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)

COMMISSION REGULATION (EU) No 272/2014

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(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 (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.

(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.

(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 2014.

(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,

HAS ADOPTED THIS REGULATION:

Article 1

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

(1) Article 3 is amended as follows:

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 272/2014. (See end of Document for details)*

(a) paragraph 1 is amended as follows:

(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’.

(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’,

— 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’.

(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’,

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

(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’.

(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’.