COUNCIL DIRECTIVE 93/40/EEC

of 14 June 1993

amending Directives 81/851/EEC and 81/852/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products

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 it is important to adopt measures with the aim of progressively establishing the internal market over a period expiring on 31 December 1992; whereas the internal market shall comprise an area without internal frontiers in which the movement of goods, persons, services and capital is ensured;

Whereas despite the progress achieved by Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products [4], further measures are necessary to abolish the remaining barriers to the free movement of veterinary medicinal products within the Community;

Whereas, with the exception of those veterinary medicinal products which are subject to the centralized Community authorization procedure established by Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [5], an authorization to place a veterinary medicinal product on the market in one Member State ought in principle to be recognized by the competent authorities of the other Member States unless there are serious grounds for supposing that the authorization of the veterinary medicinal product concerned may present a risk to human or animal health, or to the environment; whereas, in the event of a disagreement between Member States about the quality, the safety or the efficacy of a veterinary medicinal product, a scientific evaluation of the matter should be undertaken by the Committee for Veterinary Medicinal Products attached to the European Agency for the Evaluation of Medicinal Products, lead to a single decision on the area of disagreement, binding on the Member States concerned; whereas this Decision should be adopted by a rapid procedure ensuring close cooperation between the Commission and the Member States;

Whereas in order better to protect human and animal health and avoid any unnecessary duplication of effort during the examination of application for authorization to place veterinary medicinal products on the market, Member States should systematically prepare assessment reports in respect of each veterinary medicinal product which is authorized by them, and exchange the reports upon request; whereas, furthermore, a Member State should be able to suspend the examination of an application for authorization to place a veterinary medicinal product on the market which is currently under active consideration in another Member State with a view to recognizing the decision reached by the latter Member State;

Whereas following the establishment of the internal market, specific controls to guarantee the quality of veterinary medicinal products imported from third countries can be waived only if appropriate arrangements have been made by the Community to ensure that the necessary controls are carried out in the exporting country;

Whereas it is desirable to codify and improve the cooperation and exchange of information between Member States relating to the surveillance of veterinary medicinal products and in particular the monitoring of adverse reactions under practical conditions of use through the national pharmacovigilance systems;

Whereas in order to improve the protection of public health it is necessary to specify that foodstuffs for human consumption may not be taken from animals which have been used in clinical trials of veterinary medicinal products unless a maximum residue limit has been laid down for residues of the veterinary medicinal product concerned in accordance with the provisions of Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin [6],

[1] OJ No C 330, 31. 12. 1990, p. 25 and OJ No C 310, 30. 11. 1991, p. 25.
[2] OJ No C 183, 15. 7. 1991, p. 194 and OJ No C 150, 31. 5. 1993.
[3] OJ No C 269, 14. 10. 1991, p. 84.
[4] OJ No L 317, 6. 11. 1981, p. 1. Directive last amended by Directive 90/676/EEC of 13 December 1990 (OJ No L 373, 31. 12. 1990, p. 15).
[5] See page 1 of this Official Journal.
[6] OJ No L 224, 18. 8. 1990, p. 1. Regulation last amended by Regulation (EEC) No 762/92 (OJ No L 83, 28. 3. 1992, p. 14).

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

1. the first subparagraph of Article 4 (1) is replaced by the following:

'No veterinary medicinal product may be placed on the market of a Member State unless a marketing authorization has been issued by the competent authorities of that Member State in accordance with this Directive or a marketing authorization has been granted in accordance with Council Regulation (EEC) 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing an European Agency for the evaluation of medicinal products (*).

(*) OJ No L 214, 24. 8. 1993, p. 1.';

2. the following subparagraph is inserted at the end of Article 4 (2):

'From 1 January 1997 the Member States shall not permit foodstuffs for human consumption to be taken from test animals unless maximum residue limits have been established by the Community in accordance with the provisions of Regulation (EEC) No 2377/90 and an appropriate withdrawal period has been established to ensure that this maximum limit will not be exceeded in the foodstuffs.';

3. insert the following subparagraph after the first subparagraph in Article 5:

'The person responsible for placing veterinary medicinal products on the market shall be established in the Community. In respect of veterinary medicinal products authorized on the date of implementation of this Directive, the Member States shall if necessary apply this provision at the time of the five-yearly renewal of the marketing authorization provided for in Article 15.';

4. in Article 5 (2), point 13 is replaced by the following:

'13. Copies of any authorization obtained in another Member State or in a third country to place the relevant veterinary medicinal product on the market, together with a list of those Member States in which an application for authorization submitted in accordance with this Directive is under examination. Copies of the summary of the product characteristics proposed by the applicant in accordance with Article 5a or approved by the competent authority of the Member State in accordance with Article 5b and copies of the package insert proposed, details of any decision to refuse authorization, whether in the Community or a third country and the reasons for that decision.

