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‘Pharma package’: Council and Parliament reach a deal on new rules for a fairer and more competitive EU pharmaceutical sector

This press release was updated on 6 March 2026 to add the texts of the provisional agreement.

The Council and the European Parliament have reached an agreement on the **‘pharma package’**, a new set of rules that will increase patients' access to medicine and make the EU’s pharmaceutical sector fairer and more competitive.

The package represents a far-reaching reform of the EU’s pharmaceutical legislation and will help ensure **fair access to safe, effective and affordable medicines** across the EU.

It also seeks to **boost the competitiveness of the pharmaceutical industry** by cutting regulatory burdens and strengthening security of supply to prevent and manage shortages.

> I am pleased we have reached an agreement with the European Parliament on a new legislative framework for pharmaceuticals. The deal demonstrates the EU’s commitment to both innovation and to ensuring that patients in Europe have access to the medicines they need. We are strengthening incentives for priority antibiotics, reducing red tape for the life science industry, and safeguarding the availability of essential medicines. The package marks a crucial step towards making a more resilient and dynamic life science sector in Europe, and it shows that Europe is able to make the necessary decision to protect European interests.
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> *Sophie Løhde, Danish Minister for the Interior and for Health*

Regulatory protection

Under the text agreed by the co-legislators, companies placing a new medicine on the market benefit from an **eight-year data protection period**, meaning they have exclusive rights to data from pre-clinical tests and clinical trials.

They will also benefit from **one year of market protection** (the exclusive right to sell a product without immediate competition from generic medicines or biosimilars), which may be extended by an additional year for innovative medicines that satisfy two out of three conditions.

Availability of medicines

To ensure the availability of key medicines, the co-legislators have kept a provision introduced by the Council (article 56a) giving EU countries the power to **require companies to supply medicines** benefiting from regulatory protection in **sufficient quantities to meet patient needs**.

Following negotiations, safeguards have been added to the text clarifying obligations for companies and member states, and preventing the use of article 56a as an opportunity for parallel trade.

The ‘Bolar exemption’

The pharma package includes an intellectual property exemption allowing manufacturers to take the necessary steps (such as studies or trials) to ensure that **generic versions of a medicine can be made available on day one** after the intellectual property rights have expired.

The co-legislators have clarified the wording of this provision, and have maintained the Council’s extension of the scope to include **submissions for procurement tenders**.

Antimicrobial resistance

The pharma package introduces a new **transferrable exclusivity voucher** incentivising pharmaceutical companies to help combat antimicrobial resistance by **developing priority antibiotics**.

Under the agreement reached between the Council and the Parliament, this voucher will grant companies **one additional year of market protection** for a pharmaceutical product of their choice.

The Parliament has also agreed to maintain the Council’s proposed **‘blockbuster clause’**, which **limits the potential impact on national healthcare budgets** by stipulating that the transferrable voucher cannot be used on products with annual gross sales of more than €490 million in the preceding four years.

Next steps

The provisional agreement now needs to be endorsed by both the Council of the European Union and the European Parliament, before being formally adopted and entering into force upon publication in the EU’s Official Journal.

- Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency
- Directive on the Union code relating to medicinal products for human use
- ‘Pharma package’: Council agrees its position on new rules for a fairer and more competitive EU pharmaceutical sector (press release, 4 June 2025)
- The ‘pharma package’: new EU rules on medicines explained (background information)

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