Commission Regulation (EU) 2016/461 of 30 March 2016 amending Council Regulation (EC) No 297/95 as regards the adjustment of the fees of the European Medicines Agency to the inflation rate with effect from 1 April 2016 (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/461

of 30 March 2016

amending Council Regulation (EC) No 297/95 as regards the adjustment of the fees of the European Medicines Agency to the inflation rate with effect from 1 April 2016

(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 consists of a contribution from the Union and fees paid to it by undertakings. 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 2015. The inflation rate in the Union, as published by the Statistical Office of the European Union, was 0,2 % in 2015.

(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 2016.

(6) In accordance with Article 12 of Regulation (EC) No 297/95, the update is to be made with effect from 1 April 2016. 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:

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2016/461. (See end of Document for details)*

(a) paragraph 1 is amended as follows:

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

— in the first subparagraph, ‘EUR 278 200’ is replaced by ‘EUR 278 800’,

— in the second subparagraph, ‘EUR 27 900’ is replaced by ‘EUR 28 000’;

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

— in the first subparagraph, ‘EUR 108 000’ is replaced by ‘EUR 108 200’,

— in the second subparagraph, ‘EUR 179 800’ is replaced by ‘EUR 180 200’;

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

— in the first subparagraph, ‘EUR 83 500’ is replaced by ‘EUR 83 700’,

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

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

(i) in the first subparagraph, ‘EUR 83 500’ is replaced by ‘EUR 83 700’;

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

(c) paragraph 6 is amended as follows:

(i) in the first subparagraph, ‘EUR 99 800’ is replaced by ‘EUR 100 000’;

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

(2) in Article 4, in the first paragraph, ‘EUR 69 300’ is replaced by ‘EUR 69 400’;

(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 139 300’ is replaced by ‘EUR 139 600’,

— in the fourth subparagraph ‘EUR 69 300’ is replaced by ‘EUR 69 400’;

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

— in the first subparagraph, ‘EUR 69 300’ is replaced by ‘EUR 69 400’,

— in the second subparagraph, ‘EUR 117 600’ is replaced by ‘EUR 117 800’,

— in the fifth subparagraph ‘EUR 34 800’ is replaced by ‘EUR 34 900’;

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

— in the first subparagraph, ‘EUR 34 800’ is replaced by ‘EUR 34 900’,

— in the second subparagraph, ‘EUR 8 700 to EUR 26 100’ is replaced by ‘EUR 8 700 to EUR 26 200’;

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

(i) in the first subparagraph, ‘EUR 41 700’ is replaced by ‘EUR 41 800’;

(ii) in the second subparagraph, ‘EUR 10 500 to EUR 31 400’ is replaced by ‘EUR 10 500 to EUR 31 500’;

(c) in the first subparagraph of paragraph 6, ‘EUR 33 300’ is replaced by ‘EUR 33 400’;

(4) in Article 6, in the first paragraph, ‘EUR 41 700’ is replaced by ‘EUR 41 800’;

(5) in Article 7, in the first paragraph, ‘EUR 69 300’ is replaced by ‘EUR 69 400’;

(6) Article 8 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the second subparagraph, ‘EUR 83 500’ is replaced by ‘EUR 83 700’;

(ii) in the third subparagraph, ‘EUR 41 700’ is replaced by ‘EUR 41 800’;

(iii) in the fourth subparagraph, ‘EUR 20 900 to EUR 62 600’ is replaced by ‘EUR 20 900 to EUR 62 700’;

(iv) in the fifth subparagraph, ‘EUR 10 500 to EUR 31 400’ is replaced by ‘EUR 10 500 to EUR 31 500’;

(b) paragraph 2 is amended as follows:

(i) in the second subparagraph, ‘EUR 278 200’ is replaced by ‘EUR 278 800’;

(ii) in the third subparagraph, ‘EUR 139 300’ is replaced by ‘EUR 139 600’;

(iii) in the fifth subparagraph, ‘EUR 3 000 to EUR 239 800’ is replaced by ‘EUR 3 000 to EUR 240 300’;

(iv) in the sixth subparagraph, ‘EUR 3 000 to EUR 120 100’ is replaced by ‘EUR 3 000 to EUR 120 300’.

Article 2

This Regulation shall not apply to valid applications pending on 1 April 2016.

Article 3

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