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.'

8. The last sentence of Article 7 is replaced by the following:

'The experts' detailed reports shall form part of the documentation which the applicant shall lodge with the competent authorities. A brief curriculum vitae of the expert shall be appended to each report.'

9. Article 9 (2) is replaced by the following:

'2. may submit the medicinal product, its active principles and if necessary intermediate products or other constituent materials for testing by a State laboratory or by a laboratory designated for that purpose, in order to ensure that the testing methods employed by the manufacturer and described in the application documents, in accordance with point 9 of the second paragraph of Article 5, are satisfactory.'

10. In Article 9, the following point is added:

'4. may require the applicant to submit substances in the quantities necessary to verify the analytical detection method proposed by the applicant in accordance with point 8 of the second paragraph of Article 5 and to put it into effect as part of routine checks to reveal the presence of residues of the veterinary medicinal products concerned'.

11. Article 14 is replaced by the following:

'Article 14

1. After an authorization has been issued, the person responsible for placing the product on the market must, in respect of the control methods provided for in point 9 of the second paragraph of Article 5, take account of technical and scientific progress and introduce any changes that may be required to enable the veterinary medicinal product to be checked by means of generally accepted scientific methods. These changes must be approved by the competent authorities of the Member States concerned.

Upon request from the competent authorities, the person responsible for placing the product on the market shall also review the analytical detection methods provided for in point 8 of the second paragraph of Article 5 and propose any changes which may be necessary to take account of scientific and technical progress.

2. The person responsible for placing the product on the market shall forthwith inform the competent authorities of any new information which might entail the amendment of the particulars and documents referred to in Article 5 or the approved summary of the product characteristics referred to in Article 5b. In particular, he shall forthwith inform the competent authorities of any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is marketed and of any serious unexpected reaction occuring in the animals concerned or human beings.

3. The person responsible for placing the procuct on the market shall be required to maintain records of all undesirable effects observed in animals or human beings. The records so established shall be kept for at least five years and shall be made available to the competent authorities upon request.

4. The person responsible for placing the product on the market shall immediately inform the competent authorities, with a view to authorization, of any alteration he proposes to make to the particulars and documents referred to in Article 5.'

12. Article 15 is replaced by the following:

'Article 15

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.

However, veterinary medicinal products which contain active substances included in Annex III to Regulation (EEC) No 2377/90 shall be authorized only for the period for which a provisional tolerance has been established and authorization may be extended if the provisional tolerance is renewed.'

13. Chapter IV of Directive 81/851/EEC is replaced by the following:

'CHAPTER IV

Committee for Veterinary Medicinal Products

Article 16

1. In order to facilitate the adoption of a common position by the Member States with regard to decisions on the issue of authorizations to place products on the market and to promote thereby the free movement of veterinary medicinal products, a Committee for Veterinary Medicinal Products, hereinafter referred to as 'the Committee' and composed of representatives of the Member States and of the Commission, is hereby set up.

2. The Committee's task shall be to examine, at the request of a Member State or the Commission and in accordance with Articles 17 to 22, questions concerning the application of Articles 11, 36 and 49.

3. The Committee shall draw up its own rules of procedure, which shall be published by the Commission.

The rules of procedure shall provide for, in particular:

— the publication of the names and qualifications of the members of the Committee;

— appropriate safeguards to ensure that the members of the Committee discharge their responsibilities with complete impartiality.

The Commission shall maintain available for public inspection at its offices a register of all interests relating

to the pharmaceutical industry held by members of the Committee and persons taking part in its discussions.

Article 17

1. In order to make it easier to obtain an authorization to place a product on the market in at least two other Member States taking into due consideration an authorization issued in one Member State in accordance with Article 4, the holder of the latter authorization may submit an application to the competent authorities of the Member States concerned together with the information and documents referred to in Articles 5, 5a and 5b.

He shall testify to its identity with the dossier accepted by the first Member State, specifying any additions it may contain, and shall certify that all the dossiers filed as part of this procedure are identical.

2. The holder of the authorization to place a product on the market shall notify the Committee of the application, inform it of the Member States concerned and send it a copy of the authorization. He shall also inform the Member State which granted him the initial authorization and notify it of any additions to the original dossier; that State may require the applicant to provide it with all the particulars and documents necessary to enable it to check the identity of the dossiers filed with the dossier on which it took its decision.

3. The holder of the authorization to place a product on the market shall notify the dates on which the dossiers were sent to the Member States concerned; the latter shall immediately send an acknowledgement of receipt of the dossier to the Committee and to the person responsible for placing the product on the market. As soon as the Committee has noted that all the Member States concerned are in possession of the dossier, it shall forthwith inform all the Member States and the applicant of the date on which the last Member State concerned received the dossier. The Member States concerned shall either grant the authorization valid for their markets within a period of 120 days of the aforementioned date, taking into due consideration the authorization issued in accordance with paragraph 1, or put forward a reasoned objection.

