# 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.