Commission Regulation (EU) No 220/2013 of 13 March 2013 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 220/2013

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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(5) thereof,

Whereas:

(1) In accordance with 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 2012. The inflation rate in the Union, as published by the Statistical Office of the European Union (Eurostat), was 2,6 % in 2012.

(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 2013.

(6) In accordance with Article 12 of Regulation (EC) No 297/95, the update has to be made with effect from 1 April 2013. 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 267 400’ is replaced by ‘EUR 274 400’,
— in the second subparagraph, ‘EUR 26 800’ is replaced by ‘EUR 27 500’,
— in the third subparagraph, ‘EUR 6 700’ is replaced by ‘EUR 6 900’;

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 103 800’ is replaced by ‘EUR 106 500’,
— in the second subparagraph, ‘EUR 172 800’ is replaced by ‘EUR 177 300’,
— in the third subparagraph, ‘EUR 10 300’ is replaced by ‘EUR 10 600’,
— in the fourth subparagraph, ‘EUR 6 700’ is replaced by ‘EUR 6 900’;

(iii) point (c) is amended as follows:
— in the first subparagraph, ‘EUR 80 300’ is replaced by ‘EUR 82 400’,
— in the second subparagraph, ‘EUR 20 100 to EUR 60 200’ is replaced by ‘EUR 20 600 to EUR 61 800’,
— in the third subparagraph, ‘EUR 6 700’ is replaced by ‘EUR 6 900’;

(b) paragraph 2 is amended as follows:

(i) the first subparagraph of point (a) is amended as follows:
— ‘EUR 2 900’ is replaced by ‘EUR 3 000’,
— ‘EUR 6 700’ is replaced by ‘EUR 6 900’;

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 80 300’ is replaced by ‘EUR 82 400’,
— in the second subparagraph, ‘EUR 20 100 to EUR 60 200’ is replaced by ‘EUR 20 600 to EUR 61 800’;

(c) in paragraph 3, ‘EUR 13 300’ is replaced by ‘EUR 13 600’;

(d) in paragraph 4, ‘EUR 20 100’ is replaced by ‘EUR 20 600’;

(e) in paragraph 5, ‘EUR 6 700’ is replaced by ‘EUR 6 900’;

(f) paragraph 6 is amended as follows:

(i) in the first subparagraph, ‘EUR 95 900’ is replaced by ‘EUR 98 400’;

(ii) in the second subparagraph, ‘EUR 23 900 to EUR 71 900’ is replaced by ‘EUR 24 500 to EUR 73 800’;

(2) In Article 4, ‘EUR 66 700’ is replaced by ‘EUR 68 400’;

(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 133 800’ is replaced by ‘EUR 137 300’,
— in the second subparagraph, ‘EUR 13 300’ is replaced by ‘EUR 13 600’,
— in the third subparagraph, ‘EUR 6 700’ is replaced by ‘EUR 6 900’,
— the fourth subparagraph is amended as follows:
— ‘EUR 66 700’ is replaced by ‘EUR 68 400’,
— ‘EUR 6 700’ is replaced by ‘EUR 6 900’;

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 66 700’ is replaced by ‘EUR 68 400’,
— in the second subparagraph, ‘EUR 113 100’ is replaced by ‘EUR 116 000’,
— in the third subparagraph, ‘EUR 13 300’ is replaced by ‘EUR 13 600’,
— in the fourth subparagraph, ‘EUR 6 700’ is replaced by ‘EUR 6 900’,
— the fifth subparagraph is amended as follows:
— ‘EUR 33 400’ is replaced by ‘EUR 34 300’,
— ‘EUR 6 700’ is replaced by ‘EUR 6 900’;

(iii) point (c) is amended as follows:
— in the first subparagraph, ‘EUR 33 400’ is replaced by ‘EUR 34 300’,
— in the second subparagraph, ‘EUR 8 400 to EUR 25 000’ is replaced by ‘EUR 8 600 to EUR 25 700’,
— in the third subparagraph, ‘EUR 6 700’ is replaced by ‘EUR 6 900’;

(b) paragraph 2 is amended as follows:

(i) point (a) is amended as follows:
— ‘EUR 2 900’ is replaced by ‘EUR 3 000’,
— ‘EUR 6 700’ is replaced by ‘EUR 6 900’;

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 40 100’ is replaced by ‘EUR 41 100’,
— in the second subparagraph, ‘EUR 10 000 to EUR 30 100’ is replaced by ‘EUR 10 300 to EUR 30 900’,
— in the third subparagraph, ‘EUR 6 700’ is replaced by ‘EUR 6 900’;