

COMMISSION REGULATION (EU) 2020/422**of 19 March 2020****amending Council Regulation (EC) No 297/95 as regards the adjustment of the fees of the European Medicines Agency to the inflation rate with effect from 1 April 2020****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products ⁽¹⁾, and in particular the fifth paragraph of Article 12 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 to that Agency. Regulation (EC) No 297/95 lays down the categories and levels of such fees.
- (2) Those fees should be updated by reference to the inflation rate of 2019. The inflation rate in the Union, as published by the Statistical Office of the European Union ⁽³⁾, was 1,6 % in 2019.
- (3) For the sake of simplicity, the adjusted levels of the fees should be rounded to the nearest EUR 100.
- (4) Regulation (EC) No 297/95 should therefore be amended accordingly.
- (5) For reasons of legal certainty, this Regulation should not apply to valid applications which are pending on 1 April 2020.
- (6) In accordance with Article 12 of Regulation (EC) No 297/95, the update is to be made with effect from 1 April 2020. It is therefore appropriate that this Regulation enters into force as a matter of urgency and applies from that date,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 297/95 is amended as follows:

- (1) Article 3 is amended as follows:
 - (a) paragraph 1 is amended as follows:
 - (i) point (a) is amended as follows:
 - in the first subparagraph, 'EUR 291 800' is replaced by 'EUR 296 500';
 - in the second subparagraph, 'EUR 29 300' is replaced by 'EUR 29 800';
 - in the third subparagraph, 'EUR 7 300' is replaced by 'EUR 7 400';
 - (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 113 300' is replaced by 'EUR 115 100';
 - in the second subparagraph, 'EUR 188 700' is replaced by 'EUR 191 700';
 - in the third subparagraph, 'EUR 11 300' is replaced by 'EUR 11 500';
 - in the fourth subparagraph, 'EUR 7 300' is replaced by 'EUR 7 400';

⁽¹⁾ OJ L 35, 15.2.1995, p. 1.

⁽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⁾ <https://ec.europa.eu/eurostat/documents/2995521/10159211/2-17012020-AP-EN.pdf>

- (iii) point (c) is amended as follows:
 - in the first subparagraph, 'EUR 87 600' is replaced by 'EUR 89 000';
 - in the second subparagraph, 'EUR 22 000 to EUR 65 700' is replaced by 'EUR 22 400 to EUR 66 800';
 - in the third subparagraph, 'EUR 7 300' is replaced by 'EUR 7 400';
- (b) paragraph 2 is amended as follows:
 - (i) the first subparagraph of point (a) is amended as follows:
 - 'EUR 3 200' is replaced by 'EUR 3 300';
 - 'EUR 7 300' is replaced by 'EUR 7 400';
 - (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 87 600' is replaced by 'EUR 89 000';
 - in the second subparagraph, 'EUR 22 000 to EUR 65 700' is replaced by 'EUR 22 400 to EUR 66 800';
- (c) in paragraph 3, 'EUR 14 400' is replaced by 'EUR 14 600';
- (d) in the first subparagraph of paragraph 4, 'EUR 22 000' is replaced by 'EUR 22 400';
- (e) in paragraph 5, 'EUR 7 300' is replaced by 'EUR 7 400';
- (f) paragraph 6 is amended as follows:
 - (i) in the first subparagraph, 'EUR 104 600' is replaced by 'EUR 106 300';
 - (ii) in the second subparagraph, 'EUR 26 000 to EUR 78 400' is replaced by 'EUR 26 400 to EUR 79 700';
- (2) in the first paragraph of Article 4, 'EUR 72 600' is replaced by 'EUR 73 800';
- (3) Article 5 is amended as follows:
 - (a) paragraph 1 is amended as follows:
 - (i) point (a) is amended as follows:
 - in the first subparagraph, 'EUR 146 100' is replaced by 'EUR 148 400';
 - in the second subparagraph, 'EUR 14 400' is replaced by 'EUR 14 600';
 - in the third subparagraph, 'EUR 7 300' is replaced by 'EUR 7 400';
 - the fourth subparagraph is amended as follows:
 - 'EUR 72 600' is replaced by 'EUR 73 800';
 - 'EUR 7 300' is replaced by 'EUR 7 400';
 - (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 72 600' is replaced by 'EUR 73 800';
 - in the second subparagraph, 'EUR 123 300' is replaced by 'EUR 125 300';
 - in the third subparagraph, 'EUR 14 400' is replaced by 'EUR 14 600';
 - in the fourth subparagraph, 'EUR 7 300' is replaced by 'EUR 7 400';
 - the fifth subparagraph is amended as follows:
 - 'EUR 36 500' is replaced by 'EUR 37 100';
 - 'EUR 7 300' is replaced by 'EUR 7 400';
 - (iii) point (c) is amended as follows:
 - in the first subparagraph, 'EUR 36 500' is replaced by 'EUR 37 100';
 - in the second subparagraph, 'EUR 9 100 to EUR 27 500' is replaced by 'EUR 9 200 to EUR 27 900';
 - in the third subparagraph, 'EUR 7 300' is replaced by 'EUR 7 400';

