

COMMISSION DELEGATED REGULATION (EU) 2023/1766**of 29 June 2023****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), point (c), 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 2022 based on the cumulative inflation rate of 2020 and 2021. The inflation rate of the Union for 2022, as published by the Statistical Office of the European Union, was 10,4 %. Taking into consideration the level of the inflation rate for 2022, 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 to that Regulation.
- (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.
- (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 21 940' is replaced by 'EUR 24 220';
 - (b) 'EUR 14 750' is replaced by 'EUR 16 280';

⁽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 Union procedures for the authorisation and supervision of medicinal products for human 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 48 370' is replaced by 'EUR 53 400';
 - (b) point (a) is amended as follows:
 - (i) 'EUR 19 350' is replaced by 'EUR 21 360';
 - (ii) 'EUR 8 190' is replaced by 'EUR 9 040';
 - (c) point (b) is amended as follows:
 - (i) 'EUR 29 020' is replaced by 'EUR 32 040';
 - (ii) 'EUR 12 280' is replaced by 'EUR 13 560';
- (3) in Part III, point 1 is amended as follows:
- (a) the first subparagraph is amended as follows:
 - (i) 'EUR 201 450' is replaced by 'EUR 222 400';
 - (ii) 'EUR 43 670' is replaced by 'EUR 48 210';
 - (iii) 'EUR 332 460' is replaced by 'EUR 367 030';
 - (b) the second subparagraph is amended as follows:
 - (i) in point (a), 'EUR 134 290' is replaced by 'EUR 148 260';
 - (ii) in point (b), 'EUR 163 420' is replaced by 'EUR 180 420';
 - (iii) in point (c), 'EUR 192 530' is replaced by 'EUR 212 550';
 - (iv) in point (d), 'EUR 221 620' is replaced by 'EUR 244 670';
 - (c) in the fourth subparagraph, point (b) is amended as follows:
 - (i) 'EUR 1 130' is replaced by 'EUR 1 250';
 - (ii) 'EUR 2 230' is replaced by 'EUR 2 460';
 - (iii) 'EUR 3 380' is replaced by 'EUR 3 730';
- (4) in Part IV, in point 1, 'EUR 75' is replaced by 'EUR 83'.

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 4 October 2023.

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

Done at Brussels, 29 June 2023.

For the Commission
The President
Ursula VON DER LEYEN