This information shall be updated on a regular basis.';

5. Article 5b is replaced by the following:

'Article 5b

When the marketing authorization referred to in Article 4 (1) is issued, the person responsible for placing that veterinary medicinal product on the market shall be informed, by the competent authorities of the Member State concerned, of the summary of the product characteristics as approved by it. 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 marketing authorization is issued or subsequently. The competent authorities shall forward to the European Agency for the Evaluation of Medicinal Products a copy of the authorization together with the summary of the product characteristics referred to in Article 5a.

Furthermore, the competent authorities shall draw up an assessment report and comments on the dossier as regards the results of the analytical and pharmacotoxicological tests and the clinical trials of the veterinary medicinal product concerned. The assessment report shall be updated whenever new information becomes available which is of importance for the evaluation of the quality, safety or efficacy of the veterinary medicinal product concerned.';

6. Article 8 is replaced by the following:

'Article 8

1. Member States shall take all appropriate measures to ensure that the procedure for granting an authorization to place a veterinary medicinal product on the market is completed within 210 days of the submission of a valid application.

2. Where a Member State notes that an application for authorization submitted after 1 January 1995 is already under active examination in another Member State in respect of that veterinary medicinal product, the Member State concerned may decide to suspend the detailed examination of the application in order to await the assessment report prepared by the other Member State in accordance with Article 5b.

The Member State concerned shall inform the other Member State and the applicant of its decision to suspend detailed examination of the application in question. As soon as it has completed the examination of the application and reached a decision, the other Member State shall forward a copy of its assessment report to the Member State concerned.

Within 90 days of the receipt of the assessment report, the Member State concerned shall either recognize the decision of the other Member State and the summary of the product characteristics as approved by it or, if it considers that there are grounds for supposing that the authorization of the veterinary medicinal product concerned may present a risk to human or animal health or the environment (*), it shall apply the procedures set out in Articles 18 to 22 of this Directive.

(*) The expression "risk to human or animal health or the environment" refers to the quality, safety and efficacy of the veterinary medicinal product.';

7. insert the following Article 8a:

'*Article 8a*

With effect from 1 January 1998, where a Member State is informed in accordance with point 13 of the second paragraph of Article 5 that another Member State has authorized a veterinary medicinal product which is the subject of an application for authorization in the Member State concerned, that Member State shall forthwith request the authorities of the Member State which has granted the authorization to forward to it the assessement report referred to in the second paragraph of Article 5b.

Within 90 days of the receipt of the assessment report, the Member State concerned shall either recognize the decision of the first Member State and the summary of the product characteristics as approved by it or, if it considers that there are grounds for supposing that the authorization of the veterinary medicinal product concerned may present a risk to human or animal health or the environment (*), it shall apply the procedures set out in Articles 18 to 22 of this Directive.

(*) The expression "risk to human or animal health or the environment" refers to the quality, safety and efficacy of the veterinary medicinal product.';

8. the first subparagraph of Article 14 (4) is replaced by the following:

'After an authorization has been issued, the person responsible for placing the veterinary medicinal product on the market must, in respect of the methods of preparation and control provided for in points 4 and 9 of the second subparagraph of Article 5, take account of technical and scientific progress and introduce any changes that may be required to enable that veterinary medicinal product to be manufactured and checked by means of generally accepted scientific methods. These changes shall be subject to the approval of the competent authority of the Member State concerned.';

9. Article 15 is replaced by the following:

'*Article 15*

1. 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 expiry date and after consideration of a dossier updating the information previously submitted.

2. In exceptional circumstances, and following consultation with the applicant, an authorization may be granted subject to certain specific obligations, and subject to annual review, including:

— the carrying out of further studies following the granting of authorization,

— the notification of adverse reactions to the veterinary medicinal product.

