COMMISSION OF THE EUROPEAN COMMUNITIES

COM(80) 922 final

Brussels, 6th January 1981

PROPOSAL FOR A COUNCIL REGULATION (EEC)

laying down conditions for controlling the possession, distribution and administration to animals of certain substances with a hormonal action

(presented by the Commission to the Council)

COM(80) 922 final

EXPLANATORY MEMORANDUM

This proposal for a Council Regulation has been drawn up in implementation of Article 4 of the proposal for a Council Regulation (EEC) of ..... concerning the use of substances with a hormonal action and those having a thyrostatic action in domestic animals. The Article in question establishes the principle that natural hormonal substances may be used, on certain conditions, for therapeutic purposes and for oestrus synchronization in domestic animals; it also provides a proposal from the Commission to the Council on the conditions for controlling the possession, distribution and use of such substances.

This proposal for a Regulation lists the substances with an oestrogenic, androgenic or gestagenic action which may be used. The list may be amended according to the Standing Veterinary Committee procedure; the desirability of an amendment must be evaluated in the light of the interest afforded by the use of the substance for therapeutic purposes in animals and the effects of such use on consumers' health.

To avoid differing interpretations giving rise to misuse of these substances the concept of "therapeutic treatment" has been defined. The proposed definition confines the possibility of administering the substances to pathological cases diagnosed by a veterinarian; prophylactic use is therefore ruled out.

The proposed text institutes a system of control covering the stage of possession of substances with a hormonal action likely to be used for the preparation of medicinal products, whether for use in animals or in humans, and the various stages of manufacture, storage and distribution of veterinary medicinal products prepared for hormonal substances. For instance, provision is made for the keeping of registers, so that, at each stage, a record is available of the quantities produced and transmitted; in this way it will be possible to guard against excessive quantities of such products being marketed. Similarly the text spells out the conditions for retail dispensing and the administration of such medicinal products to animals.

To maintain effective control over the substances and medicinal products intended for the treatment of domestic animals of species whose meat is sold for human consumption, it is necessary to include under the system of control products which are intended for the treatment of animals of other species.

In the proposal for a Council Regulation (EEC) of ..... on the use of substances with a hormonal action and those having a thyrostatic action in domestic animals, and in the present proposal, reference is sometimes made to provisions contained in the proposal for a directive on veterinary medicinal products which is currently before the Council. This lays down the conditions for the marketing of veterinary medicinal products and their import into the Community. Its adoption is therefore also a matter of urgency.

Proposal

for a

COUNCIL REGULATION

laying down conditions for controlling the possession, distribution and administration to animals of certain substances with a hormonal action.

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community and in particular Article 43 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committée,

Having regard to the Council Regulation of ..... concerning the use of substances with a hormonal action and those having a thyrostatic action in domestic animals, and in particular Article 4 thereof,

Whereas Article 4 of the abovementioned Council Regulation provides that a list of substances with a hormonal action suitable for the therapeutic treatment of domestic animals should be drawn up; whereas decisions to amend the initial list should be taken under a procedure assuring close collaboration between the Member States and the Commission; whereas the desirability of such amendments must be assessed in the light of certain criteria, such as the interest afforded by the use of a substance for therapeutic purposes and the effects of such use on consumer health;

Whereas the meaning placed on the term "therapeutic treatment" should be defined, to prevent differing interpretations leading to misuse of veterinary medicinal products prepared from certain substances with an oestrogenic, androgenic or gestagenic action; whereas the administration of such medicinal products must be limited to pathological cases and synchronization of oestrus;

Whereas a system of control must be instituted, covering not only the various stages of manufacture, storage and distribution of veterinary medicinal products prepared from substances with a hormonal action but also the possession and the importation from non-member countries of substances with a hormonal action likely to be used for the preparation of medicinal products; whereas in order to be effective the system of control must also cover products intended for the treatment of other animal species;

Whereas it will be possible to help prevent misuse of such substances by providing that the dispensing of veterinary medicinal products prepared from substances with a hormonal action must be subject to presentation of a veterinary prescription, that a register must be kept by veterinarians, and that the administration of these medicinal products to animals must be accomplished by the veterinarians themselves or under their supervision and on their responsibility;

HAS ADOPTED THIS REGULATION :

Article 1

This Regulation lays down conditions for controlling the possession, distribution and administration to animals of certain substances with a hormonal action, whether manufactured in the Community or imported from non-member countries.

