Commission Regulation (EC) No 312/2008 of 3 April 2008 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.

(3) Since 2005, the fees of the Agency have not been adjusted to the inflation rate. It is therefore necessary to review those fees by reference to the inflation rate in the Community in the years 2006 and 2007.

(4) The inflation rate in the Community, as published by the Statistical Office of the European Communities (Eurostat), was 2,2 % in 2006 and 2,3 % in 2007.

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

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

(7) For reasons for legal certainty this Regulation should not apply to valid applications which are pending on 1 April 2008.

(8) Pursuant to Article 12 of Regulation (EC) No 297/95 the update has to be made with effect from 1 April 2008, it is therefore appropriate that this Regulation enter into force as a matter of urgency and apply from that date,

HAS ADOPTED THIS REGULATION:

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 312/2008. (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 232 000’ is replaced by ‘EUR 242 600’,
- in the second subparagraph, ‘EUR 23 200’ is replaced by ‘EUR 24 300’,
- in the third subparagraph, ‘EUR 5 800’ is replaced by ‘EUR 6 100’;

(ii) point (b) is amended as follows:
- in the first subparagraph, ‘EUR 90 000’ is replaced by ‘EUR 94 100’,
- in the second subparagraph, ‘EUR 150 000’ is replaced by ‘EUR 156 800’,
- in the third subparagraph, ‘EUR 9 000’ is replaced by ‘EUR 9 400’,
- in the fourth subparagraph, ‘EUR 5 800’ is replaced by ‘EUR 6 100’;

(iii) point (c) is amended as follows:
- in the first subparagraph, ‘EUR 69 600’ is replaced by ‘EUR 72 800’,
- in the second subparagraph, ‘EUR 17 400 to EUR 52 200’ is replaced by ‘EUR 18 200 to EUR 54 600’,
- in the third subparagraph, ‘EUR 5 800’ is replaced by ‘EUR 6 100’.

(b) Paragraph 2 is amended as follows:

(i) the first subparagraph of point (a) is amended as follows:
- ‘EUR 2 500’ is replaced by ‘EUR 2 600’,
- ‘EUR 5 800’ is replaced by ‘EUR 6 100’;

(ii) point (b) is amended as follows:
- in the first subparagraph, ‘EUR 69 600’ is replaced by ‘EUR 72 800’,
- in the second subparagraph, ‘EUR 17 400 to EUR 52 200’ is replaced by ‘EUR 18 200 to EUR 54 600’.

(c) In paragraph 3, ‘EUR 11 600’ is replaced by ‘EUR 12 100’.

(d) In paragraph 4, ‘EUR 17 400’ is replaced by ‘EUR 18 200’.

(e) In paragraph 5, ‘EUR 5 800’ is replaced by ‘EUR 6 100’.

(f) Paragraph 6 is amended as follows:

(i) in the first subparagraph, ‘EUR 83 200’ is replaced by ‘EUR 87 000’;

(ii) in the second subparagraph, ‘EUR 20 800 to EUR 62 400’ is replaced by ‘EUR 21 700 to EUR 65 200’.

2. In Article 4, ‘EUR 58 000’ is replaced by ‘EUR 60 600’.

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 116 000’ is replaced by ‘EUR 121 300’,
— in the second subparagraph, ‘EUR 11 600’ is replaced by ‘EUR 12 100’,
— in the third subparagraph, ‘EUR 5 800’ is replaced by ‘EUR 6 100’,
— the fourth subparagraph is amended as follows:
— ‘EUR 58 000’ is replaced by ‘EUR 60 600’,
— ‘EUR 5 800’ is replaced by ‘EUR 6 100’;

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 58 000’ is replaced by ‘EUR 60 600’,
— in the second subparagraph, ‘EUR 98 000’ is replaced by ‘EUR 102 500’,
— in the third subparagraph, ‘EUR 11 600’ is replaced by ‘EUR 12 100’,
— in the fourth subparagraph, ‘EUR 5 800’ is replaced by ‘EUR 6 100’,
— the fifth subparagraph is amended as follows:
— ‘EUR 29 000’ is replaced by ‘EUR 30 300’,
— ‘EUR 5 800’ is replaced by ‘EUR 6 100’;

(iii) point (c) is amended as follows:
— in the first subparagraph, ‘EUR 29 000’ is replaced by ‘EUR 30 300’,
— in the second subparagraph ‘EUR 7 200 to EUR 21 700’ is replaced by ‘EUR 7 500 to EUR 22 700’,
— in the third subparagraph, ‘EUR 5 800’ is replaced by ‘EUR 6 100’.

(b) Paragraph 2 is amended as follows:

(i) in point (a) ‘EUR 2 500’ is replaced by ‘EUR 2 600’ and ‘EUR 5 800’ is replaced by ‘EUR 6 100’;

(ii) point (b) is amended as follows:
— in the first subparagraph, ‘EUR 34 800’ is replaced by ‘EUR 36 400’,