

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(95) 27 final
Brussels, 03.02.1995

94/ 0220 (CNS)

Amended proposal for a

COUNCIL REGULATION (EC)

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 19 January 1995 the European Parliament adopted an opinion on the proposal for a Council Regulation on the fees payable to the European Agency for the Evaluation of Medicinal Products.

Four amendments to the Commission's original proposal were adopted on that occasion. The Commission agrees to incorporate Amendment 2, which requires that forecasts of fees payable the following financial year should be entered in the annual estimate adopted by the Agency's Management Board pursuant to Article 57(5) of Regulation No 2309/93.

The Commission agrees to incorporate part of Amendment 1, namely that any surpluses in the Agency's budget should accrue to the Community budget. Accordingly, the Commission proposes to include in the Regulation a provision stating that these surpluses shall be deducted from the Community contribution. The Commission also proposes to consider whether any surpluses could be used to repay previous subsidies.

On the other hand, the Commission can not accept Amendments 3 and 4 requiring use of the procedure defined in Article 189b of the EC Treaty for any amendments to the Regulation, on the grounds that use of this procedure would not allow the amount of fees to be adjusted rapidly in the light of experience and the actual needs of the Agency. In this connection, the Commission would emphasize the temporary nature of the Regulation currently under discussion; in fact, it is planning to come up with a new proposal in the course of 1997, on which Parliament will be consulted.



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FOR THE EVALUATION OF MEDICINAL PRODUCTS**

Following the opinion of the European Parliament given on 19 January 1995, the following new Article is added to the Commission's original proposal (COM)(94) 0167):

Article 1b

1. The Agency shall enter, in its annual estimate for the Commission's preliminary draft budget, forecasts of fees payable the following financial year separately from total estimated expenditure and any Community contribution.
2. Any surpluses from fees shall be used to reduce the Community contribution.

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