COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11.11.1998
COM(1998) 648 final

98/0135 (CNS)

Amended proposal for a

COUNCIL REGULATION (EC)

AMENDING REGULATION (EC) No 297/95 ON FEES PAYABLE TO THE EUROPEAN AGENCY FOR THE EVALUATION OF MEDICINAL PRODUCTS

(presented by the Commission pursuant to Article 189 a (2) of the EC-Treaty)

Explanatory Memorandum

On 7 October 1998 the European Parliament adopted an opinion on the proposal for a Council Regulation on fees payable to the European Agency for the evaluation of medicinal products.

The Commission accepted amendments 10, 11 and 16. In addition, the Commission is also incorporating in this proposal - already partially amended or subject to possible amendment - the following amendments: amendment 12 (in the event of the fee being increased on initiation of the arbitration procedure in respect of a marketing authorisation for a veterinary medicinal product, such an increase is to remain pegged within a ceiling of ECU 20 000), amendment 13 (any increase in the additional fee for an application to amend or extend an existing MLR is to remain pegged within a ceiling of ECU 15 000) and amendment 14 (introduction of the principle of maximum fees for applications for scientific advice).

The Commission has not adopted amendments 1 to 9 for the following reasons:

Amendment 1 — The Commission is opposed to a change in the legal basis of the proposed text, on the grounds that the derived legal basis (Article 10 of Regulation (EC) No 297/95) is perfectly appropriate. The Commission would also stress that the principle of consulting the European Parliament was preserved at its request, when the derived legal basis was introduced.

Amendments 2,3,5,6 and 7 — These amendments do not specifically concern the levels and structure of the fees payable to the European Agency for the evaluation of medicinal products but refer to the budget rules applicable to the Agency. Furthermore, these aspects are also the subject of a draft horizontal regulation covering all agencies currently under discussion.

Amendment 4 — The replacement of the ecu by the euro throughout all Community texts will need to be the subject of a horizontal text.

Amendments 8 and 9 — The Commission is opposed to the reintroduction of ceilings for fees directly linked to the granting of marketing authorisations under the centralised procedure. These ceilings cannot be justified either in terms of the service provided by the Agency or on public health grounds. Indeed, the principles governing the rational use of medicinal products preclude the proliferation of different pharmaceutical forms of the same medicinal product.

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ON FEES PAYABLE TO THE EUROPEAN AGENCY
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Following the opinion of the European Parliament of 7 October 1998, the initial Commission proposal (COM (1998) 21 final) is hereby amended as follows:

Original text	Amended text

ARTICLE 1, POINT 2

Article 3(2), point a), single subparagraph a) (new) (Regulation (EC) No 297/95)

	In the event of the same amendment being introduced, this fee shall cover all authorised strengths, pharmaceutical forms and presentations.

ARTICLE 1, POINT 2

Article 3(2), point b), single subparagraph a) (new) (Regulation (EC) No 297/95)

	In the event of the same amendment being introduced, this fee shall cover all authorised strengths, pharmaceutical forms and presentations.

ARTICLE 1, POINT 2

Article 5(2), point a), single subparagraph a) (new) (Regulation (EC) No 297/95)

	In the event of the same amendment being introduced, this fee shall cover all authorised strengths, pharmaceutical forms and presentations.

ARTICLE 1, POINT 2

Article 5(2), point b), third subparagraph (new) (Regulation (EC) No 297/95)

In the event of the same amendment being introduced, this fee shall cover all authorised strengths, pharmaceutical forms and presentations.