Commission Regulation (EU) 2017/612 of 30 March 2017 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 2017 (Text with EEA relevance)

COMMISSION REGULATION (EU) 2017/612

of 30 March 2017

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 2017

(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 2016. The inflation rate in the Union, as published by the Statistical Office of the European Union, was 1,2 % in 2016.

(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 2017.

(6) In accordance with Article 12 of Regulation (EC) No 297/95, the update is to be made with effect from 1 April 2017. 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) 2017/612. (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 278 800’ is replaced by ‘EUR 282 100’,

— in the second subparagraph, ‘EUR 28 000’ is replaced by ‘EUR 28 300’,

— in the third subparagraph, ‘EUR 7 000’ is replaced by ‘EUR 7 100’,

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

— in the first subparagraph, ‘EUR 108 200’ is replaced by ‘EUR 109 500’,

— in the second subparagraph, ‘EUR 180 200’ is replaced by ‘EUR 182 400’,

— in the third subparagraph, ‘EUR 10 800’ is replaced by ‘EUR 10 900’,

— in the fourth subparagraph, ‘EUR 7 000’ is replaced by ‘EUR 7 100’,

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

— in the first subparagraph, ‘EUR 83 700’ is replaced by ‘EUR 84 700’,

— in the second subparagraph, ‘EUR 20 900 to EUR 62 700’ is replaced by ‘EUR 21 200 to EUR 63 500’,

— in the third subparagraph, ‘EUR 7 000’ is replaced by ‘EUR 7 100’;

(b) paragraph 2 is amended as follows:

(i) in the first subparagraph of point (a) ‘EUR 7 000’ is replaced by ‘EUR 7 100’,

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

— in the first subparagraph, ‘EUR 83 700’ is replaced by ‘EUR 84 700’,

— in the second subparagraph, ‘EUR 20 900 to EUR 62 700’ is replaced by ‘EUR 21 200 to EUR 63 500’;

(c) in paragraph 3, ‘EUR 13 800’ is replaced by ‘EUR 14 000’;

(d) in paragraph 4, ‘EUR 20 900’ is replaced by ‘EUR 21 200’;

(e) in paragraph 5, ‘EUR 7 000’ is replaced by ‘EUR 7 100’;

(f) paragraph 6 is amended as follows:

(i) in the first subparagraph, ‘EUR 100 000’ is replaced by ‘EUR 101 200’,

(ii) in the second subparagraph, ‘EUR 24 900 to EUR 74 900’ is replaced by ‘EUR 25 200 to EUR 75 800’;

(2) in the first paragraph of Article 4, ‘EUR 69 400’ is replaced by ‘EUR 70 200’;

(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 139 600’ is replaced by ‘EUR 141 300’,

— in the second subparagraph, ‘EUR 13 800’ is replaced by ‘EUR 14 000’,

— in the third subparagraph, ‘EUR 7 000’ is replaced by ‘EUR 7 100’,

— the fourth subparagraph is amended as follows:

— ‘EUR 69 400’ is replaced by ‘EUR 70 200’,

— ‘EUR 7 000’ is replaced by ‘EUR 7 100’;

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

— in the first subparagraph, ‘EUR 69 400’ is replaced by ‘EUR 70 200’,

— in the second subparagraph, ‘EUR 117 800’ is replaced by ‘EUR 119 200’,

— in the third subparagraph, ‘EUR 13 800’ is replaced by ‘EUR 14 000’,

— in the fourth subparagraph, ‘EUR 7 000’ is replaced by ‘EUR 7 100’,

— the fifth subparagraph is amended as follows:

— ‘EUR 34 900’ is replaced by ‘EUR 35 300’,

— ‘EUR 7 000’ is replaced by ‘EUR 7 100’;

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

— in the first subparagraph, ‘EUR 34 900’ is replaced by ‘EUR 35 300’,

— in the second subparagraph, ‘EUR 8 700 to EUR 26 200’ is replaced by ‘EUR 8 800 to EUR 26 500’,

— in the third subparagraph, ‘EUR 7 000’ is replaced by ‘EUR 7 100’;

(b) paragraph 2 is amended as follows:

(i) in the first subparagraph of point (a), ‘EUR 7 000’ is replaced by ‘EUR 7 100’;

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

— in the first subparagraph, ‘EUR 41 800’ is replaced by ‘EUR 42 300’,

— in the second subparagraph, ‘EUR 10 500 to EUR 31 500’ is replaced by ‘EUR 10 600 to EUR 31 900’,

— in the third subparagraph, ‘EUR 7 000’ is replaced by ‘EUR 7 100’;

(c) in paragraph 3, ‘EUR 7 000’ is replaced by ‘EUR 7 100’;

(d) in paragraph 4, ‘EUR 20 900’ is replaced by ‘EUR 21 200’;