Article 2

For the purposes of this Regulation the following definitions shall apply :

(a) domestic animals : animals of the bovine species, swine, sheep, goats, domestic solipeds and poultry;

(b) animals : animals belonging to the species listed in (a) and other species likely to be treated with the substances with a hormonal action covered by this Regulation;

(c) therapeutic use : the administration to a domestic animal as defined in (a) of a medicinal product prepared from a substance listed in Article 5 with a view to remedying a pathological condition established after examination by a veterinarian authorized to practise his profession.

Article 3

1. (a) Substances with an oestrogenic, androgenic or gestagenic activity suitable for use in the preparation of medicinal products shall be supplied solely to natural or legal persons properly authorized to be in possession of such substances under the national laws of the Member States.

(b) Legal or natural persons manufacturing, importing from non-member countries or having in their possession substances as referred to in (a) shall record each day in a register, in chronological order and in respect of each substance, the following information :

- the quantities manufactured, imported, used or transmitted;
- the origin of the substances;
- the names and addresses of the natural or legal persons who supplied the substances and those of the persons to whom they were transmitted;
- the intended use of the substances transmitted.

2. Natural or legal persons manufacturing veterinary medicinal products from substances with a hormonal action as referred to in paragraph 1(a) or importing such medicinal products from non-member countries shall, without prejudice to the provisions of paragraph 1(b), keep a register in which they shall enter each day, in chronological order and in respect of each medicinal product, the following information :
   - the quantities manufactured, imported or transmitted;
   - the names and addresses of the natural or legal persons who supplied the veterinary medicinal products and those of the persons to whom they were transmitted.

3. The storage and wholesale distribution of the veterinary medicinal products referred to in paragraph 2, and the retail dispensing thereof, shall be accomplished only by natural or legal persons authorized to do so by the competent authority of the Member State. Such persons shall keep a register in which they shall enter each day, in chronological order and in respect of each medicinal product, the following information :
   - the origin of the medicinal products;
   - the quantities imported or transmitted;
   - the names and addresses of the natural or legal persons who supplied the veterinary medicinal products and those of the persons to whom they were transmitted.

4. Retail dispensing of the veterinary medicinal products referred to in paragraph 2 shall be accomplished only against presentation of a prescription made out by a veterinarian properly authorized to practise his profession. Such a prescription shall also be required for veterinary medicinal products supplied by veterinarians authorized to dispense such medicinal products to the retail customer in accordance with paragraph 3.

5. The veterinarian shall prescribe the veterinary medicinal products referred to in paragraph 2 solely for the animals he is treating and solely in the quantities required to attain the purpose of the treatment. A veterinarian's prescription shall be valid for only one act of dispensing.

6. Veterinarians shall record and keep up to date the following information relation to the treatments carried out with the abovementioned medicinal products : date of administration, nature and quantity of the medicinal product, disease diagnosed or nature of treatment, name and address of the owner of the treated animal, identification of the animal.

Article 4

The registers referred to in Article 3 shall be available at all times for consultation by the competent inspection authorities and shall be kept for at least one year.

Article 5

1. Within the meaning of Article 4 of the Council Regulation (EEC) of ..... concerning the use of substances with a hormonal action and those having a thyrostatic action in domestic animals, the substances with a hormonal action which may be administered to domestic animals for individual therapeutic use and for synchronization of oestrus shall be as follows :

17 oestradiol and its esters
progesterone
testosterone

This list may be amended in accordance with the procedure laid down in Article 10. In order to decide whether a substance with a hormonal action may be included in the list the following points shall be taken into account :

- the interest afforded by the use of the substance for therapeutic purposes in domestic animals;
- the effefts of the use of the substance on the health of consumers, having regard to the time required for its elimination from the body of the domestic animal, the persistance or absence of residues in the meat and the existence of routine methods for detecting and quantitatively determining any residues;

2. Therapeutic use of such substances shall be permitted only in the case of domestic animals having reached sexual maturity.

