Commission Regulation (EU) No 261/2010 of 25 March 2010 amending Council Regulation (EC) No 297/95 as regards the adjustment of the fees of the European Medicines Agency to the inflation rate

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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) Article 12 of Regulation (EC) No 297/95 requires that the fees of the Agency be updated each year by reference to the inflation rate.

(3) Those fees should therefore be updated by reference to the inflation rate of 2009. The inflation rate in the Union, as published by the Statistical Office of the European Union (Eurostat), was 1 % in 2009.

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

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

(6) For reasons of legal certainty, this Regulation should not apply to valid applications which are pending on 1 April 2010.

(7) Pursuant to Article 12 of Regulation (EC) No 297/95, the update has to be made with effect from 1 April 2010. It is therefore appropriate that this Regulation enters into force as a matter of urgency and applies from that date,

HAS ADOPTED THIS REGULATION:

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 261/2010. (See end of Document for details)*

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 251 600’ is replaced by ‘EUR 254 100’,
— in the second subparagraph, ‘EUR 25 200’ is replaced by ‘EUR 25 500’,
— in the third subparagraph, ‘EUR 6 300’ is replaced by ‘EUR 6 400’,

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 97 600’ is replaced by ‘EUR 98 600’,
— in the second subparagraph, ‘EUR 162 600’ is replaced by ‘EUR 164 200’,
— in the third subparagraph, ‘EUR 9 700’ is replaced by ‘EUR 9 800’,
— in the fourth subparagraph, ‘EUR 6 300’ is replaced by ‘EUR 6 400’,

(iii) point (c) is amended as follows:
— in the first subparagraph, ‘EUR 75 500’ is replaced by ‘EUR 76 300’,
— in the second subparagraph, ‘EUR 18 900 to EUR 56 600’ is replaced by ‘EUR 19 100 to EUR 57 200’,
— in the third subparagraph, ‘EUR 6 300’ is replaced by ‘EUR 6 400’,

(b) Paragraph 2 is amended as follows:

(i) the first subparagraph of point (a) is amended as follows:
— ‘EUR 6 300’ is replaced by ‘EUR 6 400’,

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 75 500’ is replaced by ‘EUR 76 300’,
— in the second subparagraph, ‘EUR 18 900 to EUR 56 600’ is replaced by ‘EUR 19 100 to EUR 57 200’,

(c) In paragraph 3, ‘EUR 12 500’ is replaced by ‘EUR 12 600’.

(d) In paragraph 4, ‘EUR 18 900’ is replaced by ‘EUR 19 100’.

(e) In paragraph 5, ‘EUR 6 300’ is replaced by ‘EUR 6 400’.

(f) Paragraph 6 is amended as follows:

(i) in the first subparagraph, ‘EUR 90 200’ is replaced by ‘EUR 91 100’;

(ii) in the second subparagraph, ‘EUR 22 500 to EUR 67 600’ is replaced by ‘EUR 22 700 to EUR 68 300’.

2. In Article 4, ‘EUR 62 800’ is replaced by ‘EUR 63 400’.

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 125 800’ is replaced by ‘EUR 127 100’,
— in the second subparagraph, ‘EUR 12 500’ is replaced by ‘EUR 12 600’,
— in the third subparagraph, ‘EUR 6 300’ is replaced by ‘EUR 6 400’,
— the fourth subparagraph is amended as follows:
— ‘EUR 62 800’ is replaced by ‘EUR 63 400’,
— ‘EUR 6 300’ is replaced by ‘EUR 6 400’,

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 62 800’ is replaced by ‘EUR 63 400’,
— in the second subparagraph, ‘EUR 106 300’ is replaced by ‘EUR 107 400’,
— in the third subparagraph, ‘EUR 12 500’ is replaced by ‘EUR 12 600’,
— in the fourth subparagraph, ‘EUR 6 300’ is replaced by ‘EUR 6 400’,
— the fifth subparagraph is amended as follows:
— ‘EUR 31 400’ is replaced by ‘EUR 31 700’,
— ‘EUR 6 300’ is replaced by ‘EUR 6 400’,

(iii) point (c) is amended as follows:
— in the first subparagraph, ‘EUR 31 400’ is replaced by ‘EUR 31 700’,
— in the second subparagraph, ‘EUR 7 800 to EUR 23 500’ is replaced by ‘EUR 7 900 to EUR 23 700’,
— in the third subparagraph, ‘EUR 6 300’ is replaced by ‘EUR 6 400’,

(b) Paragraph 2 is amended as follows:

(i) in point (a), ‘EUR 6 300’ is replaced by ‘EUR 6 400’;

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 37 700’ is replaced by ‘EUR 38 100’,
— in the second subparagraph, ‘EUR 9 400 to EUR 28 300’ is replaced by ‘EUR 9 500 to EUR 28 600’,
— in the third subparagraph, ‘EUR 6 300’ is replaced by ‘EUR 6 400’,