marketing authorization application within 90 days of submission of a first marketing authorization application outside of the EU.
- An approval is obtained for new therapeutic indications with significant clinical benefit.

Extensions are capped, ensuring that total protection cannot exceed 11years. This more flexible framework offers a nuanced incentive environment compared with the previous "8+2+1" system. The retention of the eight-year baseline data protection combined with the overall cap provides a certain predictability for innovators and generic manufacturers, while the extension triggers aim to encourage investment in areas where innovation is most needed, particularly high unmet need therapeutic areas.

Orphan and 'breakthrough' medicinal products

The reform significantly reshapes the incentives regime for orphan medicinal products by reducing baseline market exclusivity to **nine years**. However, "breakthrough" orphan medicinal products – those addressing diseases with no available medicinal treatment – will benefit from **11 years** of market exclusivity. This approach aims to reward high-impact research and promote development in rare disease areas where unmet needs remain acute.

Clarification and extension of the Bolar exemption

The EU institutions have clarified that manufacturers may conduct all activities necessary to prepare for

marketing authorization applications, as well as health technology assessments, pricing and reimbursement submissions, and participation in public tenders and procurement procedures, before expiry of the reference product's exclusivity – without infringing patent rights. This clarification is intended to enable more timely entry of generics and biosimilars once exclusivity ends.

Addressing antimicrobial resistance

As anticipated, the reform introduces a transferable data exclusivity voucher (TEV) granting an additional 12 months of regulatory data protection for priority antimicrobials, but only for small volume products. To limit the potential impact on national healthcare budgets, the TEV cannot be used for "blockbuster" products with annual gross sales of more than 490 million euros in the preceding four years.

The TEV represents one of the most novel instruments in the reform package. By granting an extra 12 months of data protection to reward investment in priority antimicrobials and allowing the voucher to be applied to another product, the mechanism seeks to stimulate otherwise economically unattractive antimicrobial research. Careful monitoring will be required to assess the scheme's overall effectiveness and potential impacts.

Efficiency gains and digital modernization

The Pharma Package also aims to enhance the attractiveness and competitiveness of the EU pharmaceutical regulatory system. The European Medicines Agency (EMA) review period will be shortened from 210 days to 180 days, which is intended to facilitate quicker access to innovative medicines across the EU. Digitalization measures, including the use of QR codes to replace or supplement traditional package leaflets, aim to improve patient understanding while reducing administrative burdens on companies. At the same time, strengthened supply chain transparency obligations, including a mandatory six-month notification period for anticipated shortages, reflect lessons learned from recent health crises and aim to safeguard continuity of care.

Next steps

Following this provisional agreement, the final legislative texts will move to formal adoption by the European Parliament and the Council, which is expected in early 2026. Once adopted, the new framework will include transitional measures allowing companies to adapt gradually to the reformed system (likely between 18 and 36 months). This timeline means that the new exclusivity conditions, regulatory pathways and compliance obligations will phase in over the coming years.

Pharmaceutical companies should start to assess the impact of the new exclusivity architecture on their development pipelines, particularly in relation to opportunities for additional protection based on unmet medical needs, comparative clinical evidence and EU-based research activities.

Businesses should also prepare for earlier competition due to the clarified Bolar exemption and explore potential strategic benefits of the antimicrobial voucher mechanism. Companies with products at risk of supply shortages should also review internal processes to meet the six-month advance notification requirement.

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