Medicinal products for human and veterinary use

2014/0256(COD) - 10/09/2014 - Legislative proposal

PURPOSE: to amend 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.

PROPOSED ACT: Regulation of the Council and the European Parliament.

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: Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) 726/2004 of the European Parliament and of the Council constituted the Union regulatory framework for the manufacture, authorisation and distribution of veterinary medicinal products.

In the light of the experience acquired and following the assessment by the Commission of the functioning of the internal market for veterinary medicinal products, the Commission has presented a proposal that will repeal and replace Directive 2001/82/EC on veterinary medicinal products. This proposal lays down procedures for the authorisation and supervision of medicinal products for human and veterinary use. It is therefore necessary to amend Regulation (EC) No 726/2004 to **take account of the fact that centralised marketing authorisation for veterinary products is being decoupled from that for medicines for humans**.

IMPACT ASSESSMENT: the consultation and a study, An assessment of the impact of the revision of veterinary pharmaceutical legislation, formed the basis of an impact assessment carried out for the Commission between November 2009 and June 2011. The Commission's Impact Assessment Board (IAB) released its final opinion in September 2013.

CONTENT: the proposal seeks to amend Regulation (EC) No 726/2004 so as to:

- **delete from Regulation (EC) No 726/2004 the provisions regarding granting and maintaining marketing authorisations for veterinary medicinal products**. The rules on marketing authorisations valid in all EU Member States are part of the proposal for a Regulation on veterinary medicinal products. The new Regulation on veterinary medicinal products will cover all routes granting marketing authorisations for veterinary medicinal products in the Union – both at centralised and national level;
- **establish certain principles applicable to fees payable to the Agency**, including the need to take into account, as appropriate, the specific needs for SMEs. The provisions regulating fees should be brought into line with the Treaty of Lisbon;
- **align the powers conferred on the Commission** under Regulation (EC) No 726/2004 to Articles 290 and 291 (delegated and implementing acts) of the Treaty on the Functioning of the European Union.

BUDGETARY IMPLICATION: the costs for the EMA for implementing and applying the new rules are entirely covered by fees charged to industry. Therefore, the proposal is **not expected to have any financial impact on the budget of the EU**.

As set out in the legislative financial statement the additional resource needs for EMA are approximately 8 staff plus expenditure for meetings, translation, IT, etc. The level of fees, their structure and modalities and exceptions will be set at a later stage by the Commission by way of implementing acts.

DELEGATED ACTS: the proposal contains provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the treaty on the Functioning of the European Union.