COMMISSION REGULATION (EU) 2019/480

of 22 March 2019

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 2019

(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 2018. The inflation rate in the Union, as published by the Statistical Office of the European Union ([3]), was 1,7 % in 2018.

(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 2019.

(6) In accordance with Article 12 of Regulation (EC) No 297/95, the update is to be made with effect from 1 April 2019. 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 286 900' is replaced by 'EUR 291 800';

— in the second subparagraph, 'EUR 28 800' is replaced by 'EUR 29 300';

— in the third subparagraph, 'EUR 7 200' is replaced by 'EUR 7 300';

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

— in the first subparagraph, 'EUR 111 400' is replaced by 'EUR 113 300';

— in the second subparagraph, 'EUR 185 500' is replaced by 'EUR 188 700';

— in the third subparagraph, 'EUR 11 100' is replaced by 'EUR 11 300';

— in the fourth subparagraph, 'EUR 7 200' is replaced by 'EUR 7 300';

([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/2995521/9499950/2-17012019-AP-EN.pdf/4ea467c3-8ff2-4723-bc6e-b0c85fb991e4

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

— in the first subparagraph, 'EUR 86 100' is replaced by 'EUR 87 600';

— in the second subparagraph, 'EUR 21 600 to EUR 64 600' is replaced by 'EUR 22 000 to EUR 65 700';

— in the third subparagraph, 'EUR 7 200' is replaced by 'EUR 7 300';

(b) paragraph 2 is amended as follows:

(i) the first subparagraph of point (a) is amended as follows:

— 'EUR 3 100' is replaced by 'EUR 3 200';

— 'EUR 7 200' is replaced by 'EUR 7 300';

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

— in the first subparagraph, 'EUR 86 100' is replaced by 'EUR 87 600';

— in the second subparagraph, 'EUR 21 600 to EUR 64 600' is replaced by 'EUR 22 000 to EUR 65 700';

(c) in paragraph 3, 'EUR 14 200' is replaced by 'EUR 14 400';

(d) in the first subparagraph of paragraph 4, 'EUR 21 600' is replaced by 'EUR 22 000';

(e) in paragraph 5, 'EUR 7 200' is replaced by 'EUR 7 300';

(f) paragraph 6 is amended as follows:

(i) in the first subparagraph, 'EUR 102 900' is replaced by 'EUR 104 600';

(ii) in the second subparagraph, 'EUR 25 600 to EUR 77 100' is replaced by 'EUR 26 000 to EUR 78 400';

(2) in the first paragraph of Article 4, 'EUR 71 400' is replaced by 'EUR 72 600';

(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 143 700' is replaced by 'EUR 146 100';

— in the second subparagraph, 'EUR 14 200' is replaced by 'EUR 14 400';

— in the third subparagraph, 'EUR 7 200' is replaced by 'EUR 7 300';

— the fourth subparagraph is amended as follows:

— 'EUR 71 400' is replaced by 'EUR 72 600';

— 'EUR 7 200' is replaced by 'EUR 7 300';

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

— in the first subparagraph, 'EUR 71 400' is replaced by 'EUR 72 600';

— in the second subparagraph, 'EUR 121 200' is replaced by 'EUR 123 300';

— in the third subparagraph, 'EUR 14 200' is replaced by 'EUR 14 400';

— in the fourth subparagraph, 'EUR 7 200' is replaced by 'EUR 7 300';

— the fifth subparagraph is amended as follows:

— 'EUR 35 900' is replaced by 'EUR 36 500';

— 'EUR 7 200' is replaced by 'EUR 7 300';

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

— in the first subparagraph, ‘EUR 35 900’ is replaced by ‘EUR 36 500’;

— in the second subparagraph, ‘EUR 8 900 to EUR 27 000’ is replaced by ‘EUR 9 100 to EUR 27 500’;

— in the third subparagraph, ‘EUR 7 200’ is replaced by ‘EUR 7 300’;

(b) paragraph 2 is amended as follows:

(i) the first subparagraph of point (a) is amended as follows:

— ‘EUR 3 100’ is replaced by ‘EUR 3 200’;

— ‘EUR 7 200’ is replaced by ‘EUR 7 300’;

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

— in the first subparagraph, ‘EUR 43 000’ is replaced by ‘EUR 43 700’;

— in the second subparagraph, ‘EUR 10 800 to EUR 32 400’ is replaced by ‘EUR 11 000 to EUR 33 000’;

— in the third subparagraph, ‘EUR 7 200’ is replaced by ‘EUR 7 300’;

(c) in paragraph 3, ‘EUR 7 200’ is replaced by ‘EUR 7 300’;

(d) in the first subparagraph of paragraph 4, ‘EUR 21 600’ is replaced by ‘EUR 22 000’;

(e) in paragraph 5, ‘EUR 7 200’ is replaced by ‘EUR 7 300’;

(f) paragraph 6 is amended as follows:

(i) in the first subparagraph, ‘EUR 34 400’ is replaced by ‘EUR 35 000’;

(ii) in the second subparagraph, ‘EUR 8 500 to EUR 25 600’ is replaced by ‘EUR 8 600 to EUR 26 000’;

(4) in the first paragraph of Article 6, ‘EUR 43 000’ is replaced by ‘EUR 43 700’;

(5) Article 7 is amended as follows:

(a) in the first paragraph, ‘EUR 71 400’ is replaced by ‘EUR 72 600’;

(b) in the second paragraph, ‘EUR 21 600’ is replaced by ‘EUR 22 000’;

(6) Article 8 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the second subparagraph, ‘EUR 86 100’ is replaced by ‘EUR 87 600’;

(ii) in the third subparagraph, ‘EUR 43 000’ is replaced by ‘EUR 43 700’;

(iii) in the fourth subparagraph, ‘EUR 21 600 to EUR 64 600’ is replaced by ‘EUR 22 000 to EUR 65 700’;

(iv) in the fifth subparagraph, ‘EUR 10 800 to EUR 32 400’ is replaced by ‘EUR 11 000 to EUR 33 000’;

(b) paragraph 2 is amended as follows:

(i) in the second subparagraph, ‘EUR 286 900’ is replaced by ‘EUR 291 800’;

(ii) in the third subparagraph, ‘EUR 143 700’ is replaced by ‘EUR 146 100’;

(iii) in the fifth subparagraph, ‘EUR 3 100 to EUR 247 300’ is replaced by ‘EUR 3 200 to EUR 251 500’;

(iv) in the sixth subparagraph, ‘EUR 3 100 to EUR 123 800’ is replaced by ‘EUR 3 200 to EUR 125 900’;

(c) in the first subparagraph of paragraph 3, ‘EUR 7 200’ is replaced by ‘EUR 7 300’.

Article 2

This Regulation shall not apply to valid applications pending on 1 April 2019.

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 2019.

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

Done at Brussels, 22 March 2019.

For the Commission
The President
Jean-Claude JUNCKER