COMMISSION OF THE EUROPEAN COMMUNITIES

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Amendment to the proposal for a Council Directive on the approximation of the laws of Member States relating to veterinary medicinal products

Amendment to the proposal for a Council Directive on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products

(presented by the Commission to the Council pursuant to the second paragraph of article 149 of the EEC Treaty)

EXPLANATORY MEMORANDUM

1. 13 May 1976 the Commission submitted to the Council two proposals for directives relating to veterinary medicinal products (OJEC C/152 of 5 July 1976).

2. According to Article 100 of the Treaty the Economic and Social Committee and the European Parliament have each adopted an opinion on the two proposals, respectively on 28 October 1976 (doc. CES 1066/76 of 28 October 1976) and on 19 November 1976 (doc. 1327/76 (ASS 853) of 24 November 1976). In the opinions a number of amendments have been proposed.

3. The Commission has followed the opinions by amending the proposals for directives in the following cases :

   I. Proposals for a Council Directive on the approximation of the laws of Member States relating to veterinary medicinal products :

   - Article 13
   - Article 14
   - Article 15
   - Article 33
   - Article 43

   II. Proposal for a Council Directive on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products :

   - Article 2

Amendment to the proposal for a Council Directive on the approximation of the laws of Member States relating to veterinary medicinal products

1. The eighth recital is amended as follows :
"Whereas it is advisable, in order gradually to achieve freedom of movement of veterinary medicinal products, to facilitate the granting of marketing authorizations in the Member States for one and the same medicinal product;"

2. The tenth recital is amended as follows :
"Whereas, to achieve freedom of movement of veterinary medicinal products, further measures will prove necessary in the light of experience gained, especially within the said Committee;"

3. The first paragraph of Article 13 is amended as follows :
"The person responsible for marketing shall adapt the test method provided for in 9 of the second paragraph of Article 4, in accordance with the advancement of technology and the progress of science if such adaptation allows more reliable testing of the medicinal product."

4. Article 14 is amended as follows :
" Authorization shall be valid for five years and shall be renewable for five-year periods, on application by the holder at least three months before the date of expiry, in accordance with the provisions of Article 13."

5. The second paragraph of Article 15 is amended as follows :
"The Committee shall, when so requested by a Member State, examine questions relating to the implementation of Articles 10, 26 and 40, in accordance with Articles 16 to 21."

6. Item 7 of the first paragraph of Article 33 is amended as follows :
"if necessary, the delay;"

7. The second paragraph of Article 43 is amended as follows :
"The other provisions of this Directive shall be applied progressively, within five years of its entry into force, to veterinary medicinal products placed on the market by virtue of previous provisions."

.../...

Amendment to the proposal for a Council Directive on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products

1. The ninth recital is deleted.

2. Article 2 is amended as follows :

"The Pharmaceutical Committee set up by the Council Decision of 20 May 1975 (75/320/EEC) may examine any question relating to the application of this Directive which is brought up by its chairman, either on his own initiative or at the request of the representative of a Member State."