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

2013/0222(COD) - 20/12/2013 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Linda McAVAN (S&D, UK) 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

The committee recommended that Parliament's position in first reading following the ordinary legislative procedure should amend the Commission proposal as follows:

**Purpose and scope**: an amendment aimed to confirm that homeopathic and registered herbal medicinal should be excluded from the scope of the Regulation.

Members also specified that the Regulation determined the pharmacovigilance activities performed at Union level for which fees were due, the amounts and the rules of payment of those fees and the level of remuneration of the Agency, the rapporteurs and the co-rapporteurs.

In order to ensure a clear separation between fees paid to Member States and fees paid to the European Medicines Agency, Members stated that Member States should not impose fees for pharmacovigilance tasks that are already covered by the Regulation.

**Definition of chargeable unit:** the Commission proposal had meant that companies would be charged according to the number of different market authorisations they held - and this was calculated down to the size of the pack. Members felt that the number of tablets in a pack was not relevant for pharmacovigilance. It would be more appropriate to charge **according to the number of authorisations per active ingredient, and per pharmaceutical form.**

**Annual flat fee**: this had been proposed to cover the costs of other pharmacovigilance activities carried out by the Agency, particularly signal detection.

Members proposed reducing the amount raised by the EMA, and the scope of the flat fee to **cover only the tasks to be undertaken by EMA**: Eudravigilance, the Article 57 database, PSUR repository and literature review only, turning the flat fee into a maintenance fee for EMA pharmacovigilance work.

To create a level playing field, the reduced annual fee should apply to products with **well-established safety profile.**

**Fee reduction**: the marketing authorisation holder claiming or having claimed to be entitled to a reduction or an exemption under the Regulation, should submit to the Agency, within seven calendar days from receipt of the Agency's request, the information necessary to demonstrate compliance with the relevant conditions in order for the Agency to be able to verify that those conditions were fulfilled.

**Fees for safety report**: Members felt that the variations were a consequence of periodic safety update assessment, should be seen as an integral part of the entire assessment process and not be charged additionally at national level as no second scientific assessment is required.

The committee wanted **rapporteurs and co-rapporteurs from Member States to be fairly remunerated,** in order to incentivise them to volunteer for the work involved in handling referrals. The corresponding remuneration of the rapporteur and co-rapporteur is 50% of the total fee collected.