These exceptional decisions may only be adopted for objective and verifiable reasons.';

10. Chapter IV is replaced by the following:

'CHAPTER IV

Committee for Veterinary Medicinal Products

Article 16

1. In order to facilitate the adoption of common decisions by Member States on the authorization of veterinary medicinal products on the basis of the scientific criteria of quality, safety and efficacy, and to achieve thereby the free movement of veterinary medicinal products within the Community, a Committee for Veterinary Medicinal Products, hereinafter referred to as "the Committee", is hereby set up. The Commission shall be part of the European Agency for the Evaluation of Medicinal Products established by Regulation (EEC) No 2309/93, hereinafter referred to as "the Agency".

2. In addition to the other responsibilities conferred upon it by Community law, the Committee shall examine any question relating to the granting, variation, suspension or withdrawal of authorization for a veterinary medicinal product which is submitted to it in accordance with the provisions of this Directive.

3. The Committee shall adopt own rules of procedure.

Article 17

1. In order to obtain the recognition according to the procedure laid down in this Chapter in one or more of the Member States of an authorization issued by a Member State in accordance with Article 4, the holder of the authorization shall submit an application to the competent

authorities of the Member State or Member States concerned, together with the information and particulars referred to in Articles 5, 5a and 5b. He shall testify that the dossier is identical to that accepted by the first Member State, or shall identify any additions or amendments it may contain. In the latter case, he shall certify that the summary of the product characteristics proposed by him in accordance with Article 5a is identical to that accepted by the first Member State in accordance with Article 5b. Moreover, he shall certify that all the dossiers filed as part of this procedure are identical.

2. The holder of the marketing authorization shall notify the Committee of this application, inform it of the Member States concerned and of the dates of submission of the application and send it a copy of the authorization granted by the first Member State. He shall also send the Committee copies of any such authorization which may have been granted by the other Member States in respect of the veterinary medicinal product concerned, and shall indicate whether any application for authorization is currently under consideration in any Member State.

3. Except in cases referred to in Article 8a, before submitting the application, the holder of the authorization shall inform the Member State which granted the authorization on which the application is based that an application is to be made in accordance with this Directive and shall notify it of any additions to the original dossier; that Member State may require the applicant to provide it with all the particulars and documents necessary to enable it to check that the dossiers filed are identical.

In addition the holder of the authorization shall request the Member State which granted the initial authorization to prepare an assessment report in respect of the veterinary medicinal product concerned, or, if necessary, to update any existing assessment report. That Member State shall prepare the assessment report, or update it, within 90 days of the receipt of the request.

At the same time as the application is submitted in accordance with paragraph 1 the Member State which granted the initial authorization shall forward the assessment report to the Member State or Member States concerned by the application.

4. Save in the exceptional case provided for in Article 18 (1), each Member State shall recognize the marketing authorization granted by the first Member State within 90 days of receipt of the application and the assessment report. It shall inform the Member State which granted the initial authorization, the other Member States concerned by the application, the Committee, and the person responsible for placing the veterinary medicinal product on the market.

Article 18

1. Nothwithstanding Article 17 (4), where a Member State considers that there are grounds for supposing that the authorization of the veterinary medicinal product concerned may present a risk to human or animal health or the environment (*), it shall forthwith inform the applicant, the Member State which granted the initial authorization, any other Member States concerned by the application and the Committee. The Member State shall state its reason in detail and shall indicate what action may be necessary to correct any defect in the application.

2. All the Member States concerned shall use their best endeavours to reach agreement on the action to be taken in respect of the application. They shall provide the applicant with the opportunity to make his point of view known orally or in writing. However, if the Member States have not reached agreement within the time limit referred to in Article 17 (4) they shall forthwith refer the matter to the Committee for the application of the procedure laid down in Article 21.

3. Within the time limit referred to in paragraph 2, the Member States concerned shall provide the Committee with a detailed statement of the matters on which they have been unable to reach agreement and the reasons for their disagreement. The applicant shall be provided with a copy of this information.

4. As soon as he is informed that the matter has been referred to the Committee, the applicant shall forthwith forward to the Committee a copy of the information and particulars referred to in Article 17 (1).

(*) The expression "risk to human or animal health or the environment" refers to the quality, safety and efficacy of the veterinary medicinal product.

Article 19

If several applications submitted in accordance with Articles 5 and 5a have been made for marketing authorization for a particular veterinary medicinal product and Member States have adopted divergent decisions concerning the authorization of that veterinary medicinal product, or its suspension or withdrawal from the market, a Member State, or the Commission, or the person responsible for placing the aforementioned product on the market may refer the matter to the Committee for application of the procedure laid down in Article 21.

The Member State concerned, the person responsible for placing the veterinary medicinal product on the market or the Commission shall clearly identify the question which is referred to the Committee for consideration and, if appropriate, shall inform the aforementioned person thereof.

