EUROPEAN
COMMISSION

Brussels, 30.9.2019
COM(2019) 439 final

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

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 of 15 May 2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

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 of 15 May 2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use

1. INTRODUCTION

The legal framework for the monitoring of the safety of medicinal products that have been placed on the market in the Union is provided for in Regulation (EC) No 726/2004[1] and in Directive 2001/83/EC[2]. These pharmacovigilance activities cover the whole life-cycle management of medicinal products for human use in relation to safety.

To finance these activities, Regulation (EU) No 658/2014[3] ('the Pharmacovigilance Fee Regulation') provides for fees to be charged to marketing authorisation holders. Additionally, it sets out the amounts of remuneration for the rapporteurs and the co-rapporteurs appointed by the relevant committees for the respective assessment (Parts I to IV of the Annex of the Pharmacovigilance Fee Regulation).

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 (Article 15).

2. LEGAL BASIS

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.

---

1 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p. 1.

2 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67.

3 Regulation (EU) No 658/2014 of the European Parliament and of the Council of 15 May 2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use, OJ L 189, 27.6.2014, p. 112.

3. EXERCISE OF THE DELEGATION

Under Article 15(5) of the Pharmacovigilance Fee Regulation, the Commission monitors, in relation to the amounts laid down in the Parts I to IV of the Annex of the Regulation, the inflation rate made available by Eurostat pursuant to Regulation (EC) No 2494/95. Under Article 15(6) of the Pharmacovigilance Fee Regulation, where justified in light of that monitoring, the Commission adopts delegated acts adjusting those amounts. During the 5 years period in question, the Commission adopted two delegated acts, the first one taking into account cumulatively the inflation rate of the Union for 2015 and for 2016 and the second one taking into account the inflation rate of the Union for 2017.

3.1. 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 Expert Group[4] formed by the Pharmaceutical Committee was consulted on the subject of the draft Commission Delegated Regulation through written procedure. A four-week public consultation was held from 27 July until 24 August 2017.

The Commission adopted the delegated act on 18 October 2017 and notified the European Parliament and the Council of it. Neither institution objected to the delegated act within the two-month period provided for in Article 16(5) of the Pharmacovigilance Fee Regulation. Commission Delegated Regulation (EU) 2018/92 was published in the Official Journal[5] and started applying from 12 February 2018.

3.2. 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. In accordance with Article 15(6) of Regulation (EU) No 658/2014 it was considered justified to proceed to an adjustment for 2017.

The Expert Group[4] formed by the Pharmaceutical Committee was consulted on the subject of the draft Commission Delegated Regulation through written procedure. A four-week public consultation was held from 3 April until 3 May 2018.

The Commission adopted the delegated act on 11 July 2018 and notified the European Parliament and the Council of it. Neither institution objected to the delegated act within the two-month period provided for in Article 16(5) of the Pharmacovigilance Fee

[4] Expert groups that help the Commission in relation to the preparation of delegated acts are listed in the Register of Commission Expert groups: http://ec.europa.eu/transparency/regexpert/.

[5] Commission Delegated Regulation (EU) 2018/92 of 18 October 2017 amending Regulation (EU) No 658/2014 of the European Parliament and of the Council as regards the adjustment to the inflation rate of the amounts of the fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use OJ L 17, 23.1.2018, p. 2.

Regulation. Commission Delegated Regulation (EU) 2018/1298 was published in the Official Journal[6] and started applying from 18 October 2018.

4. CONCLUSION

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. The Commission invites the European Parliament and the Council to take note of this report.

[6] Commission Delegated Regulation (EU) 2018/1298 of 11 July 2018 amending Regulation (EU) No 658/2014 of the European Parliament and of the Council as regards the adjustment to the inflation rate of the amounts of the fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use, OJ L 244, 28.9.2018, p. 1