II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2023/699

of 29 March 2023

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 2023

(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 Article 12, fifth paragraph, 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 2022. The inflation rate in the Union, as published by the Statistical Office of the European Union ([3]), was 10,4% in 2022.

(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 2023.

(6) In accordance with Article 12 of Regulation (EC) No 297/95, the update is to be made with effect from 1 April 2023. It is therefore appropriate that this Regulation enters into force as a matter of urgency and applies from that date,

([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).

([3]) https://ec.europa.eu/eurostat/documents/2995521/15725179/2-18012023-AP-EN.pdf/e301db8f-984c-27e2-1245-199a89f37bca

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) point (a) is amended as follows:

— in the first subparagraph, “EUR 313 200” is replaced by “EUR 345 800”;

— in the second subparagraph, “EUR 31 500” is replaced by “EUR 34 800”;

— in the third subparagraph, “EUR 7 800” is replaced by “EUR 8 600”;

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

— in the first subparagraph, “EUR 121 500” is replaced by “EUR 134 100”;

— in the second subparagraph, “EUR 202 500” is replaced by “EUR 223 600”;

— in the third subparagraph, “12 100” is replaced by “EUR 13 400”;

— in the fourth subparagraph, “EUR 7 800” is replaced by “EUR 8 600”;

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

— in the first subparagraph, “EUR 94 000” is replaced by “EUR 103 800”;

— in the second subparagraph, “EUR 23 700 to EUR 70 600” is replaced by “EUR 26 200 to EUR 77 900”;

— in the third subparagraph, “EUR 7 800” is replaced by “EUR 8 600”;

(b) paragraph 2 is amended as follows:

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

— “EUR 3 500” is replaced by “EUR 3 900”;

— “EUR 7 800” is replaced by “EUR 8 600”;

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

— in the first subparagraph, “EUR 94 000” is replaced by “EUR 103 800”;

— in the second subparagraph, “EUR 23 700 to EUR 70 600” is replaced by “EUR 26 200 to EUR 77 900”;

(c) in paragraph 3, “EUR 15 400” is replaced by “EUR 17 000”;

(d) in paragraph 4, first subparagraph, “EUR 23 700” is replaced by “EUR 26 200”;

(e) in paragraph 5, “EUR 7 800” is replaced by “EUR 8 600”;

(f) paragraph 6 is amended as follows:

(i) in the first subparagraph, “EUR 112 200” is replaced by “EUR 123 900”;

(ii) in the second subparagraph, “ EUR 27 900 to EUR 84 100” is replaced by “EUR 30 800 to EUR 92 800”;

(2) in Article 4, first paragraph, “EUR 77 900” is replaced by “EUR 86 000”;

(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 156 700” is replaced by “EUR 173 000”;

— in the second subparagraph, “EUR 15 400” is replaced by “EUR 17 000”;

— in the third subparagraph, “EUR 7 800” is replaced by “EUR 8 600”;

— the fourth subparagraph is amended as follows:

— “EUR 77 900” is replaced by “EUR 86 000”;

— “EUR 7 800” is replaced by “EUR 8 600”;

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

— in the first subparagraph, “EUR 77 900” is replaced by “EUR 86 000”;

— in the second subparagraph, “EUR 132 400” is replaced by “EUR 146 200”;

— in the third subparagraph, “EUR 15 400” is replaced by “EUR 17 000”;

— in the fourth subparagraph, “EUR 7 800” is replaced by “EUR 8 600”;

— the fifth subparagraph is amended as follows:

— “EUR 39 200” is replaced by “EUR 43 300”;

— “EUR 7 800” is replaced by “EUR 8 600”;

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

— in the first subparagraph, “EUR 39 200” is replaced by “EUR 43 300”;

— in the second subparagraph, “ EUR 9 700 to EUR 29 500” is replaced by “EUR 10 700 to EUR 32 600”;

— in the third subparagraph, “EUR 7 800” is replaced by “EUR 8 600”;

(b) paragraph 2 is amended as follows:

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

— “EUR 3 500” is replaced by “EUR 3 900”;

— “EUR 7 800” is replaced by “EUR 8 600”;

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

— in the first subparagraph, “EUR 46 900” is replaced by “EUR 51 800”;

— in the second subparagraph, “EUR 11 800 to EUR 35 400” is replaced by “EUR 13 000 to EUR 39 100”;

— in the third subparagraph, “EUR 7 800” is replaced by “EUR 8 600”;

(c) in paragraph 3, “EUR 7 800” is replaced by “EUR 8 600”;

(d) in paragraph 4, first subparagraph, “EUR 23 700” is replaced by “EUR 26 200”;

(e) in paragraph 5, “EUR 7 800” is replaced by “EUR 8 600”;

(f) paragraph 6 is amended as follows:

(i) in the first subparagraph, “EUR 37 600” is replaced by “EUR 41 500”;

(ii) in the second subparagraph, “EUR 9 200 to EUR 27 900” is replaced by “EUR 10 200 to EUR 30 800”;

(4) in Article 6, first paragraph, “EUR 46 900” is replaced by “EUR 51 800”;

(5) Article 7 is amended as follows:

(a) in the first paragraph, “EUR 77 900” is replaced by “EUR 86 000”;

(b) in the second paragraph, “EUR 23 700” is replaced by “EUR 26 200”;

(6) Article 8 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the second subparagraph, “EUR 94 000” is replaced by “EUR 103 800”;

(ii) in the third subparagraph, “EUR 46 900” is replaced by “EUR 51 800”;

(iii) in the fourth subparagraph, “EUR 23 700 to EUR 70 600” is replaced by “EUR 26 200 to EUR 77 900”;

(iv) in the fifth subparagraph, “EUR 11 800 to EUR 35 400” is replaced by “EUR 13 000 to EUR 39 100”;

(b) paragraph 2 is amended as follows:

(i) in the second subparagraph, “EUR 313 200” is replaced by “EUR 345 800”;

(ii) in the third subparagraph, “EUR 156 700” is replaced by “EUR 173 000”;

(iii) in the fifth subparagraph, “EUR 3 500 to EUR 269 900” is replaced by “EUR 3 900 to EUR 298 000”;

(iv) in the sixth subparagraph, “EUR 3 500 to EUR 135 100” is replaced by “EUR 3 900 to EUR 149 200”;

(c) in paragraph 3, first subparagraph, “EUR 7 800” is replaced by “EUR 8 600”.

Article 2

This Regulation shall not apply to valid applications pending on 1 April 2023.

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 2023.

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

Done at Brussels, 29 March 2023.

For the Commission
The President
Ursula VON DER LEYEN