COMMISSION OF THE EUROPEAN COMMUNITIES

COM(77) 358 final.

Brussels, 22 July 1977

PROPOSAL FOR A COUNCIL DIRECTIVE

amending the Directive of 20 May 1975 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products

(submitted to the Council by the Commission)

Explanatory Memorandum

1. In Art. 9 and 10 of 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 (O.J. L 147 of 9 June 1975) it is stated that a Member State which has issued a marketing authorization for a proprietary medicinal product shall forward to the Committee a copy of the authorization together with the documentation material if the person responsible for marketing has required to apply for marketing authorization for the product in at least five other Member States through the Committee procedure. The Committee shall hereafter without delay retransmit the dossiers to the Member States specified which transmission shall be deemed equivalent to a formal application for marketing authorization.

2. During the discussions on the Rules of Procedure within the Committee it has become clear that the obligation that the dossiers in all cases shall pass through the Committee instead of being sent directly to the Member States concerned will give rise to severe administrative problems for the Secretariat and be very time consuming as the dossiers are often very voluminous. In addition to this, the Secretariat of the Committee will not carry out any examination of the dossiers before the transmission to the Member States.

3. It is therefore proposed (see annex) to amend Art. 9 and 10 of Directive 75/319/EEC so that the dossiers will be forwarded directly to the Member States specified by the Member State which has already granted the marketing authorization.

4. The Pharmaceutical Committee set up by Council Decision 75/320/EEC has agreed in principle on the amendment and the present text has got unanimous approuval by a working party of national experts on 29 June 1977.

PROPOSAL FOR A COUNCIL DIRECTIVE

amending Second Directive 75/319/EEC on the approximation of provisions laid down by law; regulation or administrative action relating to proprietary medicinal products

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Parliament (1),

Having regard to the Opinion of the Economic and Social Committee (2),

Whereas, a Committee for Proprietary Medicinal Products has been set up by Second Council Directive 75/319/EEC of 20 Mai 1975 (3) with the responsibility to give an opinion as to whether a particular proprietary medicinal product complies with the requirements set out in Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (4);

Whereas it is stated in Articles 9 and 10 of Directive 75/319/EEC that, in cases where the Community-procedure is to be applied, the Member State which has issued the marketing authorization shall forward the dossier to the Committee which shall forthwith forward the dossier to the Member States specified by the person responsible for marketing;

Whereas experience has shown that the provision that the dossiers shall pass through the Committee instead of being sent directly to the Member States concerned results in administrative problems in processing the voluminous documentation and in delays in the work of the Committee;

(1) OJ No
(2) OJ No

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Whereas, in order to solve these problems and to reduce the delays it is necessary to amend these provisions to enable the Member State which has initially issued the marketing authorization to send the dossier directly to the Member States specified as well as to the Committee.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Article 9 of Directive 75/319/EEC is hereby amended as follows:

1. The Member State which has issued a marketing authorization for a proprietary medicinal product shall forward, if the person responsible for marketing has requested the forwarding to at least five other Member States, a dossier containing a copy of this request and a copy of the authorization together with the particulars and documents mentioned in Article 4, second paragraph of Directive 65/65/EEC to the Committee and to the competent authorities of the Member States specified.

2. Such forwarding shall be deemed to be equivalent to submitting an application for marketing authorization, within the meaning of Article 4 of Directive 65/65/EEC, to the said authorities.

3. The Committee shall forthwith inform the Member States concerned that the case has been referred to the Committee.

Article 2

In Article 10 (1) of Directive 75/319/EEC the words "forwarding referred to in Article 9 (2)" are hereby replaced by "transmission of the information referred to in Article 9 (3)".

Article 3

This Directive is addressed to the Member States.