Article 18

1. Where a Member State considers that it is unable to grant an authorization to place a product on the market, it shall forward to the Committee and to the person responsible for placing the veterinary medicinal product on the market its reasoned objection in accordance with Article 11, within the time limits stipulated in Article 17 (3).

2. Upon the expiry of this period, the matter shall be referred to the Committee and the procedure referred to in Articles 21 and 22 shall be applied.

3. On receipt of the reasoned objection referred to in paragraph 1, the person responsible for placing the product on the market shall immediately send the Committee a copy of the particulars and documents referred to in Article 17 (1).

Article 19

Where several applications submitted in accordance with Articles 5 and 5a have been made for authorization to place a particular veterinary medicinal product on the market, and one or more Member States have granted an authorization while one or more of the other Member States have refused it, one of the Member States concerned or the Commission or the person responsible for placing the product on the market may refer the matter to the Committee for application of the procedure provided for in Articles 21 and 22. The Member States will be informed each time this procedure is invoked.

The same shall apply where one or more Member States have suspended or revoked an authorization to place a product on the market while one or more Member States have not done so.

In both cases, the person responsible for placing the veterinary medicinal product on the market shall be informed of any decision of the Committee to apply the procedure provided for in Article 22.

Article 20

The competent authorities of Member States may, in specific cases where the interests of the Community are involved, refer the matter to the Committee before reaching a decision on a request for authorization to place a product on the market or on the suspension or revocation of an authorization.

Article 21

1. The competent authorities shall draw up an assessment report and comments on the dossier as regards the result of the analytical and toxico-pharmacological tests on, and clinical trials of, any veterinary medicinal products containing a new active substance which are the subject of a request for authorization to place the products on the market in the Member States concerned for the first time.

2. As soon as the notification referred to in Article 17 is received, the competent authorities shall immediately communicate to the Member States concerned an assessment report, accompanied by a summary of the dossier relating to an particular veterinary medicinal product. This report shall also be communicated to the Committee where a matter is referred to the Committee pursuant to Article 18.

The assessment report shall also be forwarded to the other Member States concerned and to the Committee as soon as a matter is referred to the Committee under the procedure laid down in Article 19. Any assessment report so forwarded shall remain confidential.

The competent authorities shall bring the assessment report up to date as soon as it is in possession of information which is of importance for the evaluation of the balance between effectiveness and risk.

Article 22

1. Where reference is made to the procedure described in this Article, the Committee shall consider the matter concerned and issue a reasoned opinion within 60 days of the date on which the matter was referred to it.

In the case referred to in Article 18, the person responsible for placing the product on the market may, at his request, provide an oral or written explanation and provide additional information before the Committee issues its opinion. The Committee may extend the time limit referred to in the preceding paragraph to give the applicant time to provide an oral or written explanation.

In the case referred to in Article 19, the person responible for placing the product on the market may be asked to provide an oral or written explanation.

2. The Committee's opinion shall concern the grounds for the objection provided for in Article 18 (1) and the grounds on which the authorization to place the product on the market has been refused, suspended or withdrawn in the cases described in Article 19.

The Committee shall immediately inform the Member States concerned and the person responsible for placing the product on the market of its opinion or of the opinions of its members where the latter differ.

3. The Member State or States concerned shall decide on the action to be taken further to the Committee's opinion within 60 days of the notification referred to in paragraph 2. They shall immediately inform the Committee of their decision.

Article 23

The Commission shall report to the Council every two years on the operation of the procedure laid down in this Chapter.'

14. Article 24 (1) is replaced by the following:

'1. Member States shall take all appropriate measures to ensure that the manufacture of veterinary medicinal products is subject to the holding of an authorization. This manufacturing authorization shall likewise be required for veterinary medicinal products intended for export.'

15. The following is added to Article 24 (3):

'Member States shall take all appropriate measures to ensure that veterinary medicinal products brought into their territory from a third country and destined for another Member State are accompanied by a copy of the authorization referred to in paragraph 1.'

16. The following Article is inserted:

'Article 24a

At the request of the manufacturer of veterinary medicinal products, the exporter thereof or the authorities of an importing third country, Member States shall certify that such manufacturer is in possession of the authorization referred to in Article 24. When issuing such certificates, Member States shall comply with the following conditions:

1. Member States shall have regard to the prevailing administrative arrangements of the World Health Organization;
2. for veterinary medicinal products intended for export which are already authorized in their territory, they shall supply the summary of the product characteristics as approved in accordance with Article 5b or, in the absence thereof, an equivalent document.

