

COMMISSION REGULATION (EU) 2018/471**of 21 March 2018****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 2018****(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 the 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 2017. The inflation rate in the Union, as made available by the Statistical Office of the European Union, was 1,7 % in 2017.
- (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 2018.
- (6) In accordance with Article 12 of Regulation (EC) No 297/95, the update is to be made with effect from 1 April 2018. 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 282 100' is replaced by 'EUR 286 900',
- in the second subparagraph, 'EUR 28 300' is replaced by 'EUR 28 800',
- in the third subparagraph, 'EUR 7 100' is replaced by 'EUR 7 200';

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

- in the first subparagraph, 'EUR 109 500' is replaced by 'EUR 111 400',
- in the second subparagraph, 'EUR 182 400' is replaced by 'EUR 185 500',
- in the third subparagraph, 'EUR 10 900' is replaced by 'EUR 11 100',
- in the fourth subparagraph, 'EUR 7 100' is replaced by 'EUR 7 200';

⁽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).

- (iii) point (c) is amended as follows:
 - in the first subparagraph, 'EUR 84 700' is replaced by 'EUR 86 100',
 - in the second subparagraph, 'EUR 21 200 to EUR 63 500' is replaced by 'EUR 21 600 to EUR 64 600',
 - in the third subparagraph, 'EUR 7 100' is replaced by 'EUR 7 200';
- (b) paragraph 2 is amended as follows:
 - (i) in the first subparagraph of point (a), 'EUR 3 000' is replaced by 'EUR 3 100' and 'EUR 7 100' is replaced by 'EUR 7 200';
 - (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 84 700' is replaced by 'EUR 86 100',
 - in the second subparagraph, 'EUR 21 200 to EUR 63 500' is replaced by 'EUR 21 600 to EUR 64 600';
- (c) in paragraph 3, 'EUR 14 000' is replaced by 'EUR 14 200';
- (d) in the first subparagraph of paragraph 4, 'EUR 21 200' is replaced by 'EUR 21 600';
- (e) in paragraph 5, 'EUR 7 100' is replaced by 'EUR 7 200';
- (f) paragraph 6 is amended as follows:
 - (i) in the first subparagraph, 'EUR 101 200' is replaced by 'EUR 102 900';
 - (ii) in the second subparagraph, 'EUR 25 200 to EUR 75 800' is replaced by 'EUR 25 600 to EUR 77 100';
- (2) in the first paragraph of Article 4, 'EUR 70 200' is replaced by 'EUR 71 400';
- (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 141 300' is replaced by 'EUR 143 700',
 - in the second subparagraph, 'EUR 14 000' is replaced by 'EUR 14 200',
 - in the third subparagraph, 'EUR 7 100' is replaced by 'EUR 7 200',
 - in the fourth subparagraph, 'EUR 70 200' is replaced by 'EUR 71 400' and 'EUR 7 100' is replaced by 'EUR 7 200';
 - (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 70 200' is replaced by 'EUR 71 400',
 - in the second subparagraph, 'EUR 119 200' is replaced by 'EUR 121 200',
 - in the third subparagraph, 'EUR 14 000' is replaced by 'EUR 14 200',
 - in the fourth subparagraph, 'EUR 7 100' is replaced by 'EUR 7 200',
 - in the fifth subparagraph, 'EUR 35 300' is replaced by 'EUR 35 900' and 'EUR 7 100' is replaced by 'EUR 7 200';
 - (iii) point (c) is amended as follows:
 - in the first subparagraph, 'EUR 35 300' is replaced by 'EUR 35 900',
 - in the second subparagraph, 'EUR 8 800 to EUR 26 500' is replaced by 'EUR 8 900 to EUR 27 000',
 - in the third subparagraph, 'EUR 7 100' is replaced by 'EUR 7 200';

- (b) paragraph 2 is amended as follows:
- (i) in the first subparagraph of point (a), 'EUR 3 000' is replaced by 'EUR 3 100' and 'EUR 7 100' is replaced by 'EUR 7 200';
 - (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 42 300' is replaced by 'EUR 43 000';
 - in the second subparagraph, 'EUR 10 600 to EUR 31 900' is replaced by 'EUR 10 800 to EUR 32 400';
 - in the third subparagraph, 'EUR 7 100' is replaced by 'EUR 7 200';
- (c) in paragraph 3, 'EUR 7 100' is replaced by 'EUR 7 200';
- (d) in the first subparagraph of paragraph 4, 'EUR 21 200' is replaced by 'EUR 21 600';
- (e) in paragraph 5, 'EUR 7 100' is replaced by 'EUR 7 200';
- (f) paragraph 6 is amended as follows:
- (i) in the first subparagraph, 'EUR 33 800' is replaced by 'EUR 34 400';
 - (ii) in the second subparagraph, 'EUR 8 400 to EUR 25 200' is replaced by 'EUR 8 500 to EUR 25 600';
- (4) in the first paragraph of Article 6, 'EUR 42 300' is replaced by 'EUR 43 000';
- (5) Article 7 is amended as follows:
- (a) in the first paragraph, 'EUR 70 200' is replaced by 'EUR 71 400';
 - (b) in the second paragraph, 'EUR 21 200' is replaced by 'EUR 21 600';
- (6) Article 8 is amended as follows:
- (a) paragraph 1 is amended as follows:
 - (i) in the second subparagraph, 'EUR 84 700' is replaced by 'EUR 86 100';
 - (ii) in the third subparagraph, 'EUR 42 300' is replaced by 'EUR 43 000';
 - (iii) in the fourth subparagraph, 'EUR 21 200 to EUR 63 500' is replaced by 'EUR 21 600 to EUR 64 600';
 - (iv) in the fifth subparagraph, 'EUR 10 600 to EUR 31 900' is replaced by 'EUR 10 800 to EUR 32 400';
 - (b) paragraph 2 is amended as follows:
 - (i) in the second subparagraph, 'EUR 282 100' is replaced by 'EUR 286 900';
 - (ii) in the third subparagraph, 'EUR 141 300' is replaced by 'EUR 143 700';
 - (iii) in the fifth subparagraph, 'EUR 3 000 to EUR 243 200' is replaced by 'EUR 3 100 to EUR 247 300';
 - (iv) in the sixth subparagraph, 'EUR 3 000 to EUR 121 700' is replaced by 'EUR 3 100 to EUR 123 800';
 - (c) in the first subparagraph of paragraph 3, 'EUR 7 100' is replaced by 'EUR 7 200'.

Article 2

This Regulation shall not apply to valid applications pending on 1 April 2018.

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 2018.

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

Done at Brussels, 21 March 2018.

For the Commission
The President
Jean-Claude JUNCKER
