Authorisation and supervision of medicinal products for human use and governing rules for the European Medicines Agency

2023/0131(COD) - 26/04/2023 - Legislative proposal

PURPOSE: to ensure the authorisation of high-quality medicinal products, including for paediatric patients and patients suffering from rare diseases throughout the Union.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: the Union pharmaceutical framework has enabled the authorisation of safe, efficacious and high-quality medicines in the Union, contributing to a high level of public health and a smooth functioning of the internal market of these products.

The **Pharmaceutical Strategy for Europe** marks a turning point with the addition of further key objectives and by creating a **modern framework** that makes innovative and established medicinal products available to patients and healthcare systems at affordable prices, while ensuring security of supply and addressing environmental concerns.

Addressing unequal patient access of medicinal products has become a key priority of the Pharmaceutical Strategy for Europe as has been highlighted by the Council and the European Parliament. Member States have called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while ensuring patient access and availability of medicinal products in all Member States.

Previous amendments to the Union pharmaceutical legislation have addressed access to medicinal products by providing for accelerated assessment for marketing authorisation applications or by allowing conditional marketing authorisation for medicinal products for unmet medical need. While these measures accelerated the authorisation of innovative and promising therapies, these medicinal products do not always reach the patient and patients in the Union still have different levels of access to medicines.

The proposed revision of the pharmaceuticals legislation consists of this proposal for a new regulation and a proposal for a new directive, which will also cover orphan and paediatric medicinal products.

CONTENT: this proposal lays down Union procedures for the **authorisation, supervision and pharmacovigilance of medicinal products for human use** at Union level, establishes rules and procedures at Union and at Member State level relating to the security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency (EMA).

This Regulation will not affect the powers of Member States' authorities as regards setting the prices of medicinal products or their inclusion in the scope of the national health system or social security schemes on the basis of health, economic and social conditions. Member States may choose from the particulars shown in the marketing authorisation those therapeutic indications and pack sizes which will be covered by their social security bodies.

Objectives

The objectives of the proposal are the following:

- guarantee a high level of public health by ensuring the quality, safety and efficacy of medicinal products for EU patients;

- harmonise the internal market for the supervision and control of medicinal products and the rights and duties incumbent upon the competent authorities of the Member States;

- make sure all patients across the EU have timely and **equitable access** to safe, effective, and affordable medicines;

- enhance **security of supply** and ensure medicines are always available to patients, regardless of where they live in the EU;

- offer an attractive **innovation-and competitiveness** friendly environment for research, development, and production of medicines in Europe;

- make medicines more **environmentally sustainable**.

The proposed regulation includes the following **main areas of revision**:

- promoting **innovation and access** to affordable medicines creating a balanced pharmaceutical ecosystem;

- modulation of the **length of the market exclusivity** for orphan medicinal products. For rare disease medicines, the standard duration of market exclusivity would be 9 years with the possibility of granting a one-year extension of market exclusivity, based on patient access in all Member States concerned;

- **paediatric investigation plans** for medicinal products for children, based on a medicinal product's mechanism of action;

- measures related to **antimicrobials** and provisions on transferable data exclusivity **vouchers.** A voucher system will provide 'transferable data exclusivity vouchers' under strict conditions to developers of new antimicrobials. Such a voucher will grant an additional year of regulatory data protection to the developer of the priority antimicrobial, which the developer can either use for any product in their own product portfolio or sell it to another marketing authorisation holder;

- strengthening the **scientific and regulatory support** of the European Medicines Agency, in particular for developers of medicines that address unmet medical needs;

- enhanced pre-authorisation scientific and regulatory support;

- temporary **emergency marketing** authorisation;

- improving security of supply of medicines;

- a framework for activities to be undertaken by Member States and the Agency to improve the EU's ability to respond in an effective and coordinated manner to support the management of medicines **shortages** at all times;

- EMA capacity to inspect sites located in non-EU countries;

- reducing **regulatory burden** and providing a flexible regulatory framework to support innovation and competitiveness;

- improved structure and governance of EMA and the regulatory network.