Commission Regulation (EU) 2020/422 of 19 March 2020 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 2020 (Text with EEA relevance)

COMMISSION REGULATION (EU) 2020/422

of 19 March 2020

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 2020

(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 that 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 2019. The inflation rate in the Union, as published by the Statistical Office of the European Union[(3)], was 1,6 % in 2019.

(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 2020.

(6) In accordance with Article 12 of Regulation (EC) No 297/95, the update is to be made with effect from 1 April 2020. 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) 2020/422. (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 291 800’ is replaced by ‘EUR 296 500’;
- in the second subparagraph, ‘EUR 29 300’ is replaced by ‘EUR 29 800’;
- in the third subparagraph, ‘EUR 7 300’ is replaced by ‘EUR 7 400’;

(ii) point (b) is amended as follows:
- in the first subparagraph, ‘EUR 113 300’ is replaced by ‘EUR 115 100’;
- in the second subparagraph, ‘EUR 188 700’ is replaced by ‘EUR 191 700’;
- in the third subparagraph, ‘EUR 11 300’ is replaced by ‘EUR 11 500’;
- in the fourth subparagraph, ‘EUR 7 300’ is replaced by ‘EUR 7 400’;

(iii) point (c) is amended as follows:
- in the first subparagraph, ‘EUR 87 600’ is replaced by ‘EUR 89 000’;
- in the second subparagraph, ‘EUR 22 000 to EUR 65 700’ is replaced by ‘EUR 22 400 to EUR 66 800’;
- in the third subparagraph, ‘EUR 7 300’ is replaced by ‘EUR 7 400’;

(b) paragraph 2 is amended as follows:

(i) the first subparagraph of point (a) is amended as follows:
- ‘EUR 3 200’ is replaced by ‘EUR 3 300’;
- ‘EUR 7 300’ is replaced by ‘EUR 7 400’;

(ii) point (b) is amended as follows:
- in the first subparagraph, ‘EUR 87 600’ is replaced by ‘EUR 89 000’;
- in the second subparagraph, ‘EUR 22 000 to EUR 65 700’ is replaced by ‘EUR 22 400 to EUR 66 800’;

(c) in paragraph 3, ‘EUR 14 400’ is replaced by ‘EUR 14 600’;

(d) in the first subparagraph of paragraph 4, ‘EUR 22 000’ is replaced by ‘EUR 22 400’;

(e) in paragraph 5, ‘EUR 7 300’ is replaced by ‘EUR 7 400’;

(f) paragraph 6 is amended as follows:

(i) in the first subparagraph, ‘EUR 104 600’ is replaced by ‘EUR 106 300’;

(ii) in the second subparagraph, ‘EUR 26 000 to EUR 78 400’ is replaced by ‘EUR 26 400 to EUR 79 700’;

(2) in the first paragraph of Article 4, ‘EUR 72 600’ is replaced by ‘EUR 73 800’;

(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 146 100’ is replaced by ‘EUR 148 400’;

— in the second subparagraph, ‘EUR 14 400’ is replaced by ‘EUR 14 600’;

— in the third subparagraph, ‘EUR 7 300’ is replaced by ‘EUR 7 400’;

— the fourth subparagraph is amended as follows:

— ‘EUR 72 600’ is replaced by ‘EUR 73 800’;

— ‘EUR 7 300’ is replaced by ‘EUR 7 400’;

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

— in the first subparagraph, ‘EUR 72 600’ is replaced by ‘EUR 73 800’;

— in the second subparagraph, ‘EUR 123 300’ is replaced by ‘EUR 125 300’;

— in the third subparagraph, ‘EUR 14 400’ is replaced by ‘EUR 14 600’;

— in the fourth subparagraph, ‘EUR 7 300’ is replaced by ‘EUR 7 400’;

— the fifth subparagraph is amended as follows:

— ‘EUR 36 500’ is replaced by ‘EUR 37 100’;

— ‘EUR 7 300’ is replaced by ‘EUR 7 400’;

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

— in the first subparagraph, ‘EUR 36 500’ is replaced by ‘EUR 37 100’;

— in the second subparagraph, ‘EUR 9 100 to EUR 27 500’ is replaced by ‘EUR 9 200 to EUR 27 900’;

— in the third subparagraph, ‘EUR 7 300’ is replaced by ‘EUR 7 400’;

(b) paragraph 2 is amended as follows:

(i) the first subparagraph of point (a) is amended as follows:

— ‘EUR 3 200’ is replaced by ‘EUR 3 300’;

— ‘EUR 7 300’ is replaced by ‘EUR 7 400’;

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

— in the first subparagraph, ‘EUR 43 700’ is replaced by ‘EUR 44 400’;

— in the second subparagraph, ‘EUR 11 000 to EUR 33 000’ is replaced by ‘EUR 11 200 to EUR 33 500’;

— in the third subparagraph, ‘EUR 7 300’ is replaced by ‘EUR 7 400’;