COUNCIL DIRECTIVE

of 22 December 1986

amending Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products

(87/20/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas, the testing of veterinary medicinal products must regularly be adapted to scientific and technical progress in order to safeguard the health of consumers of livestock products and to ensure optimum protection of animal health in the Community;

Whereas, in order to achieve this optimum protection of public health, the resources allocated to pharmaceutical research must not be squandered on obsolete or repetitive tests resulting from divergences between the Member States in assessing the state of the art in science and technology;

Whereas, for ethical reasons, it is necessary to replace the existing methods as soon as scientific and technical advances so allow by methods involving as few laboratory animals as possible;

Whereas, it is therefore necessary to introduce a rapid procedure for adapting to technical progress the requirements regarding the testing of the veterinary medicinal products listed in the Annex to Directive 81/852/EEC (4), whilst ensuring close cooperation between the Member States and the Commission within a 'Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector';

Whereas the requirements relating to the testing of veterinary medicinal products must also be capable of rapid revision by the same procedure, having regard to the evolution of test methods and of good laboratory practices recognized by the Community or in international trade in veterinary medicinal products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 81/852/EEC is hereby amended as follows:

1. The following Articles 2a, 2b and 2c shall be inserted:

'Article 2a

Any changes which are necessary in order to adapt the Annex to take account of technical progress shall be adopted in accordance with the procedure laid down in Article 2c.

If appropriate, the Commission shall propose to the Council that the procedure in Article 2c be reviewed in connection with the detailed rules set for the exercise of the powers of implementation granted to the Commission.

Article 2b

1. A Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector, hereinafter called "the Committee", is hereby set up; it shall consist of representatives of the Member States with a representative of the Commission as Chairman.

2. The Committee shall adopt its own rules of procedure.

Article 2c

1. Where the procedure laid down in this Article is to be followed, matters shall be referred to the Committee by the Chairman, either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit set by the Chairman having regard to the urgency of the matter. It shall act by a qualified majority, the votes of the Member States being weighted as provided in Article 148 (2) of the Treaty. The Chairman shall not vote.

(1) OJ No C 293, 5. 11. 1984, p. 6.
(2) OJ No C 36, 17. 2. 1986, p. 152.
(3) OJ No C 160, 1. 7. 1985, p. 18.
(4) OJ No L 317, 6. 11. 1981, p. 16.

3. (a) The Commission shall adopt the measures envisaged where they are in accordance with the opinion of the Committee.

(b) Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is adopted, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority.

(c) If, within three months of the proposal being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.' ;

2. Part 1 of the Annex, 'Analytical (Physico-Chemical, Biological or Microbiological) Tests of Veterinary Medicinal Products', shall be amended as follows :

(a) in (A), the following section shall be inserted :

'4. An explanation should be provided with regard to the choice of composition, constituents and container, supported by data on development pharmaceutics. The overage, with justification thereof, should be stated.'

(b) in (B) the following fifth indent shall be inserted :

'— experimental studies validating the manufacturing process, where a non-standard method of manufacture is used or where it is critical for the product.' ;

(c) in (C) (2), subparagraph (b) shall be replaced by the following :

'(b) the description of the substance, set down in a form similar to that used in a descriptive item in the European Pharmacopoeia, shall be accompanied by any necessary explanatory evidence, especially concerning the molecular structure where appropriate ; it must be accompanied by an appropriate description of the method of synthetic preparation. Where substances can only be described by their method of preparation, the description should be sufficiently detailed to characterize a substance which is constant both in its composition, and in its effects ;'

3. Part 2 of the Annex, 'Toxicological and Pharmacological Tests' is hereby amended as follows :

(a) The following paragraph shall be inserted after the two introductory paragraphs :

'The Member States shall ensure that the laboratory tests are executed in conformity with the principles of good laboratory practice recognized by Community law in the field of tests on dangerous substances or, in the absence thereof, with those recommended by the Organization for Economic Cooperation and Development.'

(b) In Chapter I (B) (1) the fourth subparagraph shall be replaced by the following :

'This study will cover the signs observed, including local reactions. The period during which the test animals are observed shall be fixed by the investigator as being adequate to reveal tissue or organ damage or recovery, usually for a period of 14 days but not less than seven days, but without exposing the animals to prolonged suffering. Animals dying during the observation period should be subject to autopsy as also should all animals surviving to the end of the observation period. Histopathological examination should be considered on any organ showing macroscopic changes at autopsy. The maximum amount of information should be obtained from the animals used in the study. The single dose toxicity tests should be conducted in such a way that signs of acute toxicity are revealed and the mode of death assessed as far as reasonably possible. In suitable species a quantitative evaluation of the approximate lethal dose and information on the dose effect relationship should be obtained, but a high level of precision is not required.'

Article 2

Member States shall take the measures necessary to comply with this Directive no later than 1 July 1987. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 22 December 1986.

For the Council

The President

G. SHAW