COMMISSION REGULATION (EC) No 494/2003

of 18 March 2003

amending Council Regulation (EC) No 297/95 on the fees payable to the European Agency for the Evaluation of Medicinal Products

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], as amended by Regulation (EC) No 2743/98 [2], and in particular Article 12 thereof,

Whereas:

(1) On the basis of Article 57(1) of Council Regulation (EEC) No 2309/93 of 22 July 1993, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [3], as last amended by Commission Regulation (EC) No 649/98 [4], the revenues of the Agency consist of a contribution and the fees paid by undertakings for obtaining and maintaining a Community marketing authorisation and for other services provided by the Agency.

(2) The Agency derives the majority of its revenue from fees.

(3) Since the 1998 reform of the fee system, the Agency has faced a relative decline in fee revenue due to inflation, while the prevailing market conditions have led to a rise in its expenditure.

(4) Figures from the Statistical Office of the European Communities (Eurostat) support the necessity for an increase in all fees by 10 % in order to arrive at the same level of purchasing power as was the case for the fees set in 1998.

(5) In view of the difficult economic conditions that the Agency has had to face and which are affecting its revenue and putting at risk the maintenance of its resource infrastructure and therefore its ability to carry out its tasks, an additional adjustment of all fees, except the annual fee, of 6 % is necessary.

(6) In view of the growing importance of post-authorisation surveillance activities in the work of the Agency and in order to improve the capacity of the Community to identify and manage risks arising from the use of, in particular, innovative medicines, the annual fee should be adjusted by 16 %.

(7) The general principles and overall structure of the fees will be reviewed in the context of a general reflection on the fee system, and in particular, on the basis of the modification of Council Regulation (EEC) No 2309/93, once adopted. These new amounts will therefore be applied during a limited period of time.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committees,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 297/95 is amended as follows:

1. Article 3 is amended as follows:

(a) in the first subparagraph of paragraph 1(a), 'ECU 200 000' is replaced by 'EUR 232 000';

(b) in the second subparagraph of paragraph 1(a), 'ECU 20 000' is replaced by 'EUR 23 200';

(c) in the third subparagraph of paragraph 1(a), 'ECU 5 000' is replaced by 'EUR 5 800';

(d) in the first subparagraph of paragraph 1(b), 'ECU 100 000' is replaced by 'EUR 116 000';

(e) in the second subparagraph of paragraph 1(b), 'ECU 20 000' is replaced by 'EUR 23 200';

(f) in the third subparagraph of paragraph 1(b), 'ECU 5 000' is replaced by 'EUR 5 800';

(g) in the first subparagraph of paragraph 1(c), 'ECU 50 000' is replaced by 'EUR 58 000';

(h) in the second subparagraph of paragraph 1(c), 'ECU 10 000' is replaced by 'EUR 11 600';

(i) in the first subparagraph of paragraph 2(a), 'ECU 5 000' is replaced by 'EUR 5 800';

(j) in the first subparagraph of paragraph 2(b), 'ECU 60 000' is replaced by 'EUR 69 600';

(k) in paragraph 3, 'ECU 10 000' is replaced by 'EUR 11 600';

(l) in paragraph 4, 'ECU 15 000' is replaced by 'EUR 17 400';

(m) in paragraph 5, 'ECU 5 000' is replaced by 'EUR 5 800';

(n) in paragraph 6, 'ECU 60 000' is replaced by 'EUR 75 600'.

[1] OJ L 35, 15.2.1995, p. 1.
[2] OJ L 345, 19.12.1998, p. 3.
[3] OJ L 214, 24.8.1993, p. 1.
[4] OJ L 88, 24.3.1998, p. 7.