- (b) paragraph 2 is amended as follows:
 - (i) the first subparagraph of point (a) is amended as follows:
 - ‘EUR 3 200’ is replaced by ‘EUR 3 300’;
 - ‘EUR 7 300’ is replaced by ‘EUR 7 400’;
 - (ii) point (b) is amended as follows:
 - in the first subparagraph, ‘EUR 43 700’ is replaced by ‘EUR 44 400’;
 - in the second subparagraph, ‘EUR 11 000 to EUR 33 000’ is replaced by ‘EUR 11 200 to EUR 33 500’;
 - in the third subparagraph, ‘EUR 7 300’ is replaced by ‘EUR 7 400’;
- (c) in paragraph 3, ‘EUR 7 300’ is replaced by ‘EUR 7 400’;
- (d) in the first subparagraph of paragraph 4, ‘EUR 22 000’ is replaced by ‘EUR 22 400’;
- (e) in paragraph 5, ‘EUR 7 300’ is replaced by ‘EUR 7 400’;
- (f) paragraph 6 is amended as follows:
 - (i) in the first subparagraph, ‘EUR 35 000’ is replaced by ‘EUR 35 600’;
 - (ii) in the second subparagraph, ‘EUR 8 600 to EUR 26 000’ is replaced by ‘EUR 8 700 to EUR 26 400’;
- (4) in the first paragraph of Article 6, ‘EUR 43 700’ is replaced by ‘EUR 44 400’;
- (5) Article 7 is amended as follows:
 - (a) in the first paragraph, ‘EUR 72 600’ is replaced by ‘EUR 73 800’;
 - (b) in the second paragraph, ‘EUR 22 000’ is replaced by ‘EUR 22 400’;
- (6) Article 8 is amended as follows:
 - (a) paragraph 1 is amended as follows:
 - (i) in the second subparagraph, ‘EUR 87 600’ is replaced by ‘EUR 89 000’;
 - (ii) in the third subparagraph, ‘EUR 43 700’ is replaced by ‘EUR 44 400’;
 - (iii) in the fourth subparagraph, ‘EUR 22 000 to EUR 65 700’ is replaced by ‘EUR 22 400 to EUR 66 800’;
 - (iv) in the fifth subparagraph, ‘EUR 11 000 to EUR 33 000’ is replaced by ‘EUR 11 200 to EUR 33 500’;
 - (b) paragraph 2 is amended as follows:
 - (i) in the second subparagraph, ‘EUR 291 800’ is replaced by ‘EUR 296 500’;
 - (ii) in the third subparagraph, ‘EUR 146 100’ is replaced by ‘EUR 148 400’;
 - (iii) in the fifth subparagraph, ‘EUR 3 200 to EUR 251 500’ is replaced by ‘EUR 3 300 to EUR 255 500’;
 - (iv) in the sixth subparagraph, ‘EUR 3 200 to EUR 125 900’ is replaced by ‘EUR 3 300 to EUR 127 900’;
 - (c) in the first subparagraph of paragraph 3, ‘EUR 7 300’ is replaced by ‘EUR 7 400’.

Article 2

This Regulation shall not apply to valid applications pending on 1 April 2020.

Article 3

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 April 2020.

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

Done at Brussels, 19 March 2020.

For the Commission
The President
Ursula VON DER LEYEN