Where the manufacturer is not in possession of an authorization to place the product on the market, he shall provide the authorities responsible for establishing the certificate referred to in the first paragraph with a declaration explaining why such authorization is not available.'

17. In Article 27, the following is added:

'(f) comply with the principles and the guidelines of good manufacturing practice for medicinal products laid down by Community law;

(g) keep detailed records of all veterinary medicinal products supplied by him, including samples, in accordance with the laws of the countries of destination. The following information at least shall be recorded in respect of each transaction, whether or not it is made for payment:

— date,

— name of the veterinary medicinal product,

— quantity supplied,

— name and address of the recipient,

— batch number.

These records shall be available for inspection by the competent authorities for a period of at least three years.'

18. The following Article is inserted:

'Article 27a

The principles and guidelines of good manufacturing practice for veterinary medicinal products referred to in Article 27 (f) shall be adopted in the form of a Directive

addressed to the Member States in accordance with the procedure laid down in Article 2c of Directive 81/852/EEC, taking account of the specific nature of the veterinary medicinal product. Detailed guidelines shall be published by the Commission and revised as appropriate to take account of scientific and technical progress.'

19. Article 34 is hereby amended as follows:

(a) The first paragraph is replaced by the following:

'The competent authority of the Member State concerned shall ensure by means of repeated inspection that the legal requirements relating to veterinary medicinal products are complied with.'

(b) The following paragraph is added:

'The officials representing the competent authority shall report after each of the inspections mentioned in the first paragraph on whether the manufacturer complies with the principles and guidelines of good manufacturing practice referred to in Article 27a. The inspected manufacturer shall be informed of the content of such reports.'

20. The following Article is added:

'Article 38a

Member States shall take appropriate measures to encourage veterinarians and other professionals concerned to report to the competent authorities any undesirable effect of veterinary medicinal products.'

21. Article 39 is replaced by the following:

'Article 39

Member States shall take all measures necessary to ensure that the competent authorities concerned communicate the appropriate information to each other, in particular regarding compliance with the requirements adopted for authorization as referred to in Article 24 (1), or for authorization to place products on the market, for the purpose of verifying compliance with the provisions of Chapter VIII.

Upon reasoned request, Member States shall forthwith communicate the reports referred to in the third paragraph of Article 34 to the competent authorities of another Member State. If, after considering the reports, the Member State receiving the reports considers that it cannot accept the conclusions reached by the competent authority of the Member State in which the report was established, it shall inform the competent authorities concerned of its reasons and may request further information. The Member States concerned shall attempt to reach agreement. If necessary, in the event of serious differences of opinion, one of the Member States concerned shall inform the Commission.'

22. Article 42 is replaced by the following:

'Article 42

1. Each Member State shall take all appropriate measures to ensure that the Committee is informed immediately of decisions granting marketing authorization and of all decisions refusing or withdrawing marketing authorization, cancelling a decision refusing or withdrawing marketing authorization, prohibiting supply or withdrawing a product from the market, together with the reasons on which such decisions are based.

2. The person responsible for placing a veterinary medicinal product on the market shall be obliged to notify the Member States forthwith of any action taken by him to suspend the marketing of a product or to withdraw a product from the market, together with the reasons for such action if it concerns the effectiveness of the veterinary medicinal product or the protection of public health. Member States shall ensure that this information is brought to the attention of the Committee.

3. Member States shall ensure that appropriate information about actions taken pursuant to paragraphs 1 and 2 which may affect the protection of health in third countries is forthwith brought to the attention of the relevant international organizations, with a copy to the Committee.'

23. The first paragraph to Article 43 is hereby amended as follows:

(a) Points 1 and 2 are replaced by the following:

'1. Name of the veterinary medicinal product, which may be a brand name or a non-proprietary name accompanied by a trade mark or the name of the manufacturer, or a scientific name or formula, with or without a trade mark, or the name of the manufacturer.

Where the special name of a medicinal product containing only one active ingredient is a brand name, this name must be accompanied in legible characters by the international non-propriety name recommended by the World Health Organization, where such name exists, or where no such name exists, by the usual non-proprietary name.

2. A statement of the active ingredients expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a particular volume or weight, using the international non-proprietary names recommended by the World Health Organization, where such names exist or, where no such names exist, the usual non-proprietary names.'

(b) Points 7 and 8 are replaced by the following:

'7. The withdrawal period, even if nil, in the case of veterinary medicinal products administered to food-producing animals.

8. Expiry date, in plain language.'

(c) The following point is inserted:

'9a. Special precautions for disposal of unused product or waste material, if any.'

24. In Article 48, the first paragraph is replaced by the following:

'The inclusion of a package insert in the packaging of veterinary medicinal products shall be obligatory unless all the information required by this Article can be conveyed on the container and the external packaging. Member States shall take all appropriate measures to ensure that the insert relates solely to the veterinary medicinal product with which it is included. The insert shall be in the official language or languages of the Member State in which the medicinal product is marketed.'

