# New agreement to reshape EU pharmaceutical legislation


**15 December 2025**

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A landmark political agreement has been reached by the European Commission, the European Parliament and the Council of the European Union on a comprehensive reform of the EU pharmaceutical legislation.

The agreement represents the most significant overhaul of the regulatory framework in over two decades and is described as a “once-in-a-generation opportunity to reshape medicines regulation in the EU”.

The aim of the revamp is to enable EMA and the European medicines regulatory agencies network to become more agile and efficient while upholding the highest standards of scientific rigour.

“By simplifying procedures, embracing digitalisation and rationalising our use of scientific resources, we will be better positioned to support innovation and ensure that promising new treatments reach patients faster. The new legislation also provides us with the tools to deliver on our network strategy to 2028 and address the major public health challenges of the future, from antimicrobial resistance to emerging health threats,” said Emer Cooke, EMA’s Executive Director

The new legislation is expected to simplify structures and procedures which have been introduced by different pieces of legislation over the years, namely the existing pharmaceutical legislation (Regulation 726/2004 and Directive 2001/83/EC) and the legislation on medicines for children and for rare diseases (Regulation 1901/2006 and Regulation 141/2000/EC, respectively). It also amends the advanced therapy medicinal products (ATMP) Regulation 1394/2007.

## Key areas affected by the reform

EMA will simplify its committee structure from five to two scientific committees for human medicines: the Committee for Human Medicinal Products (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC).

This streamlined structure is intended to facilitate reduced assessment time (210 to 180 days) and free up scientific resources to strengthen pre-authorisation support to medicine developers.

Marketing authorisation for a medicine will be valid by default for an unlimited period, avoiding the unnecessary administrative burden linked to renewals unless required on safety grounds.

Additionally, the reform will require applicants to submit marketing authorisation applications in electronic and structured formats and to make available approved product information in electronic form (ePI).

The European Commission will establish, at the suggestion of EMA and in consultation with Member States, a regulatory sandbox to test, under the direct supervision of the competent authorities, adapted requirements for innovative medicines that cannot be developed under current rules.

The reform will also include the creation of adapted frameworks for certain non-standard categories of medicines, such as personalised therapies, as well as improvements in the efficiency of the process for studying medicines in children.

To guard against medicine shortages, the reform will include stronger obligations for companies to ensure continuous supply of medicines, and the obligation to notify shortages and withdrawals in advance and have shortage prevention plans in place.

The reform also introduces strengthened provisions to evaluate the risk for antimicrobial resistance selection in the environment due to the manufacture of antimicrobials, and more prudent use of antimicrobials, including compulsory medical prescriptions for all antimicrobials.

The political agreement is now subject to formal approval by the European Parliament and the Council.

*Diana Turner, Deputy Editor, DDW*

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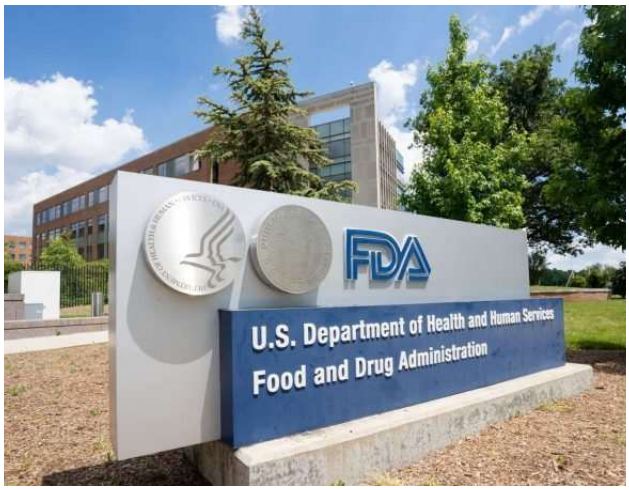


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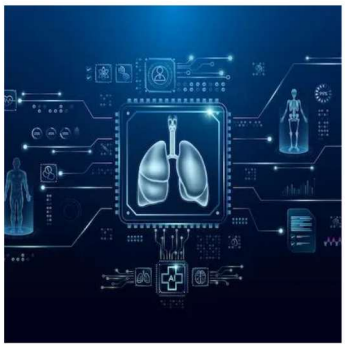

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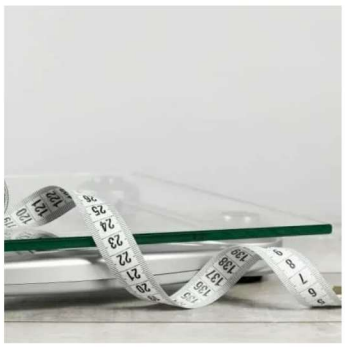

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