Commission Regulation (EU) 2018/471 of 21 March 2018 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 2018 (Text with EEA relevance)

COMMISSION REGULATION (EU) 2018/471

of 21 March 2018

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 2018

(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 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 2017. The inflation rate in the Union, as made available by the Statistical Office of the European Union, was 1,7 % in 2017.

(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 2018.

(6) In accordance with Article 12 of Regulation (EC) No 297/95, the update is to be made with effect from 1 April 2018. 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) 2018/471. (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 282 100’ is replaced by ‘EUR 286 900’,
— in the second subparagraph, ‘EUR 28 300’ is replaced by ‘EUR 28 800’,
— in the third subparagraph, ‘EUR 7 100’ is replaced by ‘EUR 7 200’;

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 109 500’ is replaced by ‘EUR 111 400’,
— in the second subparagraph, ‘EUR 182 400’ is replaced by ‘EUR 185 500’,
— in the third subparagraph, ‘EUR 10 900’ is replaced by ‘EUR 11 100’,
— in the fourth subparagraph, ‘EUR 7 100’ is replaced by ‘EUR 7 200’;

(iii) point (c) is amended as follows:
— in the first subparagraph, ‘EUR 84 700’ is replaced by ‘EUR 86 100’,
— in the second subparagraph, ‘EUR 21 200 to EUR 63 500’ is replaced by ‘EUR 21 600 to EUR 64 600’,
— in the third subparagraph, ‘EUR 7 100’ is replaced by ‘EUR 7 200’;

(b) paragraph 2 is amended as follows:

(i) in the first subparagraph of point (a), ‘EUR 3 000’ is replaced by ‘EUR 3 100’

and ‘EUR 7 100’ is replaced by ‘EUR 7 200’;

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 84 700’ is replaced by ‘EUR 86 100’,
— in the second subparagraph, ‘EUR 21 200 to EUR 63 500’ is replaced by ‘EUR 21 600 to EUR 64 600’;

(c) in paragraph 3, ‘EUR 14 000’ is replaced by ‘EUR 14 200’;

(d) in the first subparagraph of paragraph 4, ‘EUR 21 200’ is replaced by ‘EUR 21 600’;

(e) in paragraph 5, ‘EUR 7 100’ is replaced by ‘EUR 7 200’;

(f) paragraph 6 is amended as follows:

(i) in the first subparagraph, ‘EUR 101 200’ is replaced by ‘EUR 102 900’;

(ii) in the second subparagraph, ‘EUR 25 200 to EUR 75 800’ is replaced by ‘EUR 25 600 to EUR 77 100’;

(2) in the first paragraph of Article 4, ‘EUR 70 200’ is replaced by ‘EUR 71 400’;

(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 141 300’ is replaced by ‘EUR 143 700’,

— in the second subparagraph, ‘EUR 14 000’ is replaced by ‘EUR 14 200’,

— in the third subparagraph, ‘EUR 7 100’ is replaced by ‘EUR 7 200’,

— in the fourth subparagraph, ‘EUR 70 200’ is replaced by ‘EUR 71 400’ and ‘EUR 7 100’ is replaced by ‘EUR 7 200’;

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

— in the first subparagraph, ‘EUR 70 200’ is replaced by ‘EUR 71 400’,

— in the second subparagraph, ‘EUR 119 200’ is replaced by ‘EUR 121 200’,

— in the third subparagraph, ‘EUR 14 000’ is replaced by ‘EUR 14 200’,

— in the fourth subparagraph, ‘EUR 7 100’ is replaced by ‘EUR 7 200’,

— in the fifth subparagraph, ‘EUR 35 300’ is replaced by ‘EUR 35 900’ and ‘EUR 7 100’ is replaced by ‘EUR 7 200’;

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

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

— in the second subparagraph, ‘EUR 8 800 to EUR 26 500’ is replaced by ‘EUR 8 900 to EUR 27 000’,

— in the third subparagraph, ‘EUR 7 100’ is replaced by ‘EUR 7 200’;

(b) paragraph 2 is amended as follows:

(i) in the first subparagraph of point (a), ‘EUR 3 000’ is replaced by ‘EUR 3 100’ and ‘EUR 7 100’ is replaced by ‘EUR 7 200’;

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

— in the first subparagraph, ‘EUR 42 300’ is replaced by ‘EUR 43 000’,

— in the second subparagraph, ‘EUR 10 600 to EUR 31 900’ is replaced by ‘EUR 10 800 to EUR 32 400’,

— in the third subparagraph, ‘EUR 7 100’ is replaced by ‘EUR 7 200’;