Commission Regulation (EU) No 301/2011 of 28 March 2011 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 301/2011

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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) 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 2010. The inflation rate in the Union, as published by the Statistical Office of the European Union (Eurostat), was 2,1 % in 2010.

(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 2011.

(7) Pursuant to Article 12 of Regulation (EC) No 297/95, the update has to be made with effect from 1 April 2011. 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 301/2011. (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 254 100’ is replaced by ‘EUR 259 400’,
— in the second subparagraph, ‘EUR 25 500’ is replaced by ‘EUR 26 000’,
— in the third subparagraph, ‘EUR 6 400’ is replaced by ‘EUR 6 500’;

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 98 600’ is replaced by ‘EUR 100 700’,
— in the second subparagraph, ‘EUR 164 200’ is replaced by ‘EUR 167 600’,
— in the third subparagraph, ‘EUR 9 800’ is replaced by ‘EUR 10 000’,
— in the fourth subparagraph, ‘EUR 6 400’ is replaced by ‘EUR 6 500’;

(iii) point (c) is amended as follows:
— in the first subparagraph, ‘EUR 76 300’ is replaced by ‘EUR 77 900’,
— in the second subparagraph, ‘EUR 19 100 to EUR 57 200’ is replaced by ‘EUR 19 500 to EUR 58 400’,
— in the third subparagraph, ‘EUR 6 400’ is replaced by ‘EUR 6 500’;

(b) paragraph 2 is amended as follows:

(i) the first subparagraph of point (a) is amended as follows:
— ‘EUR 2 700’ is replaced by ‘EUR 2 800’,
— ‘EUR 6 400’ is replaced by ‘EUR 6 500’;

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 76 300’ is replaced by ‘EUR 77 900’,
— in the second subparagraph, ‘EUR 19 100 to EUR 57 200’ is replaced by ‘EUR 19 500 to EUR 58 400’;

(c) in paragraph 3, ‘EUR 12 600’ is replaced by ‘EUR 12 900’;

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

(e) in paragraph 5, ‘EUR 6 400’ is replaced by ‘EUR 6 500’;

(f) paragraph 6 is amended as follows:

(i) in the first subparagraph, ‘EUR 91 100’ is replaced by ‘EUR 93 000’;

(ii) in the second subparagraph, ‘EUR 22 700 to EUR 68 300’ is replaced by ‘EUR 23 200 to EUR 69 700’;

(2) in Article 4, ‘EUR 63 400’ is replaced by ‘EUR 64 700’;

(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 127 100’ is replaced by ‘EUR 129 800’,
— in the second subparagraph, ‘EUR 12 600’ is replaced by ‘EUR 12 900’,
— in the third subparagraph, ‘EUR 6 400’ is replaced by ‘EUR 6 500’,
— the fourth subparagraph is amended as follows:
— ‘EUR 63 400’ is replaced by ‘EUR 64 700’,
— ‘EUR 6 400’ is replaced by ‘EUR 6 500’;

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 63 400’ is replaced by ‘EUR 64 700’,
— in the second subparagraph, ‘EUR 107 400’ is replaced by ‘EUR 109 700’,
— in the third subparagraph,’EUR 12 600’ is replaced by ‘EUR 12 900’,
— in the fourth subparagraph, ‘EUR 6 400’ is replaced by ‘EUR 6 500’,
— the fifth subparagraph is amended as follows:
— ‘EUR 31 700’ is replaced by ‘EUR 32 400’,
— ‘EUR 6 400’ is replaced by ‘EUR 6 500’;

(iii) point (c) is amended as follows:
— in the first subparagraph, ‘EUR 31 700’ is replaced by ‘EUR 32 400’,
— in the second subparagraph, ‘EUR 7 900 to EUR 23 700’ is replaced by ‘EUR 8 100 to EUR 24 200’,
— in the third subparagraph, ‘EUR 6 400’ is replaced by ‘EUR 6 500’;

(b) paragraph 2 is amended as follows:

(i) in point (a) is amended as follows:
— ‘EUR 2 700’ is replaced by ‘EUR 2 800’,
— ‘EUR 6 400’ is replaced by ‘EUR 6 500’;

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