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

2013/0222(COD) - 26/06/2013 - Legislative proposal

PURPOSE: to contribute to the well-functioning of the internal market and the common post-marketing surveillance of medicinal products.

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

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: the legal framework of pharmacovigilance for medicinal products for human use marketed within the EU is provided for in Regulation (EC) No 726/2004 and in Directive 2001/83/EC.

Legislation in this area was revised in 2010 through Regulation (EU) No 1235/2010 and Directive 2010/84/EU which strengthen and rationalise the system for safety monitoring of medicines on the European market.

This legislation is applicable as of July 2012. It provides for a number of EU-wide procedures to assess pharmacovigilance data which may lead to regulatory action. Some additional amendments to the pharmacovigilance legislation were introduced in 2012 with Directive 2012/26/EU following the 'Mediator' case.

The revised pharmacovigilance legislation significantly **widened the tasks of the European Medicines Agency** with regard to pharmacovigilance, irrespective of whether the medicinal products have been authorised via the 'centralised procedure' (in accordance with the Regulation) or via national procedures (in accordance with the Directive). The Agency has therefore acquired pharmacovigilance competences also for nationally authorised medicines, in addition to reinforced competences for centrally authorised medicines.

Other tasks include the monitoring of literature cases, the improved information technology tools and the provision of more information to the general public.

New categories of fees should therefore be created to cover the new and specific tasks of the Agency.

IMPACT ASSESSMENT: the Impact Assessment report that accompanies this proposal considered several options, based on estimation of cost.

A combination of procedure-based fees and an annual flat fee has been considered to be the most transparent, cost-based, activity-based and proportionate way of setting the new fees, in order to cover the cost under the new pharmacovigilance legislation.

LEGAL BASIS: Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the proposed Regulation aims at setting high standards of quality and safety for medicinal products as it ensures the availability of **sufficient financial resources** to perform the pharmacovigilance activities that are necessary to guarantee that high standards are maintained once the product is authorised.

The revised pharmacovigilance legislation provides for **fees** to be charged to marketing authorisation holders. These fees should be related to pharmacovigilance activities performed at the level of the EU, notably in the context of the EU-wide assessment procedures. These procedures include scientific assessment carried out by rapporteurs from the national competent authorities of the Member States. These fees are therefore not intended to cover the pharmacovigilance activities of the national competent authorities performed at national level. Member States may accordingly continue to charge fees for the activities performed at national level which should, however, not overlap with the fees laid down in this legal proposal.

The proposal foresees **two separate types of fees**:

- **fees for procedures for the assessment** of periodic safety update reports, postauthorisation safety studies and pharmacovigilance referrals;
- **an annual flat fee** to be charged to marketing authorisation holders having at least one medicinal product that is authorised in the EU and registered in the database provided for in Regulation (EC) No 726/2004. The fee revenue from the annual flat fee shall be retained by the Agency.

Some **fee reductions and fee waivers** are foreseen in respect of the proposed fees:

- reductions for medicinal products for which the marketing authorisation holder is a **small or medium-sized enterprise** would be granted for all types of fees. Micro enterprises would be exempted from all fees;
- a reduction of the annual flat fee is therefore proposed for **authorised generic, homeopathic and herbal medicinal products** and for medicinal products authorised on grounds of well-established medical use. However, where these medicinal products are included in the Union-wide pharmacovigilance procedures, the full fees for procedures would apply.

Marketing authorisation holders would be charged as follows:

- marketing authorisation holders having at least one product involved in a Unionwide pharmacovigilance procedure would be charged a fee for procedures,
- marketing authorisation holders in the EU, with the exceptions explained above, would be charged the annual flat fee.

Fees referred to in this Regulation should be **transparent, fair and proportionate** to the work carried out.

In line with the recommendations of the European Court of Auditors and the European Parliament, it is proposed that **rapporteurs from the national competent authorities of the Member States** be remunerated according to a fixed scale based on estimations of cost.

BUDGETARY IMPLICATION: all options of legislative action, including the option which underpins this proposal, were based on the assumption that the costs related to pharmacovigilance would be covered through fees.

Therefore, no impact on the EU general budget is foreseen in the accompanying financial statement of this proposal.

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