The Member States and the person responsible for placing the veterinary medicinal product on the market shall forward to the Committee all available information relating to the matter in question.

Article 20

The Member States or the Commission or the applicant or holder of the marketing authorization may, in specific cases where the interests of the Community are involved, refer the matter to the Committee for the application of the procedure laid down in Article 21 before reaching a decision on a request for a marketing authorization or on the suspension or withdrawal of an authorization, or on any other variations to the terms of a marketing authorization which appears necessary, in particular to take account of the information collected in accordance with Chapter VIa.

The Member State concerned or the Commission shall clearly identify the question which is referred to the Committee for consideration and shall inform the person responsible for placing the veterinary medicinal product on the market.

The Member States and the aforementioned person shall forward to the Committee all available information relating to the matter in question.

Article 21

1. When reference is made to the procedure described in this Article, the Committee shall consider the matter concerned and issue a reasoned opinion within 90 days of the date on which the matter was referred to it.

However, in cases submitted to the Committee in accordance with Articles 19 and 20, this period may be extended by 90 days.

In case of urgency, on a proposal from its Chairman, the Committee may agree to impose a shorter deadline.

2. In order to consider the matter, the Committee may appoint one of its Members to act as rapporteur. The Committee may also appoint individual experts to advise it on specific questions. When appointing experts, the Committee shall define their tasks and specify the time limit for the completion of these tasks.

3. In the cases referred to in Articles 18 and 19, before issuing its opinion, the Committee shall provide the person responsible for placing the veterinary medicinal product on the market with an opportunity to present written or oral explanations.

In the case referred to in Article 20, the person responible for placing the veterinary medicinal product on the market may be asked to explain himself orally or in writing.

If it considers it appropriate, the Committee may invite any other person to provide information relating to the matter before it.

The Committee may suspend the time limit referred to in paragraph 1 in order to allow the person responsible for placing the veterinary medicinal product on the market to prepare explanations.

4. Where the opinion of the Committee is that:

— the application does not satisfy the criteria for authorization, or

— the summary of the product characteristics proposed by the applicant in accordance with Article 5a should be amended, or

— the authorization should be granted subject to conditions, with regard to conditions considered essential for the safe and effective use of the veterinary medicinal product including pharmacovigilance, or

— a marketing authorization should be suspended, varied or withdrawn,

the Agency shall forthwith inform the person responsible for placing the veterinary medicinal product on the market. Within 15 days of the receipt of the opinion, the aforementioned person may notify the Agency in writing of his intention to appeal. In that case, he shall forward the detailed grounds for appeal to the Agency within 60 days of receipt of the opinion. Within 60 days of receipt of the grounds for appeal, the Committee shall consider whether its opinion should be revised, and the conclusions reached on the appeal shall be annexed to the assessment report referred to in paragraph 5.

5. Within 30 days of its adoption, the Agency shall forward the final opinion of the Committee to the Member States, the Commission and the person responsible for placing the veterinary medicinal product on the market together with a report describing the assessment of the veterinary medicinal product and the reasons for its conclusions.

In the event of an opinion in favour of granting or maintaining an authorization to place the veterinary medicinal product concerned on the market, the following documents shall be annexed to the opinion:

(a) a draft summary of the product characteristics, as referred to in Article 5a; where necessary this will reflect differences in the veterinary conditions pertaining in the Member States.

(b) any conditions affecting the authorization within the meaning of paragraph 4.

Article 22

1. Within 30 days of the receipt of the opinion, the Commission shall prepare a draft of the decision to be taken in respect of the application, taking into account Community law.

In the event of a draft decision which envisages the granting of marketing authorization, the documents referred to in Article 21 (5) (a) and (b) shall be annexed.

Where, exceptionally, the draft decision is not in accordance with the opinion of the Agency, the Commission shall also annex a detailed explanation of the reasons for the differences.

The draft decision shall be forwarded to the Member States and the applicant.

2. A final decision on the application shall be adopted in accordance with the procedure laid down in Article 42k.

3. The rules of procedure of the Committee referred to in Article 42k shall be adjusted to take account of the tasks incumbent upon it in accordance with this Directive.

These adjustments shall involve the following:

— except in cases referred to in the third subparagraph of paragraph 1, the opinion of the Standing Committee shall be obtained in writing,

— each Member State is allowed at least 28 days to forward written observations on the draft decision to the Commission,

— each Member State is able to require in writing that the draft decision be discussed by the Standing Committee, giving its reasons in detail.

