Medicinal products for human use: fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities

2013/0222(COD) - 16/04/2014 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 544 votes to 17, with 11 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use.

Parliament adopted its position at first reading following the ordinary legislative procedure. The amendments adopted in plenary are the result of an agreement reached between the European Parliament and the Council. They amended the proposal as follows:

Subject matter and scope: Parliament and the Council agreed to adopt this Regulation in order to enable the European Medicines Agency (EMA) to charge fees for those new pharmacovigilance tasks, and **pending an overall legislative revision of the fees regimes in the medicinal products sector**.

This Regulation should establish the pharmacovigilance activities performed at Union level for which fees are due, the amounts and the rules of payment of those fees to the Agency, and the amounts of remuneration by the Agency for the services provided by the rapporteurs and, where applicable, the **co-rapporteurs**.

Homeopathic and herbal medicinal products and medicinal products which are authorised to be placed on the market in accordance with Article 126a of Directive 2001/83/EC, should be excluded from the scope of this Regulation.

Definition of chargeable unit: fees should be levied on all marketing authorisation holders on a fair basis. Therefore, a chargeable unit should be established, irrespective of the procedure under which the medicinal product has been authorised, and of the way in which authorisation numbers are assigned by the Member States or the Commission.

That objective is met by establishing the chargeable unit **on the basis of the active substance(s) and the pharmaceutical form of the medicinal products** that are subject to the obligation to be registered in the database referred to in point (l) of the second subparagraph of Article 57(1) of Regulation (EC) No 726 /2004, based on information from the list of all medicinal products authorised in the Union referred to in Article 57(2) thereof.

The active substance(s) should not be taken into account when establishing the chargeable unit in respect of authorised homeopathic medicinal products or authorised herbal medicinal products.

Types of fees: it is stipulated that where a fee is levied by the Agency, the Agency shall pay remuneration, to the national competent authorities:

- for the services provided by the rapporteurs and, where applicable, the co-rapporteurs in the Pharmacovigilance Risk Assessment Committee appointed as members of that Committee by Member States;

- for the work carried out by the Member States which act as the rapporteurs and, where applicable, co-rapporteurs in the coordination group.

Annual fee: for its pharmacovigilance activities relating to information technology systems and the monitoring of selected medical literature, the Agency should levy once per year a fee. The annual fee should be due on 1 July of every year in respect of that calendar year.

The amended text emphasises the fact that fees should be established on a basis which takes due account of the **ability of small and medium-sized enterprises to pay**. Moreover, information on those fees should be publicly available.

Where justified, the Commission should adopt delegated acts adjusting the amounts of the fees and the amounts of the remuneration for rapporteurs and co-rapporteurs to take account of inflation.

Lastly, any future revisions of the pharmacovigilance fees or other fees levied by the Agency should be based on a transparent and independent evaluation of the costs of the Agency and the costs of the tasks carried out by the national competent authorities.