Commission Regulation (EC) No 249/2009 of 23 March 2009 amending Council Regulation (EC) No 297/95 as regards the adjustment of the fees of the European Medicines Agency to the inflation rate

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 thereof,

Whereas:

(1) Article 67(3) of 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[(2)], stipulates that the revenue of the European Medicines Agency (hereinafter the Agency) shall consist of a contribution from the Community and fees paid by undertakings to the Agency. Regulation (EC) No 297/95 lays down the categories and levels of such fees.

(2) Article 12 of Regulation (EC) No 297/95 lays down that the Commission shall review the fees of the Agency by reference to the inflation rate and update them, with effect from 1 April of each year.

(3) Those fees should therefore be updated by reference to the inflation rate of 2008. The inflation rate in the Community, as published by the Statistical Office of the European Communities (Eurostat), was 3,7 % in 2008.

(4) For the sake of simplicity, the adjusted levels of the fees should be rounded to the nearest EUR 100.

(5) Regulation (EC) No 297/95 should therefore be amended accordingly.

(6) For reasons for legal certainty this Regulation should not apply to valid applications which are pending on 1 April 2009.

(7) Pursuant to Article 12 of Regulation (EC) No 297/95 the update has to be made with effect from 1 April 2009. It is therefore appropriate that this Regulation enters into force as a matter of urgency and applies from that date,

HAS ADOPTED THIS REGULATION:

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 249/2009. (See end of Document for details)*

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 242 600’ is replaced by ‘EUR 251 600’,
- in the second subparagraph, ‘EUR 24 300’ is replaced by ‘EUR 25 200’,
- in the third subparagraph, ‘EUR 6 100’ is replaced by ‘EUR 6 300’;

(ii) point (b) is amended as follows:
- in the first subparagraph, ‘EUR 94 100’ is replaced by ‘EUR 97 600’,
- in the second subparagraph, ‘EUR 156 800’ is replaced by ‘EUR 162 600’,
- in the third subparagraph, ‘EUR 9 400’ is replaced by ‘EUR 9 700’,
- in the fourth subparagraph, ‘EUR 6 100’ is replaced by ‘EUR 6 300’;

(iii) point (c) is amended as follows:
- in the first subparagraph, ‘EUR 72 800’ is replaced by ‘EUR 75 500’,
- in the second subparagraph, ‘EUR 18 200 to EUR 54 600’ is replaced by ‘EUR 18 900 to EUR 56 600’,
- in the third subparagraph, ‘EUR 6 100’ is replaced by ‘EUR 6 300’;

(b) paragraph 2 is amended as follows:

(i) the first subparagraph of point (a) is amended as follows:
- ‘EUR 2 600’ is replaced by ‘EUR 2 700’,
- ‘EUR 6 100’ is replaced by ‘EUR 6 300’;

(ii) point (b) is amended as follows:
- in the first subparagraph, ‘EUR 72 800’ is replaced by ‘EUR 75 500’,
- in the second subparagraph, ‘EUR 18 200 to EUR 54 600’ is replaced by ‘EUR 18 900 to EUR 56 600’;

(c) in paragraph 3, ‘EUR 12 100’ is replaced by ‘EUR 12 500’;

(d) in paragraph 4, ‘EUR 18 200’ is replaced by ‘EUR 18 900’;

(e) in paragraph 5, ‘EUR 6 100’ is replaced by ‘EUR 6 300’;

(f) paragraph 6 is amended as follows:

(i) in the first subparagraph, ‘EUR 87 000’ is replaced by ‘EUR 90 200’;

(ii) in the second subparagraph, ‘EUR 21 700 to EUR 65 200’ is replaced by ‘EUR 22 500 to EUR 67 600’.

2. in Article 4, ‘EUR 60 600’ is replaced by ‘EUR 62 800’.

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 121 300’ is replaced by ‘EUR 125 800’,
— in the second subparagraph, ‘EUR 12 100’ is replaced by ‘EUR 12 500’,
— in the third subparagraph, ‘EUR 6 100’ is replaced by ‘EUR 6 300’,
— the fourth subparagraph is amended as follows:
— ‘EUR 60 600’ is replaced by ‘EUR 62 800’
— ‘EUR 6 100’ is replaced by ‘EUR 6 300’;

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 60 600’ is replaced by ‘EUR 62 800’,
— in the second subparagraph, ‘EUR 102 500’ is replaced by ‘EUR 106 300’,
— in the third subparagraph, ‘EUR 12 100’ is replaced by ‘EUR 12 500’,
— in the fourth subparagraph, ‘EUR 6 100’ is replaced by ‘EUR 6 300’,
— the fifth subparagraph is amended as follows:
— ‘EUR 30 300’ is replaced by ‘EUR 31 400’
— ‘EUR 6 100’ is replaced by ‘EUR 6 300’;

(iii) point (c) is amended as follows:
— in the first subparagraph, ‘EUR 30 300’ is replaced by ‘EUR 31 400’,
— in the second subparagraph ‘EUR 7 500 to EUR 22 700’ is replaced by ‘EUR 7 800 to EUR 23 500’,
— in the third subparagraph, ‘EUR 6 100’ is replaced by ‘EUR 6 300’,

(b) Paragraph 2 is amended as follows:

(i) in point (a) ‘EUR 2 600’ is replaced by ‘EUR 2 700’ and ‘EUR 6 100’ is replaced by ‘EUR 6 300’;

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 36 400’ is replaced by ‘EUR 37 700’,