

**COMMISSION DELEGATED REGULATION (EU) 2022/1520****of 17 June 2022****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 <sup>(1)</sup>, 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 <sup>(2)</sup>, 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 <sup>(3)</sup>.
- (2) The last adjustment of the fees and remuneration amounts laid down in Regulation (EU) No 658/2014 was carried out in 2020 based on the cumulative inflation rate of 2018 and 2019. The inflation rate of the Union for the years 2020 and 2021, as published by the Statistical Office of the European Union, was respectively 0,3 % and 5,3 % <sup>(4)</sup>. 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 to that Regulation. A cumulative adjustment taking into account the inflation rates for both 2020 and 2021 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) In accordance with Article 15(6) of Regulation (EU) No 658/2014, where an 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 act. The date of application for this Regulation should be laid down in accordance with that provision.
- (6) Regulation (EU) No 658/2014 should therefore be amended accordingly,

<sup>(1)</sup> OJ L 189, 27.6.2014, p. 112.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

<sup>(4)</sup> Eurostat, euroindicators 11/2022, published on 20 January 2022.

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 20 780' is replaced by 'EUR 21 940';
  - (b) 'EUR 13 970' is replaced by '14 750';
- (2) in Part II, point 1 is amended as follows:
  - (a) in the introductory sentence, 'EUR 45 810' is replaced by 'EUR 48 370';
  - (b) point (a) is amended as follows:
    - (i) 'EUR 18 330' is replaced by 'EUR 19 350';
    - (ii) 'EUR 7 760' is replaced by 'EUR 8 190';
  - (c) point (b) is amended as follows:
    - (i) 'EUR 27 480' is replaced by 'EUR 29 020';
    - (ii) 'EUR 11 630' is replaced by 'EUR 12 280';
- (3) in Part III, point 1 is amended as follows:
  - (a) the first subparagraph is amended as follows:
    - (i) 'EUR 190 740' is replaced by 'EUR 201 450';
    - (ii) 'EUR 41 350' is replaced by 'EUR 43 670';
    - (iii) 'EUR 314 790' is replaced by 'EUR 332 460';
  - (b) the second subparagraph is amended as follows:
    - (i) in point (a), 'EUR 127 150' is replaced by 'EUR 134 290';
    - (ii) in point (b), 'EUR 154 730' is replaced by 'EUR 163 420';
    - (iii) in point (c), 'EUR 182 290' is replaced by 'EUR 192 530';
    - (iv) in point (d), 'EUR 209 840' is replaced by 'EUR 221 620';
  - (c) in the fourth subparagraph, point (b) is amended as follows:
    - (i) 'EUR 1 070' is replaced by 'EUR 1 130';
    - (ii) 'EUR 2 110' is replaced by 'EUR 2 230';
    - (iii) 'EUR 3 200' is replaced by 'EUR 3 380';
- (4) in point 1 of Part IV, 'EUR 71' is replaced by 'EUR 75'.

#### 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 3 October 2022.

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

Done at Brussels, 17 June 2022.

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

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