II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 93/39/EEC

of 14 June 1993

amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of 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 free movement of goods, persons, services and capital is ensured;

Whereas Article 15 (2) of Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (4) provides that the Commission shall submit to the Council a proposal containing appropriate measures leading towards the abolition of any remaining barriers to the free movement of proprietary medicinal products;

Whereas, in the interest of public health and of the consumer of medicinal products, it is necessary that decisions on the authorization to place medicinal products on the market be exclusively based on the criteria of quality, safety and efficacy; whereas these criteria have been extensively harmonized by Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administration action relating to medicinal products (5), by Council Directive 75/319/EEC, and by Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products (6); whereas, however, Member States should exceptionally be able to prohibit the use on their territory of medicinal products which infringe objectively defined concepts of public order or public morality;

Whereas, with the exception of those 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 (7), an authorization to place a 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 medicinal product concerned may present a risk to public health; whereas, in the event of a disagreement between Member States about the quality, the safety or the efficacy of a medicinal product, a scientific evaluation of the matter should be undertaken by the Committee for Proprietary Medicinal Products attached to the European Agency for the Evaluation of Medicinal Products, leading to a single decision on the area of disagreement binding on the Member States

(1) OJ No C 330, 31. 12. 1970, p. 18, and OJ No C 310, 30. 11. 1991, p. 22.
(2) OJ No C 183, 15. 7. 1991, p. 187, and OJ No C 150, 31. 5. 1993.
(3) OJ No C 269, 14. 10. 1991, p. 84.
(4) OJ No L 147, 9. 6. 1975, p. 13. Directive last amended by Directive 92/27/EEC (OJ No L 113, 30. 4. 1992, p. 8).
(5) OJ No 22, 9. 2. 1965, p. 369/65. Directive last amended by Directive 92/27/EEC (OJ No L 113, 30. 4. 1992, p. 8).
(6) OJ No L 147, 9. 6. 1975, p. 1. Directive last amended by Commission Directive 91/507/EEC (OJ No L 270, 26. 9. 1991, p. 32).
(7) See page 1 of this Official Journal.

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 public health and avoid any unnecessary duplication of effort during the examination of application for authorization to place medicinal products on the market, Member States should systematically prepare assessment reports in respect of each 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 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 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 supervision of medicinal products and in particular the monitoring of adverse reactions under practical conditions of use through the national pharmacovigilance systems,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 65/65/EEC is hereby amended as follows:

1. Article 3 is replaced by the following:

   'Article 3

   No 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 an authorization has been granted in accordance with 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 (*).

   The provisions of this Directive shall not affect the powers of the Member States' authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.

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

2. the following subparagraph is added between the first and second subparagraphs of Article 4:

   'The person responsible for placing medicinal products on the market shall be established in the Community. In respect of medicinal products authorized on the date of implementation of this Directive, the Member State shall if necessary apply this provision at the time of the five-yearly renewal of the marketing authorization provided for in Article 10.';

3. in the second paragraph of Article 4, points 6 and 11 are replaced by the following:

   ' 6. Posology, pharmaceutical form, method and route of administration and expected shelf life.

   If applicable, reasons for any precautionary and safety measures to be taken for the storage of the medicinal product, its administration to patients and for the disposal of waste products, together with an indication of any potential risks presented by the medicinal product for the environment.';

   '11. Copies of any authorization obtained in another Member State or in a third country to place the relevant 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 4a or approved by the competent authorities of the Member State in accordance with Article 4b. Copies of the package leaflet proposed in accordance with Article 6 of Directive 92/27/EEC or approved by the competent authorities of the Member State in accordance with Article 10 of the same Directive. Details of any decision to refuse authorization, whether in the Community or in a third country, and the reasons for such decision.

   This information shall be updated on a regular basis';

4. Article 4b is replaced by the following:

   'Article 4b

   When the marketing authorization referred to in Article 3 is issued, the person responsible for placing that 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 4a.

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 medicinal product concerned. The assessment report shall be udapted whenever new information becomes available which is of importance for the evaluation of the quality, safety or efficacy of the medicinal product concerned.';

5. Article 6 is replaced by the following:

'*Article 6*

This Directive shall not affect the application of national legislation prohibiting or restricting the sale, supply or use of medicinal products as contraceptives or abortifacients. The Member States shall communicate the national legislation concerned to the Commission';

6. Article 7 is replaced by the following:

'*Article 7*

1. Member States shall take all appropriate measures to ensure that the procedure for granting an authorization to place a 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 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 4b.

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 medicinal product concerned may present a risk to public health (*), it shall apply the procedures set out in Articles 10 to 14 of Directive 75/319/EEC.

(*) The expression "risk to public health" refers to the quality, safety and efficacy of the medicinal product.';

7. insert the following Article 7a:

'*Article 7a*

With effect from 1 January 1998, where a Member State is informed in accordance with point 11 of the second paragraph of Article 4 that another Member State has authorized a 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 assessment report referred to in the second paragraph of Article 4b.

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 medicinal product concerned may present a risk to public health (*), it shall apply the procedures set out in Articles 10 to 14 of Directive 75/319/EEC.

(*) The expression "risk to public health" refers to the quality, safety and efficacy of the medicinal product';

8. Article 9a is replaced by the following:

'*Article 9a*

After an authorization has been issued, the person responsible for placing the product on the market must, in respect of the methods of preparation and control provided for in points 4 and 7 of the second paragraph of Article 4, take account of technical and scientific progress and introduce any changes that may be required to enable that 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 10 is replaced by the following:

'*Article 10*

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 by the competent authority of a dossier containing in particular details of the data on pharmacovigilance and other information relevant to the monitoring of the medicinial product.

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

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

— the notification of adverse reactions to the medicinal product.

These exceptional decisions may be adopted only for objective and verifiable reasons and shall be based on one of the causes referred to in Part 4 (G) of the Annex to Directive 75/318/EEC.'

Article 2

In Directive 75/318/EEC, the Committee referred to in Article 2b shall be called 'the Standing Committee on Medicinal Products for Human Use'.

Article 3

Directive 75/319/EEC is hereby amended as follows:

1. Chapter III is replaced by the following:

'CHAPTER III

Committee for Proprietary Medicinal Products

Article 8

1. In order to facilitate the adoption of common decisions by Member States on the authorization of medicinal products for human use on the basis of the scientific criteria of quality, safety and efficacy, and to achieve thereby the free movement of medicinal products within the Community, a Committee for Proprietary Medicinal Products, hereinafter referred to as "the Committee", is hereby set up. The Committee shall be part of the European Agency for the Evaluation of Medicinal Products 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 (*), 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 marketing authorization for a medicinal product which is submitted to it in accordance with this Directive.

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

Article 9

1. In order to obtain the recognition according to the procedures 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 3 of Directive 65/65/EEC, 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 4, 4a and 4b of Directive 65/65/EEC. 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 4a of Directive 65/65/EEC is identical to that accepted by the first Member State in accordance with Article 4b of Directive 65/65/EEC. Moreover he shall certify that all the dossiers filed as part of the 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 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 7a of Directive 65/65/EEC, 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 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 10 (1), each Member State shall recognize the