COMMISSION REGULATION (EU) 2015/490

of 23 March 2015

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)

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 2014. The inflation rate in the Union, as published by the Statistical Office of the European Union (Eurostat), was — 0,1 % in 2014.

(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 2015.

(6) In accordance with Article 12 of Regulation (EC) No 297/95, the update is to be made with effect from 1 April 2015. 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) in point (a) in the first subparagraph, 'EUR 278 500' is replaced by 'EUR 278 200';

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

— in the first subparagraph, 'EUR 108 100' is replaced by 'EUR 108 000',

— in the second subparagraph, 'EUR 180 000' is replaced by 'EUR 179 800';

([1]) OJ L 35, 15.2.1995, p. 1.
([2]) 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 (OJ L 136, 30.4.2004, p. 1).

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

— in the first subparagraph, 'EUR 83 600' is replaced by 'EUR 83 500',

— in the second subparagraph, 'EUR 20 900 to EUR 62 700' is replaced by 'EUR 20 900 to EUR 62 600';

(b) in paragraph 2, point (b) is amended as follows:

(i) in the first subparagraph, 'EUR 83 600' is replaced by 'EUR 83 500';

(ii) in the second subparagraph, 'EUR 20 900 to EUR 62 700' is replaced by 'EUR 20 900 to EUR 62 600';

(c) paragraph 6 is amended as follows:

(i) in the first subparagraph, 'EUR 99 900' is replaced by 'EUR 99 800';

(ii) in the second subparagraph, 'EUR 24 900 to EUR 74 900' is replaced by 'EUR 24 900 to EUR 74 800';

(2) in Article 4, 'EUR 69 400' is replaced by 'EUR 69 300';

(3) in Article 5, paragraph 1 is amended as follows:

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

(i) in the first subparagraph, 'EUR 139 400' is replaced by 'EUR 139 300';

(ii) in the fourth subparagraph, 'EUR 69 400' is replaced by 'EUR 69 300';

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

(i) in the first subparagraph, 'EUR 69 400' is replaced by 'EUR 69 300';

(ii) in the second subparagraph, 'EUR 117 700' is replaced by 'EUR 117 600';

(4) in Article 7, in the first paragraph, 'EUR 69 400' is replaced by 'EUR 69 300';

(5) Article 8 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the second subparagraph, 'EUR 83 600' is replaced by 'EUR 83 500';

(ii) in the fourth subparagraph, 'EUR 20 900 to EUR 62 700' is replaced by 'EUR 20 900 to EUR 62 600';

(b) paragraph 2 is amended as follows:

(i) in the second subparagraph, 'EUR 278 500' is replaced by 'EUR 278 200';

(ii) in the third subparagraph, 'EUR 139 400' is replaced by 'EUR 139 300';

(iii) in the fifth subparagraph, 'EUR 3 000 to EUR 240 000' is replaced by 'EUR 3 000 to EUR 239 800';

(iv) in the sixth subparagraph, 'EUR 3 000 to EUR 120 200' is replaced by 'EUR 3 000 to EUR 120 100'.

Article 2

This Regulation shall not apply to valid applications pending on 1 April 2015.

Article 3

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 April 2015.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 March 2015.

For the Commission
The President
Jean-Claude JUNCKER