

COMMISSION REGULATION (EU) 2022/510
of 29 March 2022
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 2022

(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 subparagraph, 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 2020 and 2021. The inflation rate in the Union, as published by the Statistical Office of the European Union ⁽³⁾, was 0,3 % in 2020 and 5,3 % in 2021.
- (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 2022.
- (6) In accordance with Article 12 of Regulation (EC) No 297/95, the update is to be made with effect from 1 April 2022. 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⁾ 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⁾ Eurostat, euroindicators 11/2022, published on 20 January 2022

(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 296 500' is replaced by 'EUR 313 200',
- in the second subparagraph, 'EUR 29 800' is replaced by 'EUR 31 500',
- in the third subparagraph, 'EUR 7 400' is replaced by 'EUR 7 800';

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

- in the first subparagraph, 'EUR 115 100' is replaced by 'EUR 121 500',
- in the second subparagraph, 'EUR 191 700' is replaced by 'EUR 202 500',
- in the third subparagraph, '11 500' is replaced by 'EUR 12 100',
- in the fourth subparagraph, 'EUR 7 400' is replaced by 'EUR 7 800';

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

- in the first subparagraph, 'EUR 89 000' is replaced by 'EUR 94 000',
- in the second subparagraph, 'EUR 22 400 to EUR 66 800' is replaced by 'EUR 23 700 to EUR 70 600',
- in the third subparagraph, 'EUR 7 400' is replaced by 'EUR 7 800';

(b) paragraph 2 is amended as follows:

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

- 'EUR 3 300' is replaced by 'EUR 3 500',
- 'EUR 7 400' is replaced by 'EUR 7 800';

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

- in the first subparagraph, 'EUR 89 000' is replaced by 'EUR 94 000',
- in the second subparagraph, 'EUR 22 400 to EUR 66 800' is replaced by 'EUR 23 700 to EUR 70 600';

(c) in paragraph 3, 'EUR 14 600' is replaced by 'EUR 15 400';

(d) in paragraph 4, first subparagraph, 'EUR 22 400' is replaced by 'EUR 23 700';

(e) in paragraph 5, 'EUR 7 400' is replaced by 'EUR 7 800';

(f) paragraph 6 is amended as follows:

- (i) in the first subparagraph, 'EUR 106 300' is replaced by 'EUR 112 200';
- (ii) in the second subparagraph, 'EUR 26 400 to EUR 79 700' is replaced by 'EUR 27 900 to EUR 84 100';

(2) in Article 4, first subparagraph, 'EUR 73 800' is replaced by 'EUR 77 900';

(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 148 400' is replaced by 'EUR 156 700',
- in the second subparagraph, 'EUR 14 600' is replaced by 'EUR 15 400',
- in the third subparagraph, 'EUR 7 400' is replaced by 'EUR 7 800',
- the fourth subparagraph is amended as follows:
 - 'EUR 73 800' is replaced by 'EUR 77 900',
 - 'EUR 7 400' is replaced by 'EUR 7 800';

- (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 73 800' is replaced by 'EUR 77 900',
 - in the second subparagraph, 'EUR 125 300' is replaced by 'EUR 132 400',
 - in the third subparagraph, 'EUR 14 600' is replaced by 'EUR 15 400',
 - in the fourth subparagraph, 'EUR 7 400' is replaced by 'EUR 7 800',
 - the fifth subparagraph is amended as follows:
 - 'EUR 37 100' is replaced by 'EUR 39 200',
 - 'EUR 7 400' is replaced by 'EUR 7 800';
- (iii) point (c) is amended as follows:
 - in the first subparagraph, 'EUR 37 100' is replaced by 'EUR 39 200',
 - in the second subparagraph, 'EUR 9 200 to EUR 27 900' is replaced by 'EUR 9 700 to EUR 29 500',
 - in the third subparagraph, 'EUR 7 400' is replaced by 'EUR 7 800';
- (b) paragraph 2 is amended as follows:
 - (i) point (a), first subparagraph, is amended as follows:
 - 'EUR 3 300' is replaced by 'EUR 3 500',
 - 'EUR 7 400' is replaced by 'EUR 7 800';
 - (ii) point (b) is amended as follows:
 - in the first subparagraph, 'EUR 44 400' is replaced by 'EUR 46 900',
 - in the second subparagraph, 'EUR 11 200 to EUR 33 500' is replaced by 'EUR 11 800 to EUR 35 400',
 - in the third subparagraph, 'EUR 7 400' is replaced by 'EUR 7 800';
- (c) in paragraph 3, 'EUR 7 400' is replaced by 'EUR 7 800';
- (d) in paragraph 4, first subparagraph, 'EUR 22 400' is replaced by 'EUR 23 700';
- (e) in paragraph 5, 'EUR 7 400' is replaced by 'EUR 7 800';
- (f) paragraph 6 is amended as follows:
 - (i) in the first subparagraph, 'EUR 35 600' is replaced by 'EUR 37 600';
 - (ii) in the second subparagraph, 'EUR 8 700 to EUR 26 400' is replaced by 'EUR 9 200 to EUR 27 900';
- (4) in Article 6, first subparagraph, 'EUR 44 400' is replaced by 'EUR 46 900';
- (5) Article 7 is amended as follows:
 - (a) in the first paragraph, 'EUR 73 800' is replaced by 'EUR 77 900';
 - (b) in the second paragraph, 'EUR 22 400' is replaced by 'EUR 23 700';
- (6) Article 8 is amended as follows:
 - (a) paragraph 1 is amended as follows:
 - (i) in the second subparagraph, 'EUR 89 000' is replaced by 'EUR 94 000';
 - (ii) in the third subparagraph, 'EUR 44 400' is replaced by 'EUR 46 900';
 - (iii) in the fourth subparagraph, 'EUR 22 400 to EUR 66 800' is replaced by 'EUR 23 700 to EUR 70 600';
 - (iv) in the fifth subparagraph, 'EUR 11 200 to EUR 33 500' is replaced by 'EUR 11 800 to EUR 35 400';

(b) paragraph 2 is amended as follows:

- (i) in the second subparagraph, 'EUR 296 500' is replaced by 'EUR 313 200';
 - (ii) in the third subparagraph, 'EUR 148 400' is replaced by 'EUR 156 700';
 - (iii) in the fifth subparagraph, 'EUR 3 300 to EUR 255 500' is replaced by 'EUR 3 500 to EUR 269 900';
 - (iv) in the sixth subparagraph, 'EUR 3 300 to EUR 127 900' is replaced by 'EUR 3 500 to EUR 135 100';
- (c) in paragraph 3, first subparagraph, 'EUR 7 400' is replaced by 'EUR 7 800'.

Article 2

This Regulation shall not apply to valid applications pending on 1 April 2022.

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 2022.

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

Done at Brussels, 29 March 2022.

For the Commission
The President
Ursula VON DER LEYEN
