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 (Text with EEA relevance)

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard 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)], and in particular Article 15(6) thereof,

Whereas:

(1) In accordance with Article 67(3) of Regulation (EC) No 726/2004 of the European Parliament and of the Council[(2)], the revenue of the European Medicines Agency consists of a contribution from the Union and fees paid by undertakings for obtaining and maintaining Union marketing authorisations and for other services provided by the Agency, or by the coordination group as regards the fulfilment of its tasks in accordance with Articles 107c, 107e, 107g, 107k and 107q of Directive 2001/83/EC of the European Parliament and of the Council[(3)].

(2) The inflation rate of the Union for 2017, as made available by the Statistical Office of the European Union, was 1,7 %. Taking into consideration the level of the inflation rate for that year, it is considered justified to adjust, in accordance with Article 15(6) of Regulation (EU) No 658/2014, 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.

(3) For the sake of simplicity, the adjusted amounts should be rounded to the nearest EUR 10, with the exception of the annual fee for information technology systems and literature monitoring where the adjusted level should be rounded to the nearest EUR 1.

(4) Fees laid down in Regulation (EU) No 658/2014 are due either at the date of the start of the respective procedure or, in the case of the annual fee for information technology systems and literature monitoring, on 1 July of every year. Consequently, the applicable

amount will be determined by the due date of the fee and there is no need to set specific transitional provisions for pending procedures.

(5) According to Article 15(6) of Regulation (EU) No 658/2014, where a delegated act adjusting the amounts of the fees laid down in Parts I to IV of the Annex to that Regulation enters into force before 1 July, the adjustments are to take effect as from 1 July, whereas where it enters into force after 30 June, the adjustments are to take effect from the date of entry into force of the delegated act.

(6) Regulation (EU) No 658/2014 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 658/2014 is amended as follows:

(1) in Part I, point 1 is amended as follows:

(a) ‘EUR 19 770’ is replaced by ‘EUR 20 110’;

(b) ‘EUR 13 290’ is replaced by ‘13 520’;

(2) in Part II, point 1 is amended as follows:

(a) in the introductory sentence, ‘EUR 43 600’ is replaced by ‘EUR 44 340’;

(b) point (a) is amended as follows:

(i) ‘EUR 17 440’ is replaced by ‘EUR 17 740’;

(ii) ‘EUR 7 380’ is replaced by ‘EUR 7 510’;

(c) point (b) is amended as follows:

(i) ‘EUR 26 160’ is replaced by ‘EUR 26 600’;

(ii) ‘EUR 11 070’ is replaced by ‘11 260’;

(3) in Part III, point 1 is amended as follows:

(a) the first subparagraph is amended as follows:

(i) ‘EUR 181 510’ is replaced by ‘EUR 184 600’;

(ii) ‘EUR 39 350’ is replaced by ‘EUR 40 020’;

(iii) ‘EUR 299 560’ is replaced by ‘EUR 304 660’;

(b) the second subparagraph is amended as follows:

(i) in point (a), ‘EUR 121 000’ is replaced by ‘EUR 123 060’;

(ii) in point (b), ‘EUR 147 240’ is replaced by ‘EUR 149 740’;

(iii) in point (c), ‘EUR 173 470’ is replaced by ‘EUR 176 420’;

(iv) in point (d), ‘EUR 199 700’ is replaced by ‘EUR 203 090’;

(c) in the fourth subparagraph, point (b) is amended as follows: