COUNCIL DIRECTIVE

of 13 December 1990

amending Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products

(90/676/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

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

In cooperation with the European Parliament (2),

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

Whereas Article 23 (2) of Council Directive 81/851/EEC (4) provides that the Commission should submit to the Council a proposal containing appropriate measures leading towards the elimination of any remaining barriers to trade or to the free movement of veterinary medicinal products not later than four years after the implementation of the abovementioned Directive;

Whereas the Directives on the approximation of laws relating to veterinary medicinal products must be adapted to scientific progress and improved to take account of the experience acquired since their adoption;

Whereas it is necessary from the point of view of public health and the free movement of veterinary medicinal products for the competent authorities to have at their disposal all useful information on authorized veterinary medicinal products in the form of approved summaries of the characteristics of products;

Whereas the approximation of laws brought about in this connection must enable a veterinary medicinal product, manufactured and placed on the market in one Member State on the basis of harmonized provisions, to be allowed into the other Member States, taking due consideration of the initial authorization, save in exceptional cases submitted for an opinion to the Committee for Veterinary Medicinal Products set up by Directive 81/851/EEC;

Whereas the system for package inserts accompanying veterinary medicinal products should be improved;

Whereas it is advisable to stipulate more precisely the cases in which the results of pharmacological and toxicological tests or clinical trials do not have to be provided with a view to obtaining authorization for a veterinary medicinal product which is essentially similar to an innovative product, while ensuring that innovative firms are not placed at a disadvantage; whereas, however, there are reasons of public policy for not repeating tests carried out on animals without overriding cause;

Whereas the guarantees of the quality of veterinary medicinal products manufactured within the Community should be maintained by requiring compliance with the principles of good manufacturing practice for medicinal products irrespective of the final destination of the products;

Whereas the Commission should be empowered to define in detail principles of good manufacturing practice for veterinary medicinal products in close cooperation with the Committee for Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector established by Article 2b of Council Directive 81/852/EEC of 28 September 1981 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 (5), as amended by Directive 87/20/EEC (6);

Whereas measures should be taken to improve the provision of information for third countries about the conditions of use of veterinary medicinal products within the Member States and the Community;

Whereas measures should also be taken to ensure that distributors of veterinary medicinal products are authorized by Member States and maintain adequate records,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 81/851/EEC is hereby amended as follows:

1. Article 1 (5) is replaced by the following:

'5. Member States shall take all measures necessary to ensure that only persons empowered under their national legislation in force possess or have under their control veterinary medicinal products or substances which may be used as veterinary medicinal products that have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties.

(1) OJ No C 61, 10. 3. 1989, p. 11 and OJ No C 131, 30. 5. 1990, p. 16.
(2) OJ No C 96, 17. 4. 1990, p. 104 and Decision of 21 November 1990 (not yet published in the Official Journal).
(3) OJ No C 201, 7. 8. 1989, p. 1.
(4) OJ No L 317, 6. 11. 1981, p. 1.
(5) OJ No L 317, 6. 11. 1981, p. 16.
(6) OJ No L 15, 17. 1. 1987, p. 34.

Member States shall maintain a register of producers and dealers permitted to be in possession of active substances which may be used in the manufacture of veterinary medicinal products having the properties referred to in the first subparagraph. Such persons must maintain detailed records of all dealings in substances which may be used in the manufacture of veterinary medicinal products and keep these records available for inspection by the competent authorities for a period of at least three years.

Any amendments to be made to the list of substances referred to in the first subparagraph shall be adopted in accordance with the procedure referred to in Article 2c of Directive 81/852/EEC (*) as amended by Directive 87/20/EEC (**).

(*) OJ No L 317, 6. 11. 1981, p. 16.
(**) OJ No L 15, 17. 1. 1987, p. 34.'

2. The following subparagraph is added to Article 2 (1):

'This Directive shall apply to veterinary medicinal products used in order to produce active or passive immunity or to diagnose the state of immunity, in accordance with the provisions of Directive 90/676/EEC (***) which widens the scope of this Directive.

(***) OJ No L 373, 31. 12. 1990, p. 15.'

3. The second and fourth indents of Article 2 (2) are deleted.

4. Article 4 is replaced by the following:

'Article 4

1. No veterinary medicinal product may be placed on the market in a Member State unless authorization has previously been granted by the competent authority of that Member State.

However, where the health situation so requires, a Member State may authorize the placing on the market or administration to animals of veterinary medicinal products which have been authorized by another Member State in accordance with this Directive.

In the event of a serious disease epidemic the States may provisionally allow the use of immunological veterinary medicinal products without an authorization for placing on the market, in the absence of a suitable medicinal product and after informing the Commission of the detailed conditions of use.

2. A Member State shall not authorize the placing on the market of a veterinary medicinal product intended for administration to food-producing animals whose flesh or products are intended for human consumption, unless:

(a) the active substance or substances capable of pharmacological action contained in the veterinary medicinal product were authorized for use in other veterinary medicinal products in the Member State concerned on the date of entry into force of Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the fixing of maximum levels of residues of veterinary medicinal products in foodstuffs of animal origin (*);

(b) the active substance or substances capable of pharmacological action is or are mentioned in Annex I, II or III to the aforementioned Regulation.

3. No veterinary medicinal product may be administered to animals unless the authorization referred to above has been issued, except for the tests of veterinary medicinal products referred to in point 10 of Article 5 which have been accepted by the competent national authorities, following notification or authorization, in accordance with the national rules in force.

The Member States shall permit the placing on the market of foodstuffs obtained from animals treated during these tests only if they are satisfied that the foodstuffs do not contain residues which may present a risk for human health.

Without prejudice to stricter Community or national rules relating to dispensing veterinary medicinal products and to protect human and animal health, a prescription shall be required for dispensing to the public the following veterinary medicinal products;

(a) those products subject to official restrictions on supply or use, such as:

— the restrictions resulting from the implementation of the relevant United Nations conventions on narcotic and psychotropic substances,

— the restrictions on the use of veterinary medicinal products resulting from Community law;

(b) those products in respect of which special precautions must be taken by the veterinarian in order to avoid any unnecessary risk to:

— the target species,

— the person administering the products to the animal,

— the consumer of foodstuffs obtained from the treated animal,

— the environment;

(c) those products intended for treatments or pathological processes which require a precise prior diagnosis or the use of which may cause effects which impede or interfere with subsequent diagnostic or therapeutic measures;

(d) magistral formulae intended for animals.

In addition, a prescription shall be required for new veterinary medicinal products containing an active ingredient which has been authorized for use in a

veterinary medicinal product for less than five years unless, having regard to the information and particulars provided by the applicant, or experience acquired in the practical use of the product, the competent authorities are satisfied that none of the criteria referred to in (a) to (d) of the third subparagraph apply.

4. However, where there exists no authorized medicinal product for a condition, Member States may exceptionally, in particular in order to avoid causing unacceptable suffering to the animals concerned, permit the administration by a veterinarian or under his/her direct personal responsibility to an animal or to a small number of animals on a particular holding (*):

(a) of a veterinary medicinal product authorized in the Member State concerned for use in another animal species, or for another condition in the same species; or

(b) if there is no product such as referred to in point (a), of a medicinal product authorized for use in the Member State concerned in human beings in accordance with Directive 65/65/EEC of 26 January 1965; or

(c) if there is no product such as referred to in point (b) and within the limits of the law of the Member State concerned, of a veterinary medicinal product prepared extemporaneously by a person authorized to do so under national legislation in accordance with the terms of a veterinary prescription,

provided that the medicinal product, where administered to animals whose flesh or products are intended for human consumption, contains only substances to be found in a veterinary medicinal product authorized for such animals in the Member State concerned and that in the case of food-producing animals the veterinarian responsible specifies an appropriate withdrawal period to ensure that food produced from the treated animals does not contain residues harmful to consumers.

Unless the product used indicates a withdrawal period for the species concerned, the specified withdrawal period shall not be less than:

7 days:	eggs,
7 days:	milk,
28 days:	meat from poultry and mammals including fat and offal,
500 degree days:	meat from fish.

The veterinarian shall keep adequate records of the date of examination of the animals, details of the owner, the number of animals treated, the diagnosis, the medicinal products prescribed, the dosages administered, the duration of treatment and the withdrawal periods recommended, and make these records available for inspection by the competent authorities for a period of at least three years. This requirement may be extended by the Member States to animals whose flesh or products are not intended for human consumption.