Where, in the opinion of the Commission, the written observations of a Member State raise important new questions of a scientific or technical nature which have not been addressed in the opinion of the Agency, the Chairman shall suspend the procedure and refer the application back to the Agency for further consideration.

The provisions necessary for the implementation of this paragraph shall be adopted by the Commission in accordance with the procedure laid down in Article 42j.

4. A decision adopted in accordance with this Article shall be addressed to the Member States concerned by the matter and to the person responsible for placing the veterinary medicinal product on the market. The Member States shall either grant or withdraw marketing authorization, or vary the terms of a marketing authorization as necessary to comply with the decision within 30 days of its notification. They shall inform the Commission and the Committee thereof.

5. The procedure referred to in Articles 16 to 22 shall not apply in the cases provided for in Article 9 (2) of Council Directive 92/74/EEC of 22 September 1992 widening the scope of Directive 81/851/EEC on the approximation of the laws of the Member States on veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products (*).

(*) OJ No L 297, 13. 10. 1992, p. 12.

Article 23

Any application by the person responsible for placing the veterinary medicinal product on the market to vary a marketing authorization which has been granted in accordance with the provisions of this Chapter shall be submitted to all the Member States which have previously authorized the veterinary medicinal product concerned.

The Commission shall, in consultation with the Agency, adopt appropriate arrangements for the examination of variations to the terms of a marketing authorization.

These arrangements shall include a notification system or administration procedures concerning minor variations and define precisely the concept of "a minor variation".

These arrangements shall be adopted by the Commission in the form of an implementing Regulation in accordance with the procedure laid down in Article 42j.

The procedure laid down in Articles 21 and 22 shall apply by analogy to variations made to marketing authorizations for products subject to the Commission's arbitration.

Article 23a

1. Where a Member State considers that the variation of the terms of a marketing authorization which has been granted in accordance with the provisions of this Chapter or its suspension or withdrawal is necessary for the protection of human or animal health or the environment, the Member State concerned shall forthwith refer the matter to the Committee for the application of the procedures laid down in Articles 21 and 22.

2. Without prejudice to the provisions of Article 20, in exceptional cases, where urgent action is essential to protect human or animal health or the environment, until a definitive decision is adopted, a Member State may suspend the marketing and the use of the veterinary medicinal product concerned on its territory. It shall inform the Commission and the other Member States no later than the following working day of the reasons for its action.

Article 23b

Articles 23 and 23a shall apply by analogy to veterinary medicinal products authorized by Member States following an opinion of the Committee given in accordance with Article 4 of Directive 87/22/EEC before 1 January 1995.

Article 23c

1. The Agency shall publish an annual report on the operation of the procedures laid down in this

Chapter and shall forward that report to the European Parliament and the Council for information.

2. By 1 January 2001, the Commission shall publish a detailed review of the operation of the procedures laid down in this Chapter and shall propose any amendments which may be necessary to improve these procedures.

The Council shall decide, under the conditions provided for in the Treaty, on the Commission proposal within one year of its submission.';

11. the third subparagraph of Article 30 (1) is replaced by the following:

'In the case of veterinary medicinal products imported from a third country, where appropriate arrangements have been made by the Community with the exporting country to ensure that the manufacturer of the veterinary medicinal product applies standards of good manufacturing practice at least equivalent to those laid down by the Community and to ensure that the controls referred to under (b) have been carried out in the exporting country, the qualified person may be relieved of responsibility for carrying out those controls.';

12. the following Chapter VIa is inserted after Article 42:

'CHAPTER VIa

Pharmacovigilance

Article 42a

In order to ensure the adoption of appropriate regulatory decisions concerning the veterinary medicinal products authorized within the Community, having regard to information obtained about suspected adverse reactions to medicinal products under normal conditions of use, the Member States shall establish a pharmacovigilance system. This system shall be used to collect information useful in the surveillance of veterinary medicinal products, with particular reference to adverse reactions in animals, and to evaluate such information scientifically.

Such information shall be collated with data on consumption of veterinary medicinal products.

This system shall also collate information on frequently observed misuse and serious abuse of veterinary medicinal products.

Article 42b

For the purpose of this Directive, the following definitions shall apply:

— *"adverse reaction"* means a reaction which is harmful and unintended and which occurs at doses normally used in animals for the prophylaxis, diagnosis or treatment of disease or the modification of physiological function.

