

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

2013/0222(COD) - 30/09/2019 - Follow-up document

The Commission presented its report on the exercise of the delegation conferred on the Commission pursuant to 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.

Delimitation of the delegation of powers

The Pharmacovigilance Fee Regulation empowers the Commission to adopt delegated acts adjusting the amounts of the fees and the amounts of the remuneration for rapporteurs and co-rapporteurs, where such adjustment is considered justified in light of an annual monitoring of the inflation rate, measured by means of the European Index of Consumer prices published by Eurostat.

The present report is a requirement under Article 16(2) of the Pharmacovigilance Fee Regulation. This provision delegates powers to the Commission for five years, starting from 17 July 2014. A report on the exercise of the delegation should be drawn up not later than nine months before the end of this period. The delegation of powers is to be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

Exercise of the delegation

To date the Commission has exercised in two instances the delegated powers provided for by Regulation (EU) No 658/2014 to adjust to the inflation the amounts of fees and remuneration laid down in that Regulation :

(1) Delegated act adjusting the amounts laid down in the Pharmacovigilance Fee Regulation taking into account cumulatively the inflation rate of the Union for 2015 and for 2016: the inflation rate of the Union, as made available by Eurostat, was 0.2 % for 2015 and 1.2 % for 2016. In view of these inflation rates, it was considered justified to proceed to an adjustment in 2017. A cumulative adjustment, taking into account the inflation rates for 2015 and for 2016, was therefore applied. The Commission adopted the [Delegated Regulation \(EU\) 2018/92](#) which started to apply from 12 February 2018.

(2) Delegated act adjusting the amounts laid down in the Pharmacovigilance Fee Regulation taking into account the inflation rate of the Union for 2017: the inflation rate of the Union, as made available by Eurostat, was 1.7 % for 2017.

It was considered justified to proceed to an adjustment for 2017. The Commission adopted [Delegated Regulation \(EU\) 2018/1298](#) which started to apply from 18 October 2018.