Medicinal products for human and veterinary use

2014/0256(COD) - 11/12/2018 - Final act

PURPOSE: to amend Regulation (EC) No 726/2004 establishing the European Medicines Agency and the centralised authorization and monitoring procedure for medicinal products, in order to avoid any overlap with the procedures laid down in the new Regulation on veterinary medicinal products.

LEGISLATIVE ACT: Regulation (EU) 2019/5 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, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use.

CONTENT: this Regulation amends Regulation (EC) No 726/2004 by removing from Regulation (EC) No 726/2004 the provisions on the granting and maintenance of authorisations for the placing on the market of veterinary medicinal products as these procedures now fall under the new Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products.

The amending Regulation clarifies the following points:

Marketing authorisation

For certain categories of medicinal products for human use intended to treat, prevent and diagnose seriously debilitating or life-threatening diseases, the amending Regulation provides for the possibility of issuing marketing authorisations before comprehensive clinical data is available, to meet unmet medical needs of patients and in the interest of public health. These authorisations will only be issued if they comply with specific obligations, in particular to complete the studies in progress or to conduct new studies in order to confirm that the benefit / risk ratio is favourable.

Variations

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. Those categories shall range from changes to the terms of the marketing authorisation that have the highest potential impact on the quality, safety or efficacy of the medicinal product, to changes that have no or minimal impact thereon. The procedures for examination of applications for variations shall be proportionate to the risk and impact involved.

The transfer of marketing authorisation to a new holder will not be considered as a variation. It will be subject to prior approval by the Commission after submission of a transfer request to the European Medicines Agency.

European Medicines Agency

The Agency shall provide the Member States and the institutions of the Union with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human use or veterinary medicinal products which is referred to it in accordance with the Union legislation relating to medicinal products for human use or veterinary medicinal products.

The new rules provide that the Agency will:

- provide advice for the regulatory acceptance of innovative development methods in the context of research and development of medicinal products for human use and veterinary medicinal products;

- contribute to the development of joint reporting with the European Food Safety Authority and the European Centre for Disease Prevention and Control on the sale and use of antimicrobials in the fields of human and veterinary medicine, and on antimicrobial resistance in the Union, based on contributions received from Member States. Such joint reporting will be carried out at least every three years.

The Executive Director will be appointed by the Management Board, on a proposal from the Commission, for a period of five years (renewable once), on the basis of a list of candidates proposed by the Commission following publication in the Official Journal of the European Union. Before being appointed, the candidate selected by the Management Board will be invited to make a statement to the European Parliament and to answer questions put by Members.

Fees

The Regulation lays down certain principles applicable to fees payable to the Agency.

By 2019 at the latest, the Commission will review the regulatory framework governing the fees collected by the Agency in the field of medicinal products for human use and veterinary medicinal products. The Commission will present, as appropriate, legislative proposals to update this framework. When reviewing the regulatory framework, the Commission will pay attention to any risks arising from the fluctuations in the fee revenue of the Agency.

Lastly, the Directive aligns the powers conferred on the Commission by Regulation (EC) No 726/2004 with Articles 290 and 291 of the Treaty on the Functioning of the European Union (delegated and implementing powers).

ENTRY INTO FORCE: 27.1.2019.

APPLICATION: from 28.1.2019 and from 28.1.2022 depending on the provisions.