COUNCIL DIRECTIVE

of 3 May 1989

amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products

(89/341/EEC)

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 the essential aim of any rules governing the production, distribution or use of medicinal products must be to safeguard public health;

Whereas the Directives on the approximation of the laws relating to proprietary medicinal products must be adapted to scientific progress and take account of the experience obtained since their adoption so as to ensure improved quality and greater safety and efficacy;

Whereas, in its conclusions of 15 May 1987 on improvement in the use of proprietary medicinal products by consumers (4), the Council considered that the system for leaflets accompanying proprietary medicinal products, for human consumption, on the market in the Community should be improved;

Whereas the guarantees of the quality of medicinal products manufactured within the Community should be maintained by requiring compliance with the principles of good manufacturing practice for medicinal products irrespective of the final destination of the products;

Whereas the Commission should be empowered to define in detail the principles of good manufacturing practice for medicinal products in close cooperation with the Committee for Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers in the Proprietary Medicinal Products Sector;

Whereas, having regard to the resolution of the European Parliament of 13 June 1986 on the export of pharmaceutical products to the Third World, measures should be taken to improve the provision of information for third countries on the conditions of use of medicinal products within the Member States;

Whereas the scope of Directive 65/65/EEC (5), as last amended by Directive 87/21/EEC (6), of Directive 75/318/EEC (7), as last amended by Directive 87/19/EEC (8), and of Second Directive 75/319/EEC (9), as last amended by Directive 83/570/EEC (10), should be extended to cover other industrially produced medicinal products hitherto excluded,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

1. In the title, preamble and Chapters II to V, all references to 'proprietary medicinal product' are replaced by 'medicinal product'.

2. In Article 1, the following points are inserted:

'4. *Magistral formula:*

Any medicinal product prepared in a pharmacy in accordance with a prescription for an individual patient.

5. *Official formula:*

Any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question.'

3. Article 2 is replaced by the following:

'Article 2

1. Chapters II to V shall apply to proprietary medicinal products for human use intended to be placed on the market in Member States.

(1) OJ No C 36, 8. 2. 1988, p. 22.
(2) OJ No C 290, 14. 11. 1988, p. 128; OJ No C 120, 16. 5. 1989.
(3) OJ No C 208, 8. 8. 1988, p. 64.
(4) OJ No C 178, 7. 7. 1987, p. 2.
(5) OJ No 22, 9. 2. 1965, p. 369/65.
(6) OJ No L 15, 17. 1. 1987, p. 36.
(7) OJ No L 147, 9. 6. 1975, p. 1.
(8) OJ No L 15, 17. 1. 1987, p. 31.
(9) OJ No L 147, 9. 6. 1975, p. 13.
(10) OJ No L 332, 28. 11. 1983, p. 1.