5. Notwithstanding paragraph 3, Member States shall ensure that veterinarians providing services in another Member State can take with them and administer to animals small quantities of ready-made veterinary medicinal products not exceeding daily requirements other than immunological veterinary medicinal products which are not authorized for use in the Member State in which the services are provided (host Member State), providing that the following conditions are satisfied:

(a) the authorization to place the product on the market provided for in paragraph 1 has been issued by the competent authorities of the Member State in which the veterinarian is established;

(b) the veterinary medicinal products are transported by the veterinarian in the original manufacturer's packaging;

(c) the veterinary medicinal products intended for administration to food-producing animals have the same qualitative and quantitative composition in terms of active principles as the medicinal products authorized in accordance with paragraph 1 in the host Member State;

(d) a veterinarian providing services in another Member State shall acquaint himself with the good veterinary practices applied in that Member State. He shall ensure that the withdrawal period specified on the labelling of the veterinary medicinal product concerned is complied with, unless he could reasonably be expected to know that a longer withdrawal period should be specified to comply with these good veterinary practices;

(e) the veterinarian shall not furnish any veterinary medicinal product to the owner or keeper of the animals treated in the host Member State unless this is permissible on the basis of the rules of the host Member State; in this case he shall, however, supply only in relation to animals under his care and only the minimum quantities of veterinary medicinal product necessary to complete the treatment of animals concerned on that occasion;

(f) the veterinarian shall be required to keep detailed records of the animals treated, the diagnosis, the veterinary medicinal products administered, the dosage administered, the duration of treatment and the withdrawal period applied. These records shall be available for inspection by the competent authorities of the host State for a period of at least three years;

(g) the overall range and quantity of veterinary medicinal products carried by the veterinarian shall not exceed that generally required for the daily needs of good veterinary practice.

(*) OJ No L 224, 18. 8. 1990, p. 1.

(**) The phrase "an animal or a small number of animals on a particular holding" also covers pets, and should be interpreted more flexibly for minor or exotic animal species which do not produce food.'

5. Article 5 is replaced by the following:

'*Article 5*

For the purpose of obtaining the authorization for placing a product on the market provided for in Article 4, the person responsible for placing the product on the market shall lodge an application with the competent authority of the Member State.

The following particulars and documents shall accompany such application:

1. name or business name and permanent address or registered place of business of the person responsible for placing the product on the market and, if different, of the manufacturer or manufacturers involved and of the sites of manufacture;

2. name of the veterinary medicinal product (brand name, non-proprietary name, whith or without a trademark, or name of the manufacturer or scientific name or formula, with or without a trademark, or the name of the manufacturer);

3. qualitative and quantitative particulars of all the constituents of the veterinary medicinal product, using the usual terminology but not empirical chemical formula and giving the international non-proprietary name recommended by the World Health Organization, where such a name exists;

4. description of the method of preparation;

5. therapeutic indications, contra-indications and side-effects;

6. dosage for the various species of animal for which the veterinary medicinal product is intended, its pharmaceutical form, method and route of administration and proposed shelf life;

7. if applicable, explanations of the precautionary and safety measures to be taken when the product is stored, when it is administered to animals and when waste therefrom is disposed of, together with an indication of any potential risks the medicinal product might pose to the environment and the health of humans, animals or plants;

8. indication of the withdrawal period necessary between the last administration of the veterinary medicinal product to animals under normal conditions of use and the production of foodstuffs from such animals in order to ensure that such foodstuffs do not contain residues in quantities in excess of the maximum limits laid down. Where necessary, the applicant shall propose and justify a tolerance level for residues which may be accepted in foodstuffs without risk for the consumer, together with routine analysis methods which could by used by the competent authorities to trace residues;

9. description of the control testing methods employed by the manufacturer (qualitative and quantitative analysis of the constituents and the finished product, specific tests, e.g. sterility tests, test for the presence of pyrogens, for the presence of heavy metals, stability tests, biological and toxicity tests, tests on intermediate products);

10. results of:

— physico-chemical, biological or microbiological tests,

— toxicological and pharmacological tests,

— clinical trials.

