Medicinal products for human use

2023/0132(COD) - 10/04/2024 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 495 votes to 57, with 45 abstentions, a legislative resolution on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC.

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

Subject matter and scope

The proposed Directive should apply to medicinal products for human use intended to be placed on the market in Member States. Where questions arise as to the regulatory status of a substance or a product, the competent authority or, in the case of a centralised marketing authorisation, the Agency should consult other relevant advisory and regulatory bodies with a view to reaching a decision on the regulatory status of the substance or a product concerned.

Advanced therapy medicinal products prepared under hospital exemption

Member States should ensure that advanced therapy medicinal products prepared under hospital exemption comply with the good pharmacy preparation practices that are adapted to hospital processes while still equivalent to the good manufacturing practices and traceability for advanced therapy medicinal products. This should include site inspections as well as traceability and pharmacovigilance plans and the evaluation of the preclinical and clinical data generated by the applicant.

Any relevant data from patient follow-up for a sufficient period of time after the administration of the advanced therapy medicinal product should be collected and reported by the hospital exemption approval holder to the competent authority of the Member State at least annually.

The Agency should, in collaboration with the competent authorities of Member States and the Commission, set up and maintain via regular updates a repository of that data as well as of information on the authorisation, suspension or withdrawal of hospital exemption approvals, which should be updated regularly. The repository should be publicly available except for personal data and commercially confidential information.

Animal testing

The marketing authorisation applicant should not carry out animal testing in case scientifically satisfactory non-animal testing methods are available. Where scientifically satisfactory non-animal testing methods are not available, applicants that use animal testing should ensure that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been applied with regard to any animal study conducted for the purpose of supporting the application.

Antimicrobials

The marketing authorisation holder should ensure, wherever possible, that the antimicrobial may be dispensed per unit in a number corresponding to the quantities corresponding to the duration of treatment. If an antimicrobial cannot be dispensed per unit, the marketing authorisation holder should ensure that the pack size of the antimicrobial corresponds to the usual posology and duration of treatment. Member States should promote the use of unit dose pre-cut blisters in hospital environment and, progressively, in dispensing pharmacies, when necessary.

The Commission should therefore issue, after consulting the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC) and the European Environment Agency (EEA), guidelines on how to conduct ERAs for AMR selection for microbials other than bacteria.

Environmental risk assessment and other environmental information

Members insisted that risk mitigation measures (relating to the prevention and limitation of emissions into the air, water and soil) should cover the entire lifecycle of medicinal products.

Medicinal products subject to medical prescription

A medicinal product should be subject to medical prescription where it: (i) is an antibiotic or any other antimicrobial for which there is an identified risk of antimicrobial resistance; or (ii) contains an active substance, adjuvants or any other ingredients or constituent parts which are persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or persistent, mobile and toxic, or very persistent and very mobile for which medical prescription is required as risk minimisation measure with regard to the environment.

A prescription for antibiotic products should: (a) be limited to the amount required for the treatment or therapy concerned; (b) only be prescribed for a limited duration to cover the period of risk when used as prophylaxis; (c) in the event that a diagnostic test has not been performed, a justification should be required.

Pharmacists and other health care professionals should play a role in antimicrobial stewardship, including advising on the prudent use of antibiotics and other antimicrobials, as well as their correct disposal.

Application for pricing and reimbursement

In order to increase the availability of medicines and contribute to reducing access inequalities within the Union, the marketing authorisation holders of medicinal products should submit an application for pricing and reimbursement in Member States upon request. The application for pricing and reimbursement for the medicinal product should be submitted no later than 12 months from the date when the Member State made its request, or within 24 months from that date in the case of SMEs.

Product information and labelling

Member States should make the package leaflet available electronically and in paper format, except where the Member State decides to make only the electronic product information available. The package leaflet should be easily legible, clearly comprehensible by users, including especially the target patient groups, and indelible.

With a view to combating misinformation, in particular during health pact of online pharmaceutical advertising and promotions and adopt specific rules to regulate such advertising and promotional practices. emergencies such as the COVID-19 pandemic, Member States should ensure that healthcare professionals are not hampered in their ability to communicate clear, impartial and independent information, whether in their dialogue with a patient or in broader communications.

Members States should introduce appropriate disposal systems for antimicrobials in the community setting and inform the general public on the correct disposal methods for antimicrobial. The Commission should assess the exposure and impact of pharmaceutical advertising and promotions online and adopt specific rules to regulate such advertising and promotional practices.

Pharmacovigilance

Member States should record all suspected adverse reactions occurring on their territory and brought to their attention by healthcare professionals or patients. They should endeavour to inform directly interested parties who have reported a suspected adverse reaction about decisions taken concerning the safety of the medicinal product. Reports of adverse reactions arising from incorrect administration or dispensation of a medicinal product should be available in the Eudravigilance database and shall be included in periodic safety update reports.