— *"serious adverse reaction"* means an adverse reaction which is fatal, life-threatening, lesion-producing, disabling, incapacitating, or which results in permanent or prolonged symptoms in the animals treated,

— *"unexpected adverse reaction"* means an adverse reaction which is not mentioned in the summary of the product characteristics,

— *"serious unexpected adverse reaction"* means an adverse reaction which is both serious and unexpected.

Article 42c

The person responsible for placing the veterinary medicinal product on the market shall have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance.

That qualified person shall be responsible for the following:

(a) the establishment and maintenance of a system which ensures that information about all suspected adverse reactions which are reported to the personnel of the company, including its representatives, is collected and collated at a single point;

(b) the preparation for the competent authorities of the reports referred to in Article 42d, in such form as may be laid down by those authorities, in accordance with the relevant national or Community guidelines;

(c) ensuring that any request from the competent authorities for the provision of additional information necessary for the evaluation of the benefits and risks afforded by a veterinary medicinal product is answered fully and promptly, including the provision of information about the volume of sales or prescriptions of the veterinary medicinal product concerned.

Article 42d

1. The person responsible for placing the veterinary medicinal product on the market shall be required to record and to report all suspected serious adverse reactions which are brought to his attention to the competent authorities immediately, and in any case within 15 days of their receipt at the latest.

2. In addition, the person responsible for placing the veterinary medicinal product on the market shall

be required to maintain detailed records of all other suspected adverse reactions which are reported to him.

Unless other requirements have been laid down as a condition of the granting of authorization, these records shall be submitted to the competent authorities immediately upon request or at least every six months during the first two years following authorization, and once a year for the following three years. Thereafter, the records shall be submitted at five-yearly intervals together with the application for renewal of the authorization, or immediately upon request. These records shall be accompanied by a scientific evaluation.

Article 42e

The Member States shall take all appropriate measures to encourage the reporting of suspected adverse reactions to the competent authorities.

Article 42f

The Member States shall ensure that reports of suspected serious adverse reactions are immediately brought to the attention of the Agency and the person responsible for placing the veterinary medicinal product on the market, and in any case within 15 days of their notification, at the latest.

Article 42g

In order to facilitate the exchange of information about pharmacovigilance within the Community, the Commission, in consultation with the Agency, Member States and interested parties, shall draw up guidance on the collection, verification and presentation of adverse reaction reports.

This guidance shall take account of international harmonization work carried out with regard to terminology and classification in the field of pharmacovigilance when use of such work can be made in the field of the veterinary medicinal product concerned.

Article 42h

Where as a result of the evaluation of adverse reaction reports a Member State considers that a marketing authorization should be varied, suspended or withdrawn, it shall forthwith inform the Agency and the person responsible for placing the veterinary medicinal product on the market.

In case of urgency, the Member State concerned may suspend the marketing of a veterinary medicinal product, provided the Agency is informed no later than on the following working day.

Article 42i

Any amendments which may be necessary to update the provisions of this Chapter to take account of scientific and technical progress shall be adopted in accordance with the procedure laid down in Article 42j.';

13. the following Chapter VIb is inserted after Article 42i:

'Chapter VIb

Standing Committee procedure

Article 42j

Where the procedure laid down in this Article is to be followed the Commission shall be assisted by the Standing Comittee on Veterinary Medicinal Products.

The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

If the measures envisaged 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 relating to the measures to be taken. The Council shall act by a qualified majority.

If on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 42k

Where the procedure laid down in this Article is to be followed the Commission shall be assisted by the Standing Committee on Veterinary Medicinal Products.

The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

If the measures envisaged 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 relating to the measures to be taken. The Council shall act by a qualified majority.

If on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.';

14. in Articles 1 (5) and 27a of Directive 81/851/EEC, the reference to Article 2c of Directive 81/852/EEC shall be replaced by reference to Article 42j.

Article 2

The Committee referred to in Article 2b of Directive 81/852/EEC shall be called the 'Standing Committee on Veterinary Medicinal Products'.

Article 3

Member States shall take all appropriate measures to comply with this Directive, with the exception of Article 1 (7), before 1 January 1995. They shall forthwith inform the Commission thereof.

Member States shall take all appropriate measures to comply with Article 1 (7) of this Directive before 1 January 1998. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The methods of making such a reference shall be laid down by Member States.

Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field governed by this Directive.

Article 4

This Directive is addressed to the Member States.

Done at Luxembourg, 14 June 1993.

For the Council
The President
J. TRØJBORG