

COMMISSION REGULATION (EU) No 272/2014

of 17 March 2014

amending Council Regulation (EC) No 297/95 as regards the adjustment of the fees of the European Medicines Agency to the inflation rate

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

HAS ADOPTED THIS REGULATION:

Article 1

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

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

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,

(1) Article 3 is amended as follows:

Whereas:

(a) paragraph 1 is amended as follows:

(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 (hereinafter 'the 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.

(i) point (a) is amended as follows:

— in the first subparagraph, 'EUR 274 400' is replaced by 'EUR 278 500',

— in the second subparagraph, 'EUR 27 500' is replaced by 'EUR 27 900',

— in the third subparagraph, 'EUR 6 900' is replaced by 'EUR 7 000'.

(2) Those fees should be updated by reference to the inflation rate of 2013. The inflation rate in the Union, as published by the Statistical Office of the European Union (Eurostat), was 1,5 % in 2013.

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

— in the first subparagraph, 'EUR 106 500' is replaced by 'EUR 108 100',

— in the second subparagraph, 'EUR 177 300' is replaced by 'EUR 180 000',

(3) For the sake of simplicity, the adjusted levels of the fees should be rounded to the nearest EUR 100.

— in the third subparagraph, 'EUR 10 600' is replaced by 'EUR 10 800',

— in the fourth subparagraph, 'EUR 6 900' is replaced by 'EUR 7 000'.

(4) Regulation (EC) No 297/95 should therefore be amended accordingly.

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

— in the first subparagraph, 'EUR 82 400' is replaced by 'EUR 83 600',

— in the second subparagraph, 'EUR 20 600 to EUR 61 800' is replaced by 'EUR 20 900 to EUR 62 700',

(5) For reasons of legal certainty, this Regulation should not apply to valid applications which are pending on 1 April 2014.

— in the third subparagraph, 'EUR 6 900' is replaced by 'EUR 7 000'.

(6) In accordance with Article 12 of Regulation (EC) No 297/95, the update is to be made with effect from 1 April 2014. It is therefore appropriate that this Regulation enters into force as a matter of urgency and applies from that date,

(b) paragraph 2 is amended as follows:

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

— 'EUR 6 900' is replaced by 'EUR 7 000'.

⁽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).

- (ii) point (b) is amended as follows:
- in the first subparagraph, 'EUR 82 400' is replaced by 'EUR 83 600',
 - in the second subparagraph, 'EUR 20 600 to EUR 61 800' is replaced by 'EUR 20 900 to EUR 62 700'.
- (c) in paragraph 3, 'EUR 13 600' is replaced by 'EUR 13 800'.
- (d) in paragraph 4, 'EUR 20 600' is replaced by 'EUR 20 900'.
- (e) in paragraph 5, 'EUR 6 900' is replaced by 'EUR 7 000'.
- (f) paragraph 6 is amended as follows:
- (i) in the first subparagraph, 'EUR 98 400' is replaced by 'EUR 99 900',
 - (ii) in the second subparagraph, 'EUR 24 500 to EUR 73 800' is replaced by 'EUR 24 900 to EUR 74 900'.
- (2) in Article 4, 'EUR 68 400' is replaced by 'EUR 69 400'.
- (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 137 300' is replaced by 'EUR 139 400',
 - in the second subparagraph, 'EUR 13 600' is replaced by 'EUR 13 800',
 - in the third subparagraph, 'EUR 6 900' is replaced by 'EUR 7 000',
 - the fourth subparagraph is amended as follows:
 - 'EUR 68 400' is replaced by 'EUR 69 400',
 - 'EUR 6 900' is replaced by 'EUR 7 000'.
 - (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 68 400' is replaced by 'EUR 69 400',
 - in the second subparagraph, 'EUR 116 000' is replaced by 'EUR 117 700',
 - in the third subparagraph, 'EUR 13 600' is replaced by 'EUR 13 800',
 - in the fourth subparagraph, 'EUR 6 900' is replaced by 'EUR 7 000',
 - the fifth subparagraph is amended as follows:
 - 'EUR 34 300' is replaced by 'EUR 34 800',
- 'EUR 6 900' is replaced by 'EUR 7 000'.
- (iii) point (c) is amended as follows:
- in the first subparagraph, 'EUR 34 300' is replaced by 'EUR 34 800',
 - in the second subparagraph, 'EUR 8 600 to EUR 25 700' is replaced by 'EUR 8 700 to EUR 26 100',
 - in the third subparagraph, 'EUR 6 900' is replaced by 'EUR 7 000'.
- (b) paragraph 2 is amended as follows:
- (i) point (a) is amended as follows:
 - 'EUR 6 900' is replaced by 'EUR 7 000'.
 - (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 41 100' is replaced by 'EUR 41 700',
 - in the second subparagraph, 'EUR 10 300 to EUR 30 900' is replaced by 'EUR 10 500 to EUR 31 400',
 - in the third subparagraph, 'EUR 6 900' is replaced by 'EUR 7 000'.
- (c) in paragraph 3, 'EUR 6 900' is replaced by 'EUR 7 000'.
- (d) in paragraph 4, 'EUR 20 600' is replaced by 'EUR 20 900'.
- (e) in paragraph 5, 'EUR 6 900' is replaced by 'EUR 7 000'.
- (f) paragraph 6 is amended as follows:
- (i) in the first subparagraph, 'EUR 32 800' is replaced by 'EUR 33 300',
 - (ii) in the second subparagraph, 'EUR 8 200 to EUR 24 500' is replaced by 'EUR 8 300 to EUR 24 900'.
- (4) in Article 6, 'EUR 41 100' is replaced by 'EUR 41 700'.
- (5) Article 7 is amended as follows:
- (a) in the first paragraph, 'EUR 68 400' is replaced by 'EUR 69 400',
 - (b) in the second paragraph, 'EUR 20 600' is replaced by 'EUR 20 900'.
- (6) Article 8 is amended as follows:
- (a) paragraph 1 is amended as follows:
 - (i) in the second subparagraph, 'EUR 82 400' is replaced by 'EUR 83 600',

- (ii) in the third subparagraph, 'EUR 41 100' is replaced by 'EUR 41 700',
- (iii) in the fourth subparagraph, 'EUR 20 600 to EUR 61 800' is replaced by 'EUR 20 900 to EUR 62 700',
- (iv) in the fifth subparagraph, 'EUR 10 300 to EUR 30 900' is replaced by 'EUR 10 500 to EUR 31 400'.
- (b) paragraph 2 is amended as follows:
- (i) in the second subparagraph, 'EUR 274 400' is replaced by 'EUR 278 500',
- (ii) in the third subparagraph, 'EUR 137 300' is replaced by 'EUR 139 400',
- (iii) in the fifth subparagraph, 'EUR 3 000 to EUR 236 500' is replaced by 'EUR 3 000 to EUR 240 000',
- (iv) in the sixth subparagraph, 'EUR 3 000 to EUR 118 400' is replaced by 'EUR 3 000 to EUR 120 200'.
- (c) in paragraph 3, 'EUR 6 900' is replaced by 'EUR 7 000'.

Article 2

This Regulation shall not apply to valid applications pending on 1 April 2014.

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 2014.

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

Done at Brussels, 17 March 2014.

For the Commission
The President

José Manuel BARROSO