Article 6

1. Without prejudice to Article 9 of the Council Regulation referred to in Article 5 above the manufacture of veterinary medicinal products for use in domestic animals from substances with an oestrogenic, androgenic or gestagenic action not listed in Article 5, or the possession of such products or the importing thereof from non-member countries, shall be prohibited.

However, the manufacture of such medicinal products for export to non-member countries may be authorized by the competent authorities of the Member State concerned. In such cases the Member State shall take all necessary measures to control the manufacture, possession and transport of the medicinal products to ensure that they cannot in any circumstances be used on the territory of the Community.

2. The veterinary medicinal products intended for administration to domestic animals and prepared from substances with a hormonal action listed in Article 5 may be marketed only in a form which precludes oral administration.

3. The packaging of the medicinal products referred to in 2. shall include a leaflet bearing the instructions provided for in the Council Directive of ..... on the harmonization of the laws of the Member States relating to veterinary medicinal products, and in particular the specification of the waiting period, even if it is nil, to be observed between the last administration of the medicinal product to the domestic animal in normal conditions of use and the slaughter of the animal to ensure that the meat contains no residues potentially hazardous to consumer health.

Article 7

1. Where the veterinarian's prescription provided for in Article 3(4) concerns domestic aniamls it must be made out in duplicate; one copy shall be kept by the supplier of the veterinary medicinal product and the other by the holder of the domestic animal to which the veterinary medicinal product will be administered.

On the prescription the veterinarian shall state the name and address of the holder of the domestic animal. On the copy of the prescription intended for the owner he shall also state the identification of the domestic animal, the date of administratic of the medicinal product and, on the basis of the information contained, in the leaflet provided for in Article 6.2., the waiting period to be observed before the animal may be slaughtered.

2. The holder of the domestic animal shall keep the prescription for 3 months from the date of issue and he must have it available for consultation by the competent inspection authorities at all times.

3. If the domestic animal is transferred to a new holder during the period of 3 months provided for in paragraph 2, the former holder shall hand over to the new holder the copy of the prescription provided for in paragraph 1; the new holder must keep the prescription until the end of this period.

4. During the waiting period referred to in paragraph 1 the domestic animal may not be slaughtered for human consumption.

Article 8

Veterinary medicinal products prepared from substances with a hormonal action listed in Article 5 shall be administered to domestic animals by the veterinarians themselves; for the purpose of oestrus synchronization they shall be administered by the veterinarians themselves or under their responsibility.

Article 9

The competent authorities of the Member States shall conduct inspections to ensure that the provisions of this Regulation are complied with.

Inspections shall be performed by representatives of the competent authorities in particular at the following stages :

- manufacture, importation and possession of substances with a hormonal action as referred to in Article 3(1);
- manufacture, importation, storage, wholesale distribution, retail dispensing and utilization of the medicinal products referred to in Article "(2).

Article 10

1. Where the procedure laid down in this Article is to be used, the matter shall be referred without delay to the Standing Veterinary Committee (hereinafter referred to as 'the Committee'), set up by the Council Decision of 15 October 1968, by the chairman, either on his own initiative or at the request of the Member State.

2. Within the Committee, the votes of the Member States shall be weighted as provided in Article 148(2) of the Treaty. The chairman shall not vote.

3. The Commission representative shall submit a draft of the measures to be adopted. The Committee shall deliver its opinion on the measures within a period to be determined by the chairman in keeping with the urgency of the question submitted for examination. Opinions shall be delivered by a majority of 45 votes.

4. The Commission shall adopt the measures and shall implement them immediately, where they are in accordance with the opinion of the Committee. Where they are not in accordance with the opinion of the Committee or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal on the measures to be adopted. The Council shall adopt the measures by a qualified majority.

If the Council has not adopted any measures within 3 months from the date on which the proposal was submitted to it, the Commission shall adopt the proposed measures and apply them immediately.

Article 11

This Regulation shall enter into force on .....

This Regulation shall be binding in its entirety and directly applicable in all Member States.