Medicinal products for human and veterinary use

2014/0256(COD) - 25/10/2018 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 563 votes to 48, with 10 abstentions, a legislative resolution on the proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amended the Commission proposal as follows:

Marketing authorisation: for certain categories of medicinal products for human use, the amended text provides for the possibility of granting marketing authorisations **before comprehensive clinical data are provided** in order to meet the unmet medical needs of patients and in the interest of public health.

Marketing authorisations granted shall be subject to **specific obligations**, including being required to complete ongoing studies, or to conduct new studies, with a view to confirming that the risk-benefit balance is favourable. The categories of medicinal products for human use concerned should be the medicinal products, including orphan medicinal products, that aim at the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases, or that are intended to be used in emergency situations in response to public health threats.

When the specific obligations have been fulfilled, the Commission may, following an application by the marketing authorisation holder, and after receiving a favourable opinion from the Agency, grant a **marketing authorisation valid for five years and renewable**.

Surveillance: **variations** shall be classified in different categories **depending on the level of risk** to public health and the potential impact on the quality, safety and efficacy of the medicinal product concerned. The procedures for examination of applications for variations shall be proportionate to the risk and impact involved.

A marketing authorisation may be **transferred** to a new marketing authorisation holder. Such a transfer shall not be considered to be a variation. The transfer shall be subject to prior approval by the Commission, following the submission of an application for the transfer to the Agency.

Where the Agency concludes that a holder of a marketing authorisation granted failed to comply with the obligations laid down in the marketing authorisation, the Agency shall inform the Commission accordingly. The Commission shall adopt a decision to **vary, suspend or revoke** that marketing authorisation.

European Medicines Agency: the Agency shall be responsible for coordinating the existing scientific resources put at its disposal by the Member States for the **evaluation, supervision and pharmacovigilance** of medicinal products for human use and of veterinary medicinal products. Each of the Agency's committees shall establish a standing working party with the sole remit of providing scientific advice to undertakings.

The Agency shall perform, among other things, the following tasks:

- coordinate the **scientific evaluation of the quality, safety and efficacy** of medicinal products for human use and of veterinary medicinal products which are subject to Union marketing authorisation procedures;
- transmit on request and making publicly available assessment reports, summaries of product characteristics, labels and package leaflets for the medicinal products for human use;
- coordinate the **monitoring** of medicinal products for human use and of veterinary medicinal products which have been authorised in the Union and providing advice on the measures necessary to ensure the safe and effective use of those products;
- ensure the collation and dissemination of information on suspected **adverse reactions** to medicinal products for human use and to veterinary medicinal products authorised in the Union by means of databases that are permanently accessible to all Member States;
- assist Member States with the rapid communication of information on pharmacovigilance concerns;
- distribute appropriate information on pharmacovigilance concerns relating to medicinal products for human use to the general public, in particular by setting up and maintaining a European medicines web-portal;
- coordinate the monitoring of compliance with the standards of good manufacturing practice;
- **advise undertakings** on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medecines.

Considering the seriousness of the threat from **antimicrobial resistance**, it is appropriate that the Agency continue to contribute to periodic reporting on antimicrobial resistance at least every three years.

The **Executive Director** shall be appointed by the Management Board, on a proposal from the Commission, for a period of five years on the basis of a list of candidates proposed by the Commission following a call for expressions of interest published in the Official Journal of the European Union and, as appropriate, by other means. Before appointment, the candidate nominated by the Management Board shall be immediately invited to make a **statement to the European Parliament** and to answer any questions put by its Members.

Penalties: the Commission may impose **financial penalties** for non-compliance with the obligations set out in Annex II in the context of marketing authorisations. It may also impose the financial penalties on a legal entity or legal entities other than the marketing authorisation holder provided that such entities form part of the same economic entity as the marketing authorisation holder.