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

2013/0222(COD) - 15/05/2014 - Final act

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

LEGISLATIVE ACT: Regulation (EU) No 658/2014 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.

CONTENT: in order to enable the Agency 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 has been adopted. The revised 2010 legislation provides for new pharmacovigilance tasks for the Agency, including pharmacovigilance procedures carried out at Union level, the monitoring of literature cases and the improved use of information technology tools.

Subject matter and scope: this Regulation shall apply to **fees for pharmacovigilance activities** relating to medicinal products for human use authorised in the Union and which shall be levied by the European Medicines Agency on marketing authorisation holders.

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

This Regulation establishes 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.

Chargeable unit: a chargeable unit is defined **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.

Types of fees: the types of fees charged to marketing authorisation holders are as follows:

- ***Fees for the assessment of periodic safety update reports***: EUR 19 500 per procedure. From that amount, the remuneration for the rapporteur shall be EUR 13 100. That remuneration shall be shared, where applicable, between the rapporteur and the co-rapporteur(s).
- ***Fees for the assessment of post-authorisation safety studies***: EUR 43 000 to be paid in two instalments as follows: (a) EUR 17 200 shall be due at the date of the start of the procedure for the assessment of the draft protocol referred to in Directive 2001/83/EC; (b) EUR 25 800 shall be due at the date of the start of the procedure for the assessment of the final study report by the Pharmacovigilance Risk Assessment Committee as referred to in the same Directive.
- ***Fees for assessments in the context of referrals initiated as a result of pharmacovigilance data***: EUR 179 000 where one or two active substances and/or combinations of active substances are

included in the assessment. That fee shall be increased by EUR 38 800 per each additional active substance or combination of active substances as of the third active substance or combination of substances. That fee shall not exceed EUR 295 400 irrespective of the number of active substances and/or combinations of active substances.

- ***An annual flat-rate fee*** of EUR 67 per chargeable unit. This fee is intended to cover the costs of general pharmacovigilance activities of EMA, such as safety data management, literature monitoring and information technology, notably maintenance of the EudraVigilance database. **The annual flat fee will be charged as from 1 July 2015**.

Reductions and exonerations: small and medium-sized enterprises will benefit of a fee reduction of 40% from all fees covered by the regulation and micro-enterprises are exempted from any fees. **Micro enterprises** should be exempted from all fees. Generic medicinal products, medicinal products authorised under the provisions relating to well-established medicinal use, authorised homeopathic medicinal products and authorised herbal medicinal products should be subject to a **reduced annual fee**.

Transparency: the fees established in this Regulation should be transparent, fair and proportionate to the work carried out. Information on those fees should be **publicly available**. 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.

ENTRY INTO FORCE: 17.07.2014.

DELEGATED ACTS: the Commission shall be empowered to adopt delegated acts in order to adjust the amounts of the fees and the amounts of the remuneration for rapporteurs and co-rapporteurs to take account of inflation. The power to adopt delegated acts shall be conferred on the Commission for a period of **five years from 17 July 2014**. The European Parliament or the Council may raise objections to a delegated act within a period of two months from the date of notification (this may be extended by two months). If the European Parliament or Council express objections, the delegated act will not enter into force.