



2024/848

15.3.2024

COMMISSION REGULATION (EU) 2024/848

of 14 March 2024

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 2024

(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 Article 12, fifth paragraph, 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 in particular 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) The fees should be reviewed and updated by reference to the inflation rate of 2023 as published by the Statistical Office of the European Union ⁽³⁾. The inflation rate in the Union was 3,4 % in 2023.
- (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 2024.
- (6) In accordance with Article 12 of Regulation (EC) No 297/95, the update is to be made with effect from 1 April 2024. 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 345 800' is replaced by 'EUR 357 600';
- in the second subparagraph, 'EUR 34 800' is replaced by 'EUR 36 000';
- in the third subparagraph, 'EUR 8 600' is replaced by 'EUR 8 900';

⁽¹⁾ OJ L 35, 15.2.1995, p. 1, ELI: <http://data.europa.eu/eli/reg/1995/297/oj>.

⁽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, ELI: <http://data.europa.eu/eli/reg/2004/726/oj>).

⁽³⁾ <https://ec.europa.eu/eurostat/documents/29955521/18343103/2-17012024-AP-EN.pdf/9d885442-f323-cdde-e149-17ed99a63a6f>.

- (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 134 100' is replaced by 'EUR 138 700';
 - in the second subparagraph, 'EUR 223 600' is replaced by 'EUR 231 200';
 - in the third subparagraph, 'EUR 13 400' is replaced by 'EUR 13 900';
 - in the fourth subparagraph, 'EUR 8 600' is replaced by 'EUR 8 900';
- (iii) point (c) is amended as follows:
 - in the first subparagraph, 'EUR 103 800' is replaced by 'EUR 107 300';
 - in the second subparagraph, 'EUR 26 200 to EUR 77 900' is replaced by 'EUR 27 100 to EUR 80 500';
 - in the third subparagraph, 'EUR 8 600' is replaced by 'EUR 8 900';
- (b) paragraph 2 is amended as follows:
 - (i) in point (a), the first subparagraph is amended as follows:
 - 'EUR 3 900' is replaced by 'EUR 4 000';
 - 'EUR 8 600' is replaced by 'EUR 8 900';
 - (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 103 800' is replaced by 'EUR 107 300';
 - in the second subparagraph, 'EUR 26 200 to EUR 77 900' is replaced by 'EUR 27 100 to EUR 80 500';
- (c) in paragraph 3, 'EUR 17 000' is replaced by 'EUR 17 600';
- (d) in paragraph 4, first subparagraph, 'EUR 26 200' is replaced by 'EUR 27 100';
- (e) in paragraph 5, 'EUR 8 600' is replaced by 'EUR 8 900';
- (f) paragraph 6 is amended as follows:
 - (i) in the first subparagraph, 'EUR 123 900' is replaced by 'EUR 128 100';
 - (ii) in the second subparagraph, 'EUR 30 800 to EUR 92 800' is replaced by 'EUR 31 800 to EUR 96 000';
- (2) in Article 4, first paragraph, 'EUR 86 000' is replaced by 'EUR 88 900';
- (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 173 000' is replaced by 'EUR 178 900';
 - in the second subparagraph, 'EUR 17 000' is replaced by 'EUR 17 600';
 - in the third subparagraph, 'EUR 8 600' is replaced by 'EUR 8 900';
 - the fourth subparagraph is amended as follows:
 - 'EUR 86 000' is replaced by 'EUR 88 900';
 - 'EUR 8 600' is replaced by 'EUR 8 900';
 - (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 86 000' is replaced by 'EUR 88 900';
 - in the second subparagraph, 'EUR 146 200' is replaced by 'EUR 151 200';
 - in the third subparagraph, 'EUR 17 000' is replaced by 'EUR 17 600';
 - in the fourth subparagraph, 'EUR 8 600' is replaced by 'EUR 8 900';
 - the fifth subparagraph is amended as follows:
 - 'EUR 43 300' is replaced by 'EUR 44 800';
 - 'EUR 8 600' is replaced by 'EUR 8 900';

- (iii) point (c) is amended as follows:
 - in the first subparagraph, 'EUR 43 300' is replaced by 'EUR 44 800';
 - in the second subparagraph, 'EUR 10 700 to EUR 32 600' is replaced by 'EUR 11 100 to EUR 33 700';
 - in the third subparagraph, 'EUR 8 600' is replaced by 'EUR 8 900';
- (b) paragraph 2 is amended as follows:
 - (i) in point (a), the first subparagraph is amended as follows:
 - 'EUR 3 900' is replaced by 'EUR 4 000';
 - 'EUR 8 600' is replaced by 'EUR 8 900';
 - (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 51 800' is replaced by 'EUR 53 600';
 - in the second subparagraph, 'EUR 13 000 to EUR 39 100' is replaced by 'EUR 13 400 to EUR 40 400';
 - in the third subparagraph, 'EUR 8 600' is replaced by 'EUR 8 900';
- (c) in paragraph 3, 'EUR 8 600' is replaced by 'EUR 8 900';
- (d) in paragraph 4, first subparagraph, 'EUR 26 200' is replaced by 'EUR 27 100';
- (e) in paragraph 5, 'EUR 8 600' is replaced by 'EUR 8 900';
- (f) paragraph 6 is amended as follows:
 - (i) in the first subparagraph, 'EUR 41 500' is replaced by 'EUR 42 900';
 - (ii) in the second subparagraph, 'EUR 10 200 to EUR 30 800' is replaced by 'EUR 10 500 to EUR 31 800';
- (4) in Article 6, first paragraph, 'EUR 51 800' is replaced by 'EUR 53 600';
- (5) Article 7(1) is amended as follows:
 - (a) in the first subparagraph, 'EUR 86 000' is replaced by 'EUR 88 900';
 - (b) in the second subparagraph, 'EUR 26 200' is replaced by 'EUR 27 100';
- (6) Article 8 is amended as follows:
 - (a) paragraph 1 is amended as follows:
 - (i) in the second subparagraph, 'EUR 103 800' is replaced by 'EUR 107 300';
 - (ii) in the third subparagraph, 'EUR 51 800' is replaced by 'EUR 53 600';
 - (iii) in the fourth subparagraph, 'EUR 26 200 to EUR 77 900' is replaced by 'EUR 27 100 to EUR 80 500';
 - (iv) in the fifth subparagraph, 'EUR 13 000 to EUR 39 100' is replaced by 'EUR 13 400 to EUR 40 400';
 - (b) paragraph 2 is amended as follows:
 - (i) in the second subparagraph, 'EUR 345 800' is replaced by 'EUR 357 600';
 - (ii) in the third subparagraph, 'EUR 173 000' is replaced by 'EUR 178 900';
 - (iii) in the fifth subparagraph, 'EUR 3 900 to EUR 298 000' is replaced by 'EUR 4 000 to EUR 308 100';
 - (iv) in the sixth subparagraph, 'EUR 3 900 to EUR 149 200' is replaced by 'EUR 4 000 to EUR 154 300';
 - (c) in paragraph 3, first subparagraph, 'EUR 8 600' is replaced by 'EUR 8 900'.

Article 2

This Regulation shall not apply to valid applications pending on 1 April 2024.

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 2024.

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

Done at Brussels, 14 March 2024.

For the Commission

The President

Ursula VON DER LEYEN
