Commission Regulation (EU) No 273/2012 of 27 March 2012 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 273/2012

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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 Article 12 thereof,

Whereas:

(1) According to Article 67(3) of 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[(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 2011. The inflation rate in the Union, as published by the Statistical Office of the European Union (Eurostat), was 3,1 % in 2011.

(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 2012.

(6) Pursuant to Article 12 of Regulation (EC) No 297/95, the update has to be made with effect from 1 April 2012. 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:

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 273/2012. (See end of Document for details)*

(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 259 400’ is replaced by ‘EUR 267 400’,
— in the second subparagraph, ‘EUR 26 000’ is replaced by ‘EUR 26 800’,
— in the third subparagraph, ‘EUR 6 500’ is replaced by ‘EUR 6 700’;

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 100 700’ is replaced by ‘EUR 103 800’,
— in the second subparagraph, ‘EUR 167 600’ is replaced by ‘EUR 172 800’,
— in the third subparagraph, ‘EUR 10 000’ is replaced by ‘EUR 10 300’,
— in the fourth subparagraph, ‘EUR 6 500’ is replaced by ‘EUR 6 700’;

(iii) point (c) is amended as follows:
— in the first subparagraph, ‘EUR 77 900’ is replaced by ‘EUR 80 300’,
— in the second subparagraph, ‘EUR 19 500 to EUR 58 400’ is replaced by ‘EUR 20 100 to EUR 60 200’,
— in the third subparagraph, ‘EUR 6 500’ is replaced by ‘EUR 6 700’;

(b) paragraph 2 is amended as follows:

(i) the first subparagraph of point (a) is amended as follows:
— ‘EUR 2 800’ is replaced by ‘EUR 2 900’,
— ‘EUR 6 500’ is replaced by ‘EUR 6 700’;

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 77 900’ is replaced by ‘EUR 80 300’,
— in the second subparagraph, ‘EUR 19 500 to EUR 58 400’ is replaced by ‘EUR 20 100 to EUR 60 200’;

(c) in paragraph 3, ‘EUR 12 900’ is replaced by ‘EUR 13 300’;

(d) in paragraph 4, ‘EUR 19 500’ is replaced by ‘EUR 20 100’;

(e) in paragraph 5, ‘EUR 6 500’ is replaced by ‘EUR 6 700’;

(f) paragraph 6 is amended as follows:

(i) in the first subparagraph, ‘EUR 93 000’ is replaced by ‘EUR 95 900’;

(ii) in the second subparagraph, ‘EUR 23 200 to EUR 69 700’ is replaced by ‘EUR 23 900 to EUR 71 900’;

(2) in Article 4, ‘EUR 64 700’ is replaced by ‘EUR 66 700’;

(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 129 800’ is replaced by ‘EUR 133 800’,

— in the second subparagraph, ‘EUR 12 900’ is replaced by ‘EUR 13 300’,

— in the third subparagraph, ‘EUR 6 500’ is replaced by ‘EUR 6 700’,

— the fourth subparagraph is amended as follows:

— ‘EUR 64 700’ is replaced by ‘EUR 66 700’,

— ‘EUR 6 500’ is replaced by ‘EUR 6 700’;

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

— in the first subparagraph, ‘EUR 64 700’ is replaced by ‘EUR 66 700’,

— in the second subparagraph, ‘EUR 109 700’ is replaced by ‘EUR 113 100’,

— in the third subparagraph, ‘EUR 12 900’ is replaced by ‘EUR 13 300’,

— in the fourth subparagraph, ‘EUR 6 500’ is replaced by ‘EUR 6 700’,

— the fifth subparagraph is amended as follows:

— ‘EUR 32 400’ is replaced by ‘EUR 33 400’,

— ‘EUR 6 500’ is replaced by ‘EUR 6 700’;

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

— in the first subparagraph, ‘EUR 32 400’ is replaced by ‘EUR 33 400’,

— in the second subparagraph, ‘EUR 8 100 to EUR 24 200’ is replaced by ‘EUR 8 400 to EUR 25 000’,

— in the third subparagraph, ‘EUR 6 500’ is replaced by ‘EUR 6 700’;

(b) paragraph 2 is amended as follows:

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

— ‘EUR 2 800’ is replaced by ‘EUR 2 900’,

— ‘EUR 6 500’ is replaced by ‘EUR 6 700’;

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

— in the first subparagraph, ‘EUR 38 900’ is replaced by ‘EUR 40 100’,

— in the second subparagraph, ‘EUR 9 700 to EUR 29 200’ is replaced by ‘EUR 10 000 to EUR 30 100’,

— in the third subparagraph, ‘EUR 6 500’ is replaced by ‘EUR 6 700’;