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Working Documents

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DOCUMENT 1-303/81

Report

drawn up on behalf of the Committee on Economic and Monetary Affairs

on the proposal from the Commission of the European Communities to the Council (Doc. 1-248/80) for a directive amending Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products

Rapporteur: Mr G. DELEAU

By letter of 16 June 1980 the President of the Council of the European Communities consulted the European Parliament on the proposal from the Commission of the European Communities to the Council (Doc. 1-248/80) for a directive amending Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.

The President of Parliament referred this proposal at the plenary sitting of 19 June 1980 to the Committee on Economic and Monetary Affairs as the committee responsible and on 16 June 1981 to the Committee on the Environment, Public Health and Consumer Protection for an opinion.

At its meeting of 21 October 1980 the Committee on Economic and Monetary Affairs appointed Mr DELEAU rapporteur.

The Committee on Economic and Monetary Affairs considered this proposal at its meetings of 13 May and 10 June 1981. At the latter meeting it rejected the Commission's proposal by 12 votes to 9, with one abstention.

Present: Mr Jacques Moreau, chairman; Mr De Ferranti, vice-chairman; Mr Deleau, vice-chairman and rapporteur; Mr Albers (deputizing for Mr Ruffolo), Mrs Baduel-Glorioso (deputizing for Mr Fernandez), Mr Beazley, Mr Beumer, Mr von Bismarck, Mr Bonaccini, Mr Collomb, Miss Forster, Mr Giavazzi, Mr Herman, Mr Leonardi, Mrs Lizin (deputizing for Mr Schintzel), Mr Mihr, Mr E. Nielsen, (deputizing for Mr Combe), Mr Petronio, Sir Brandon Rhys-Williams, Mr Rogers, Mr Tuckman, (deputizing for Mr Hopper) and Mr von Wogau.

The opinion of the Committee on the Environment, Public Health and Consumer Protection will be published separately.

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The Committee on Economic and Monetary Affairs hereby submits to the European Parliament the following motion for a resolution, together with explanatory statement :

MOTION FOR A RESOLUTION

embodying the opinion of the European Parliament on the proposal from the Commission of the European Communities to the Council for a directive amending Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.

The European Parliament,

- having regard to the proposal from the Commission of the European Communities to the Council¹,
- having been consulted by the Council pursuant to Article 100 of the EEC Treaty (Doc. 1-248/80),
- having regard to the report of the Committee on Economic and Monetary Affairs and the opinion of the Committee on the Environment, Public Health and Consumer Protection (Doc. 1-303/81)

1. Rejects the Commission's proposal for a directive;
2. Instructs its President to forward this resolution and the report to the Commission.

¹ OJ No. C 143, 12.6 1980, p. 8

EXPLANATORY STATEMENT

1. In the present state of the market and with the existing price fixing systems, it is possible for proprietary medicinal products to be sold at prices varying substantially from one Member State to another.

This naturally leads to a demand for imports of successful products where there is a substantial price difference.

In the Centra farm judgment of 30 May 1976 (Case 104/75) the European Court of Justice found against national rules or practices which, as regards parallel imports, had the effect of channelling imports in the sense that only certain traders could undertake them, others being excluded. Such restrictions amount to measures having equivalent effect to quantitative restrictions within the meaning of Article 30 of the EEC Treaty.

The Commission has remarked that not all the Member States have drawn the same conclusions from this judgment in that some have expressly amended their legislation while others have merely raised no objection to the importation and marketing of proprietary medicinal products.

In the light of this situation the Commission thought it useful to submit a proposal for a directive amending Directives 65/65/EEC and 75/319/EEC with a view to eliminating such restrictions.

- Position of the majority of the members of the committee

2. The majority of the members of the Committee on Economic and Monetary Affairs doubts whether the Commission's proposal for a directive is justified.

The Member States have complied with the decision of the Court of Justice of the European Communities in Case 104/75. This is demonstrated by the fact that no trader has since brought proceedings against a Member State except in the special case of registration fees (Case 32/80) where the Court found in favour of the Member State.

Moreover, the task of ensuring that national laws and practices conform with the interpretation of the EEC Treaty as contained in the judgments of the Court of Justice is a matter for the Member States and does not require the harmonization of national laws. In the event of a Member State not complying with a judgment of the Court, it would be either for the injured party to institute proceedings or, more generally, for the Commission to bring an action under Article 169 of the Treaty.

Thus the Commission's proposal for a Council directive appears superfluous. Furthermore, as an interpretation of the judgment of the Court of Justice in Case 104/75 it goes beyond the actual content and unduly extends the scope of that decision.

Although the Court of Justice has declared laws and regulations standing in the way of 'parallel' imports to be contrary to the EEC Treaty, the free circulation of proprietary medicinal products made possible by the Court's decision benefits only the parallel importers and hence applies in very special cases involving a very small amount of trade; there remain to be determined the general conditions governing such free circulation, that is to say: the elimination of technical barriers by the mutual recognition of marketing authorizations and of economic barriers through the dismantling of national measures having equivalent effect to quantitative restrictions.

The majority of the members of the Committee on Economic and Monetary Affairs therefore rejects the Commission's proposal for a directive.

- Position of the minority of the members of the committee

3. The minority of the members of the Committee on Economic and Monetary Affairs feels that the Commission's proposal is not superfluous in that it contains provisions likely through the adoption of a uniform practice on parallel imports in all the Member States to promote greater competition in this field. However, like the majority, the minority recognizes the need for more general measures for the progressive elimination of both technical barriers (mutual recognition of marketing authorizations) and also economic barriers (elimination of national measures having equivalent effect to quantitative restrictions).