25. The second paragraph of Article 48 is hereby amended as follows:

(a) Point (e) is replaced by the following:

'(e) the withdrawal period, even if this is nil, in the case of veterinary medicinal products administered to food-producing animals;'

(b) The following point is added:

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

26. The final paragraph of Article 48 is deleted.

27. The following Chapter VIII is inserted:

'CHAPTER VIIIa

Distribution of veterinary medicinal products

Article 50a

1. Member States shall take all appropriate measures to ensure that wholesale dealing in veterinary medicinal products is subject to the holding of an authorization and to ensure that the time taken for the procedure for granting this authorization does not exceed 90 days from the date on which the competent authority receives the application.

For the purposes of this Directive, wholesale dealing shall include the purchase, sale, import, export, or any other commercial transaction in veterinary medicinal products, whether or not for profit, except for:

— the supply by a manufacturer of veterinary medicinal products manufactured by himself,

— retail supplies of veterinary medicinal products by persons permitted to carry out such supplies in accordance with Article 50b.

Member States may also exclude supplies of small quantities of veterinary medicinal products from one retailer to another.

2. In order to obtain the authorization referred to in paragraph 1, the applicant shall have at his disposal technically competent staff and suitable and sufficient premises complying with the requirements laid down in the Member State concerned as regards the storage and handling of products.

3. The holder of the authorization referred to in paragraph 1 shall be required to keep detailed records. The following minimum information shall be recorded in respect of each incoming or outgoing transaction:

(a) date;

(b) precise identity of the veterinary medicinal product;

(c) manufacturer's batch number, expiry date;

(d) quantity received or supplied;

(e) name and address of the supplier or recipient.

At least once a year a detailed audit shall be carried out to compare incoming and outgoing supplies with supplies currently held in stock, any discrepancies being recorded.

These records shall be available for inspection by the competent authorities for a period of at least three years.

4. Member States shall take all appropriate measures to ensure that wholesalers supply veterinary medicinal products only to persons permitted to carry out retail activities in accordance with Article 50b, or to other persons who are lawfully permitted to receive veterinary medicinal products from wholesalers.

Article 50b

1. Member States shall take all appropriate measures to ensure that the retail supply of veterinary medicinal products is conducted only by persons who are permitted to carry out such operations by the legislation of the Member State concerned.

2. Any person permitted under the preceding paragraph to sell veterinary medicinal products shall be required to keep detailed records. The following information shall be recorded in respect of each incoming or outgoing transaction:

(a) date;

(b) precise identity of the veterinary medicinal product;

(c) manufacturer's batch number;

(d) quantity received or supplied;

(e) name and address of the supplier or recipient;

(f) where relevant, name and address of the prescribing veterinarian and a copy of the prescription.

At least once a year a detailed audit shall be carried out, and incoming and outgoing products shall be reconciled with products currently held in stock, any discrepancies being recorded.

These records shall be available for inspection by the competent authorities for a period of three years.

3. Member States may limit the scope of the record-keeping requirements referred to in paragraph 2. However, these requirements shall always be applied in case of veterinary medicinal products intended for administration to animals whose flesh or products are intended for human consumption and which are available only on veterinary prescription or in respect of which a withdrawal period must be observed.

4. Not later that 1 January 1992, Member States shall communicate to the Commission a list of the veterinary medicinal products which are available without prescription. After having taken note of the communication from the Member States, the Commission shall examine whether suitable measures should be proposed for drawing up a Community list of such products.

Article 50c

Member States shall ensure that the owners or keepers of food-producing animals can provide proof of purchase, possession and administration of veterinary medicinal products containing the substances set out in Article 1 (5); Member States may extend the scope of this obligation to other medicinal veterinary products.

In particular, Member States may require the maintenance of a record giving at least the following information:

(a) date;

(b) identity of the veterinary medicinal product;

(c) quantity;

(d) name and address of the supplier of the medicinal product;

(e) identification of the animals treated.'

Article 2

1. Member States shall take the necessary measures to comply with this Directive not later than 1 January 1992. They shall forthwith inform the Commission thereof.

2. By way of derogation from paragraph 1, Member States shall take the necessary measures to comply with Article 27 (f) and the third paragraph of Article 34 not later than two years after notification of the Directive referred to in Article 27a.

3. Where Member States adopt the provisions referred to in paragraphs 1 and 2, such provisions shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

4. Request for authorization to place products on the market lodged from the date set out in paragraph 1 must comply with the provisions of this Directive.

5. Within four years of the date set out in paragraph 1, Article 1 shall, where relevant, be progressively extended to existing veterinary medicinal products.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 13 December 1990.

For the Council

The President

P. ROMITA