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

2023/0131(COD) - 10/04/2024 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 488 votes to 67, with 34 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006.

The position adopted by the European Parliament at first reading under the ordinary legislative procedure amends the proposal as follows:

Subject matter and scope

The proposed regulation: (i) lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, (ii) establishes rules and procedures at Union and at Member State level relating to the monitoring and management of shortages and critical shortages and the security of supply of medicinal products and (iii) lays down the governance provisions of the European Medicines Agency.

Environmental risk assessment

The environmental risk assessment of medicinal products consisting of or containing genetically modified organisms should include the identification and characterisation of risks to the environment, animals and human health **throughout the life-cycle** of the medicinal product, including its production, and the risk reduction and mitigation strategies proposed to address the identified risks.

Combating antimicrobial resistance (AMR)

In order to support the development of antimicrobials and address existing market failures, Members wish to introduce market entry rewards and intermediate reward payment systems. Accordingly, they suggested developing a **milestone payment reward scheme**, complemented by a subscription model voluntary joint procurement scheme, should be developed to ensure that a market exists for developers that delink volumes sold from payment received.

Milestone payments are an early-stage financial reward granted upon achieving certain R&D objectives prior to market approval. While such mechanisms would serve primarily to provide access to existing antimicrobials, they could also support new antimicrobials in the development phase.

Granting the right to a transferable data exclusivity voucher

Following a request by the applicant for a marketing authorisation, made before the marketing authorisation is granted, the Commission may, by means of implementing acts, grant a transferable data

exclusivity voucher to a 'priority antimicrobial', under certain conditions based on a scientific assessment by the Agency. The voucher should give the right to its holder to a maximum of **additional 12 months** of data protection for one authorised medicinal product.

The Commission should adopt delegated acts by setting up the eligibility of pathogens for the protection periods referred to in the regulation in accordance with the WHO priority pathogens list or an equivalent established at Union level, with **12 months** of data protection for an authorised product ranked 'critical'**, 9 months** of data protection for those ranked 'high' and **6 months** of data protection for those ranked 'medium'.

A voucher should only be **used once** and in relation to a single centrally authorised medicinal product and only if that product is within its first four years of regulatory data protection. The voucher should not be used for a product which already benefited from the maximum regulatory data protection period.

By five years from the date of entry into force of this regulation, the Commission should submit an evaluation report to the European Parliament and to the Council containing a scientific assessment measuring the progress with regard to antimicrobial research and development and the effectiveness of the incentives and rewards in this regulation.

Agency's scientific advice

The Agency should, to the greatest extent possible, ensure that there is a separation between those responsible for providing scientific advice to a given medicinal product developer and those subsequently responsible for the evaluation of the marketing authorisation application for the same medicinal product. The Agency should ensure that at least one of the two rapporteurs for a marketing authorisation application has not taken part in any pre-submission activities concerning the medicinal product.

Orphan drugs

Orphan drugs (medicines developed to treat rare diseases) would benefit from up to **11 years of market exclusivity** if they address a high unmet medical need. By 24 months from the date of entry into force of this regulation, the Commission should, following a consultation with the Member States, patient organisations and other relevant stakeholders, propose a needs-driven and goals-based **Union Framework for Rare Diseases** with a view to better framing and coordinating Union policies and programmes.

Transparency

To increase transparency of scientific assessments and all other activities, a user-friendly **European medicines web-portal** should be created and maintained by the Agency. The portal should provide information for all centrally authorised medicinal products, *inter alia* on safety, efficacy, environmental risk, patient populations, and where relevant information on antimicrobial resistance, shortages, and pending obligations for marketing authorisation holders. Sufficient budgetary resources should be allocated to the Agency to ensure its transparency obligations and commitments are appropriately implemented.

Medicine shortages

The marketing authorisation holder should notify and explain its decision to temporarily suspend the marketing of a medicinal product in that Member State as soon as possible and no less than **six months** before the start of the temporary suspension of supply of that medicinal product into the market of a given Member State by the marketing authorisation holder.

The Agency should be empowered to monitor shortages of medicinal products that are authorised through the centralised procedure, also based on notifications of marketing authorisation holders. Information on such shortages should be made available on the **European medicines web-portal** provided for in this regulation.

When critical shortages are identified, both national competent authorities and the Agency should work in a coordinated manner to communicate the necessary information to patients, consumers and healthcare professionals, including on the estimated duration of the shortage and available alternatives, and manage those critical shortages.