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PHARMA PACKAGE – DEAL AT THE EU LEVEL ON A MAJOR PHARMA REFORM

IT and Data Protection European Law Patent Law | 12/12/25 | François Pochart Geoffrey Grandjean

LIFE SCIENCES & HEALTHCARE

Yesterday, 11 December 2025, the Parliament and the Council of the EU, the two co-legislators in the EU, reached a provisional agreement on the so called "Pharma Package" during a trilogue between the European Commission, the Parliament and the Council of the EU[1]. The Pharma Package gathers a new regulation[2], as well as new directive[3] and is the biggest reform of EU pharma law since 20 years, amending among others Directive 2001/83/EC.

The European Commission presented a revision of the pharmaceutical framework on 26 April 2023[4]. Parliament adopted its position in April 2024[5], and the Council of the EU one year later, under the Polish Presidency of the Council of the EU[6].

This agreement is a success for the Danish Presidency of the Council of the EU, which listed the adoption of the Pharma Package as one of the goals of its presidency[7].

Here are some keys elements of the Pharma Package[8]:

- Regulatory protection (Art. 81.2.a of the future directive): An eightyear regulatory data protection period, with one year of market protection, with three possibilities of prolongation of the regulatory data market protection period of 12 months. However, the total possible regulatory protection cannot exceed 11 years (Art. 81.2.a of the future directive).
- Bolar exemption (Art. 85 of the upcoming directive): The protection provided by patent or SPC shall not be regarded as infringed when the necessary studies, trials and other activities are conducted for the purposes of:
- Obtaining a MA of medicinal products, notably of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations
- Conducting health technology assessment
- Obtaining pricing and reimbursement approval
- Complying with subsequent practical requirement associated with the activities referred above
- Submitting an application on procurement tenders, to the extent that at it does not entail the sale or offering for sale or marketing of the medicinal product concerned during the protection period provided by patent rights or supplementary protection certificate

The Pharma Package also tackles the issue of availability of medicines with mechanism that gives EU countries the power to require companies to supply medicines benefiting from regulatory protection in sufficient quantities to meet patient needs (art. 56.3 of the upcoming directive). The MA holder shall also notify market cessations, withdrawals, temporary suspensions and temporary disruptions (Art. 116 of the upcoming regulation).

The Pharma Package also introduces a new transferrable exclusivity voucher to encourage pharma companies to develop priority antibiotics. This voucher will grant pharma companies one additional year of market protection for a product of their choice but cannot be used on products with annual gross sales of more than €490 million in the preceding four years (Art. 40 of the upcoming regulation).

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

AD will report more detailly once the regulation and directive will be published.

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[1] European Parliament Press Release, 11 Dec. 2025 "Deal on comprehensive reform of EU pharmaceutical legislation" (https://www.europarl.europa.eu/news/en/press-room/20251209IPR32110/deal-on-comprehensive-reform-of-eu-pharmaceutical-legislation); Council of the EU Press Release, 11 Dec. 2025 "'Pharma package': Council and Parliament reach a deal on new rules for a fairer and more competitive EU pharmaceutical sector (https://www.consilium.europa.eu/en/press/press-releases/2025/12/11/pharma-package-council-and-parliament-reach-a-deal-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/)

[2] Council of the EU, Proposal of regulation – Mandate for negotiations with the European Parliament, 2 June 2025 (https://data.consilium.europa.eu/doc/document/ST-9286-2025-INIT/en/pdf)

[3] Council of the EU, Proposal of directive – Mandate for negotiations with the European Parliament, 2 June 2025 (https://data.consilium.europa.eu/doc/document/ST-9285-2025-INIT/en/pdf)

[4] European Commission Press Release, 26 April 2023 “European Health Union: Commission proposes pharmaceuticals reform for more accessible, affordable and innovative medicines” (https://ec.europa.eu/commission/presscorner/detail/en/ip_23_1843)

[5] Directive Text adopted by the Parliament on 10 April 2024 (https://www.europarl.europa.eu/doceo/document/TA-9-2024-0220_EN.html) and Regulation Text adopted by the Parliament on 10 April 2024 (https://www.europarl.europa.eu/doceo/document/TA-9-2024-0221_EN.html)

[6] Council of the EU Press Release, 4 June 2025 “Pharma package’: Council agrees its position on new rules for a fairer and more competitive EU pharmaceutical sector – Consilium” (‘Pharma package’: Council agrees its position on new rules for a fairer and more competitive EU pharmaceutical sector - Consilium)

[7] European Parliament, Briefing outlook for upcoming Presidency, Priority dossiers under the Danish EU Council Presidency, 1st July 2025, (https://www.europarl.europa.eu/RegData/etudes/BRIE/2025/775852/EPRS_BRI(2025)775852_EN.pdf), page 4.

[8] For more details see European Parliament Press Release, 11 Dec. 2025 “Background note: pharmaceutical package provisional agreement elements” (Background note: pharmaceutical package provisional agreement elements | News | European Parliament).