Medicinal products for human use

2023/0132(COD) - 26/04/2023 - Legislative proposal

PURPOSE: to review pharmaceutical legislation with a view to establishing rules on medicinal products ensuring the protection of public health and the environment as well as the functioning of the internal market.

PROPOSED ACT: Directive 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: EU pharmaceutical legislation has enabled the authorisation of safe, efficacious and high-quality medicinal products. However, patient access to medicinal products across the EU and security of supply are growing concerns. There is also a growing problem of shortages of medicinal products for many EU/EEA countries. Consequences of such shortages include decreased quality of treatment received by patients and increased burden on health systems and on healthcare professionals, who need to identify and provide alternative treatments. While the pharmaceutical legislation creates regulatory incentives for innovation and regulatory tools to support timely authorisation of innovative and promising therapies, these medicinal products do not always reach the patient, and patients in the EU have differing levels of access.

Moreover, innovation is not always focused on unmet medical needs, and there are market failures, especially in the development of priority antimicrobials that can help address antimicrobial resistance. Scientific and technological developments and digitalisation are not fully exploited, while the environmental impact of medicinal products needs attention.

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.

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

CONTENT: the overall pharmaceutical framework needs to be simplified, adapted to scientific and technological changes, and contribute to reducing the environmental impact of medicinal products. This proposed reform is comprehensive but targeted and focuses on provisions relevant to achieving its specific objectives; therefore it covers all provisions apart from those concerning advertising, falsified medicinal products, and homeopathic and traditional herbal medicinal products.

The proposed Directive lays down rules for the **placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of medicinal products for human use**. It will apply to medicinal products for human use intended to be placed on the market. It will also apply to starting materials, active substances, excipients and intermediate products.

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 Directive includes the following main areas of revision:

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

- introduction of variable incentives related to regulatory data protection and **rewarding of innovation** in areas of unmet medical needs: companies marketing innovative medicines will benefit from a minimum regulatory protection period of 8 years, including 6 years of data protection and 2 years of market protection. They will be eligible for additional periods of data protection if they launch the medicinal products in all Member States covered by the marketing authorisation (+2 years), if the medicinal product meets an unmet medical need (+6 months) or if comparative clinical trials are conducted (+6 months);

- measures that will facilitate faster market entry of **generics and biosimilars**, thereby increasing competition;

- increased **transparency** on the contribution of public funding to research & development costs;

- strengthening the requirements for environmental risk assessment (ERA) in the marketing authorisation of medicines;

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

- specific provisions for **new platform technologies**;

- specific measures related to **quality and manufacturing**: a flexible, risk-based approach will enable the manufacture or testing of a wide range of medicinal products in close proximity to the patient.