Revision of EU pharmaceutical legislation

During its April I plenary session, the European Parliament is expected to adopt its position at first reading on two Commission proposals to revise the EU's pharmaceutical legislation. The revision seeks to enhance the security of supply of medicine, making medicines more available, accessible and affordable across EU countries, while supporting the attractiveness of the EU pharmaceutical industry by fostering research and innovation.

Background

In 2020, the Commission adopted a pharmaceutical strategy for Europe to ensure that patients have access to high-quality, effective and safe medicines, and support the pharmaceutical industry's innovation efforts. The revision of EU pharmaceutical legislation is central to a strong European health union and follows on from the pharmaceutical strategy. It also draws lessons from the COVID-19 pandemic, which demonstrated the importance of a crisis-resistant system and availability of medicines under all circumstances.

European Commission proposals

In April 2023, the Commission put forward two legislative proposals – for a regulation and a directive – to amend and repeal several regulations, including the legislation on medicines for children and for rare diseases. The aim is to give patients better access to affordable medicines and innovative drugs (for instance for unmet medical needs); to address medicine shortages and ensure security of supply (for instance through monitoring); and to promote innovation and competitiveness (for example with a simplified regulatory framework and incentives for innovation). The 'package' was completed by a recommendation to step up the fight against antimicrobial resistance, which was adopted by the Council in June 2023.

European Parliament position

Parliament has consistently promoted the establishment of a coherent policy on pharmaceuticals that takes both public health interests and industrial aspects into account. On 19 March 2024, the Committee on the Environment, Public Health and Food Safety (ENVI) adopted its report on the proposal for a regulation (67 votes in favour, 6 against and 7 abstentions), and the report on the proposal for a directive (66 votes in favour, 2 against and 9 abstentions). To boost EU research and market attractiveness, the reports call for a regulatory data protection period of a minimum of seven and a half years for new medicines, in addition to a two-year period of market protection following market authorisation (during which generic or biosimilar products may not be sold). Longer protection periods would be granted under certain circumstances (such as unmet medical needs, clinical trials). Medicines developed to treat rare diseases (orphan drugs) would benefit from up to 11 years of market exclusivity if they meet a 'high unmet medical need' (protecting them from competition from similar medicines with similar indications, which cannot be marketed during the exclusivity period). New measures would promote the prudent use of antimicrobials – for instance prescriptions would be limited to the amount required for treatment, for a limited duration – and would encourage the development of new antimicrobials. New rules would require companies to submit an 'environmental risk assessment' when applying for market authorisation.

First reading: (a) 2023/0131(COD) and (b) 2023/0132(COD)
Committee responsible: ENVI; Rapporteurs: (a) Tiemo Wölken (S&D, Germany), (b) Pernille Weiss (EPP, Denmark). For further information see our 'EU Legislation in progress' briefing.

Outcome of the Conference on the Future of Europe: This proposal is relevant for measures 8(3); 10(2), (4), (6); 12(12), 17(3), (7).

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