# REGULATIONS

## COMMISSION DELEGATED REGULATION (EU) 2020/1431

**of 14 July 2020**

**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**

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 includes fees paid by undertakings for obtaining and maintaining Union marketing authorisations and for other services provided by the Agency, and for services provided 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 last adjustment of the fees and remuneration amounts laid down in Regulation (EU) No 658/2014 was carried out in 2018 based on the inflation rate of 2017. The inflation rate of the Union for the years 2018 and 2019, as published by the Statistical Office of the European Union, was respectively 1,7 % and 1,6 %. Taking into consideration the level of the inflation rates for those years, it is considered justified to adjust, in accordance with Article 15(6) of Regulation (EU) No 658/2014, the amounts of the fees and the amounts of the remuneration for rapporteurs and co-rapporteurs referred to in Parts I to IV of the Annex of that Regulation. A cumulative adjustment taking into account the inflation rates for both 2018 and 2019 should therefore be applied.

(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) 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 20 110' is replaced by 'EUR 20 780';

(b) 'EUR 13 520' is replaced by 13 970';

([1]) OJ L 189, 27.6.2014, p. 112.

([2]) 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).

([3]) 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).

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

(a) in the introductory sentence, 'EUR 44 340' is replaced by 'EUR 45 810';

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

(i) 'EUR 17 740' is replaced by 'EUR 18 330';

(ii) 'EUR 7 510' is replaced by 'EUR 7 760';

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

(i) 'EUR 26 600' is replaced by 'EUR 27 480';

(ii) 'EUR 11 260' is replaced by '11 630';

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

(a) the first subparagraph is amended as follows:

(i) 'EUR 184 600' is replaced by 'EUR 190 740';

(ii) 'EUR 40 020' is replaced by 'EUR 41 350';

(iii) 'EUR 304 660' is replaced by 'EUR 314 790';

(b) the second subparagraph is amended as follows:

(i) in point (a), 'EUR 123 060' is replaced by 'EUR 127 150';

(ii) in point (b), 'EUR 149 740' is replaced by 'EUR 154 730';

(iii) in point (c), 'EUR 176 420' is replaced by 'EUR 182 290';

(iv) in point (d), 'EUR 203 090' is replaced by 'EUR 209 840';

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

(i) 'EUR 1 030' is replaced by 'EUR 1 070';

(ii) 'EUR 2 050' is replaced by 'EUR 2 110';

(iii) 'EUR 3 100' is replaced by 'EUR 3 200';

(4) in point 1 of Part IV, 'EUR 69' is replaced by 'EUR 71'.

*Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*. It shall apply from 1 November 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 July 2020.

*For the Commission*
*The President*
Ursula VON DER LEYEN