COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT

pursuant to Article 149.2(b) of the EEC Treaty

Common positions of the Council on two proposals relating to veterinary medicinal products.

Proposal for a Council Directive amending Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products (SYN 189).

Proposal for a Council Directive extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products (SYN 190).

COMMUNICATION OF THE COMMISSION TO THE PARLIAMENT

Subject : Common positions of the Council on two proposals relating to veterinary medicinal products.

On 10 January 1989, the Commission transmitted to the Council a package of proposals relating to veterinary medicinal products (COM (88) 779 final), including two coming under the scope of the cooperation procedure;

a) a proposal for a Council Directive amending Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products (SYN 189);

b) a proposal for a Council Directive extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products (SYN 190).

Following the opinions of the European Parliament, given on March 1990, the Commission amended the two proposals on 26 April 1990 (COM (90) 135 final).

On 26 June 1990, the Council adopted common positions in respect of the two proposals.

The main points on which the Council's common positions differ from the Commission proposal are outlined below.

1. Proposal for a Council Directive amending Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products (SYN 189);

1.1 Scope of the Directive (Article 1(1))

Because of fears of creating a legal vacuum between Directive 81/851/EEC and Directive 70/524/EEC on additives for animal feedingstuffs, the Council has not accepted the proposal in Article 1(1) to amend the definition of a veterinary medicinal product. Instead, in a minutes statement, the Commission is requested to take whatever measures necessary to clarify the borderline between the two directives.

1.2 Substances used in veterinary medicinal products subject to special controls (Art. 1(2))

The Council has changed the drafting of this amendment to Article 1(5) of Directive 81/851/EEC in order to clarify the list of substances to be subject to special controls.

For drafting reasons, the last sub-paragraph has been transferred to Article 52.

1.3 Marketing authorization for veterinary medicinal products (Article 1(4))

A number of detailed changes have been made to this amendment to Article 4 of Directive 81/851/EEC, in order to:

- specify the conditions under which Member States may grant emergency marketing authorizations;
- clarify the criteria according to which veterinary medicines are to be available on prescription only;
- clarify the scope of the exception allowing for the conduct of clinical trials;
- restrict the circumstances under which veterinarians may have recourse to non-authorized medicinal products in order to treat animals under their care;
- provide for proper control of veterinarians providing trans-frontier services.

1.4 Documentation accompanying applications for authorization (Article 1 (5))

The Council has changed paragraph 8 of this amendment to Article 5 of Directive 81/851/EEC in order to require applicants to submit details of a routine method of analysis which can be used by the public authorities to detect residues. A new paragraph 9a in Article 1 of the proposal requires the applicant to submit any samples necessary for the verification of the method, and a new paragraph in Article 1 (10) provides for the updating of the method, when necessary.

In addition, the Council has amended paragraph 10, concerning the duration of the period of protection to be given to the manufacturers of innovatory products in order to align veterinary medicines legislation with the rules laid down for medicinal products for human use in Article 4 point 8 of Directive 65/65/EEC as amended by Directive 87/21/EEC.

1.5 The Committee for Veterinary Medicinal products (Article 1(11)

The Council has extended the scope of the amendments proposed to Article 16 concerning the publication of details of the members of the CVMP and the maintenance of a register of interests, to cover the case of experts who may attend CVMP meetings on an occasional basis, but are not members of the Committee.

Bearing in mind that the Commission is expected to bring forward comprehensive proposals shortly for the establishment of a future system for the authorization of medicinal products in the Community and for the establishment of a European Medicines Evaluation Agency, the Council has deleted the proposed amendment to Article 22 (3) of Directive 81/851/EEC which would have made compliance with CVMP opinions compulsory for Member States and has aligned the procedure on the corresponding provisions of Directive 75/319/EEC as amended by Directive 83/570/EEC relating to medicinal products for human use.

1.6 Veterinary medicinal products in transit (Article 1 (12a))

The Council has inserted a new clause to ensure the appropriate supervision of veterinary medicinal products in transit.

1.7 Veterinary pharmacovigilance (Article 1 (17a))

A new paragraph 17a has been inserted in Article 1 to encourage the reporting of adverse reactions to veterinary medicines by veterinarians.

1.8 Supervision of distribution (Article 1 (18))

The terms of Article 39 of Directive 81/851/EEC have been amended to require Member states to exchange the information necessary to ensure that the new distribution requirements contained in Chapter VIII of the Directive are complied with.

1.9 Labelling of veterinary medicinal products (Article 1 (20))

The drafting of this amendment to Article 43 of Directive 81/851/EEC has been changed to align it with the corresponding provisions relating to medicinal products for human use.

1.10 Package leaflets (Article 1 (21))

A minor drafting change has been made to clarify the linguistic requirements for package leaflets.

1.11 Distribution of veterinary medicinal products (Article 1 (22))

Although the Council has accepted the principles underlying the proposal to insert a new Chapter in Directive 81/851/EEC dealing with controls on the distribution of veterinary medicinal products, the Council has made a number of detailed changes in order to strike the correct balance between ensuring appropriate controls on veterinary distribution, but avoidung unnecessarily onerous record keeping requirements. In addition, the Council has inserted a new Article covering record keeping requirements for farmers.

Although it considered that it was not possible, at present, to adopt agreed Community lists of medicines available with or without prescription, in a minutes statement, the Council has requested the Commission to consider this as a matter of urgency, once it has received the necessary information from the Member States.

The Commission can accept the Council's common position.

2. **Proposal for a Council Directive extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products (SYN 190).**

2.1 Autogenous vaccines

The Council has altered the terms of Article 1(3) to allow Member States to exempt non-inactivated autogenous vaccines, which are not traded within the Community from the requirement to obtain authorization.

2.2 Batch testing of immunological veterinary medicines

The Council has changed the terms of Article 3(3) in order to allow Member states to carry out further tests on batches of products which have already tested in one Member State, if these additional tests are necessary because of differences in veterinary conditions. In order to ensure that this provision is not abused, the Commission is to be informed each time additional tests are required.

2.3 Restrictions on the use of immunological veterinary medicines

For drafting reasons, the Council has merged the text of subparagraphs (a) and (c).

2.4 Application of the Directive to existing products

Because of the very large number of products to be reviewed, in excess of 500 in certain Member States, the Council has extended the time limit for the application of the Directive to existing products from 3 to 5 years.

The Commission can accept the Council's common position.