However, and without prejudice to the law relating to the protection of industrial and commercial property:

(a) the applicant shall not be required to provide the results of toxicological and pharmacological tests and clinical trials if he can demonstrate:

(i) either that the veterinary medicinal product is essentially similar to a medicinal product authorized in the Member State concerned by the application and that the person responsible for placing the original veterinary medicinal product on the market has agreed that the toxicological, pharmacological or clinical references contained in the file on the original veterinary medicinal product may be used for the purpose of examining the application in question;

(ii) or by detailed references to the scientific literature presented in accordance with the second paragraph of Article 1 of Directive 81/852/EEC, as amended by Directive 87/20/EEC, that the constituent or constituents of the veterinary medicinal product have a well-established medicinal use, with recognized efficacy and an acceptable level of safety;

(iii) or that the veterinary medicinal product is essentially similar to a product which has been authorized within the Community, in accordance with Community provisions in force, for not less than six years and is marketed in the Member State for which the application is made; this period shall be extended to 10 years in the case of high-technology medicinal products appearing on the list in Part A of the Annex to Directive 87/22/EEC (*) or of a medicinal product appearing on the list in Part B of the Annex to that Directive for which the procedure laid down in Article 2 of that Directive has been followed. Furthermore, a Member State may also extend this period to 10 years by a single

Decision covering all the products marketed in its territory where it considers this necessary in the interest of public health. Member States are at liberty not to apply the abovementioned six-year period beyond the date of expiry of a patent protecting the original product;

(b) in the case of new veterinary medicinal products containing known constituents not hitherto used in combination for therapeutic purposes, the results of toxicological and pharmacological tests and of clinical trials relating to that combination must be provided, but it shall not be necessary to provide references relating to each individual constituent;

11. a summary in accordance with Article 5a of the product characteristics, one or more specimens or mock-ups of the sales presentation of the veterinary medicinal product together with the package insert referred to in Article 48 (1);

12. a document showing that the manufacturer is authorized in his own country to produce veterinary medicinal products;

13. any authorization to place the relevant veterinary medicinal product on the market which may have been obtained in another Member State or in a third country, together with a list of those countries to which an application for authorization to place the product on the market has been made and explanation of the reasons for which the Member State or third country has refused to grant authorization for the veterinary medicinal product concerned;

14. in the case of medicinal products containing new active ingredients which are not mentioned in Annex I, II or III to Regulation (EEC) No 2377/90, a copy of the documents submitted to the Commission in accordance with Annex V to the Regulation.

(*) OJ No L 15, 17. 1. 1987, p. 38.'

6. The following Article is inserted:

'Article 5a

The summary of the product characteristics referred to in point 11 of point 2 of the second paragraph of Article 5 shall contain the following information:

1. name of the veterinary medicinal product;

2. qualitative and quantitative composition in terms of the active ingredients and constituents of the excipient, knowledge of which is essential for proper administration of the medicinal product; the international non-proprietary names recommended by the World Health Organization shall be used, where such names exist, or failing this, the usual non-proprietary name or chemical description;

3. pharmaceutical form;

4. pharmacological properties and, in so far as this information is useful for therapeutic purposes, pharmacokinetic particulars;

5. clinical particulars:

5.0 target species,

5.1 indications for use, specifying the target species,

5.2 contra-indications,

5.3 undesirable effects (frequency and seriousness),

5.4 special precautions for use,

5.5 use during pregnancy and lactation,

5.6 interaction with other medicaments and other forms of interaction,

5.7 posology and method of administration,

5.8 overdose (symptoms, emergency procedures, antidotes) (if necessary),

5.9 special warnings for each target species,

5.10 withdrawal periods,

5.11 special precautions to be taken by the person administering the product to animals;

6. pharmaceutical particulars:

6.1 incompatibilities (major),

6.2 shelf life, when necessary after reconstitution of the product or when the container is opened for the first time,

6.3 special precautions for storage,

6.4 nature and contents of container,

6.5 name or style and permanent address or registered place of business of the holder of the authorization to place the product on the market,

6.6 special precautions for the disposal of unused product or waste materials, if any.'

7. The following Article is inserted:

'Article 5b

When the authorization to place the product on the market, referred to in Article 4 (1), is issued, the person responsible for placing that product on the market shall be informed, by the competent authorities of the Member States concerned, of the summary of the product characteristics as approved by them. The competent authorities shall take all necessary measures to ensure that the information given in the summary is in conformity with that accepted when the authorization to place the product on the market is issued or subsequently.'