Medicinal products for human and veterinary use

2014/0256(COD) - 10/03/2016 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted **amendments** to 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 matter has been referred back to the committee. **The vote on the legislative resolution has been postponed to a subsequent sitting**.

The main elements adopted in plenary are as follows:

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 (Financial Regulation).

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. The total amount of such a safeguard fund shall not exceed the Agency's appropriations for the fee revenue of the past year.

Financial provisions: the Executive Director shall implement the budget of the Agency. By 1 March of the following financial year, the Agency's accounting officer shall send the provisional accounts to the Commission's Accounting Officer and to the Court of Auditors.

By 31 March of the following financial year, the Executive Director shall send the report on the budgetary and financial management to the European Parliament, the Commission, the Council and the Court of Auditors.

Structure and level of fees: 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: in the interest of public health, authorisation decisions adopted under the centralised procedure should be taken on the basis of the objective scientific criteria of quality, safety and efficacy. It is proposed for reference to be made to the new Veterinary Medicines Regulation, and that the role of the EMA in the authorisation and supervision of veterinary products through the centralised procedure should be stressed.

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. These concepts may be based on human-relevant computer or cellular models, pathways of toxicity, or adverse outcome pathways.

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).