Medicinal products for human and veterinary use

2014/0256(COD) - 23/02/2016 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Claudiu Ciprian TNSESCU (S&D, RO) 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 committee recommended that Parliament make the following amendments to the Commission proposal:

Fees: Members clarified and separated the Agency's sources of revenue, stating that revenue will consist of:

- a contribution from the Union;
- a contribution from any European third country with which the Union has concluded agreements;
- the fees paid by undertakings for obtaining and maintaining Union marketing authorisations for human and veterinary medicinal products and for other services provided by the Agency;
- charges for any other services provided by the Agency; and
- other sources of income, including any ad-hoc grants within the scope of Regulation (EU, Euratom) No 966/2012 on the general budget of the Union.

The European Parliament and the Council will re-examine, when necessary, the level of the Union contribution on the basis of an evaluation of needs and by taking account of the level of fees.

Reserve fund: in order to safeguard fluctuations in fee revenue, any positive budget outturn of a financial year will be set aside as assigned revenue and serve as a reserve in the event that actual fee revenue be below budgeted appropriations.

Co-decision rather than an implementing act: Members felt that matters relating to the **structure and level of fees should be decided through the co-decision procedure** rather than through implementing acts. Accordingly, they deleted the relevant parts of the text that empowered the Commission to adopt implementing acts relating to fees.

Centralised procedure: the committee referred to the new Veterinary Medicines Regulation, and stressed the role of the EMA in the authorisation and supervision of veterinary products through the centralised procedure.

Alternative models: the Agency shall develop a framework for the regulatory acceptance of alternative models and take into consideration the opportunities presented by new concepts which aim at providing for more predictive medicines.

Transitional arrangements: with regard to the level and the structure of the fees, Regulation (EC) No 297 /95 and Regulation (EU) No 658/2014 will be applicable until an amendment of Regulation (EC) No 297 /95 or any other relevant provisions on fees are adopted and become applicable.

Report: a report on the experience acquired through the Regulation will be published every five years (rather than every ten years).