II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 14 June 1989

extending the scope of 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 and laying down special provisions for medicinal products derived from human blood or human plasma

(89/381/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 disparities in the laws, regulations or administrative provisions of Member States may hinder trade in medicinal products derived from human blood or human plasma within the Community;

Whereas the essential aim of any rules governing the production, distribution or use of medicinal products must be to ensure a high level of protection of public health;

Whereas the provisions laid down by Directive 65/65/EEC (4), as last amended by Directive 87/21/EEC (5), and by Directive 75/319/EEC (6), as last amended by Directive 83/570/EEC (7), both concerning the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, although appropriate, are inadequate with regard to medicinal products derived from human blood or human plasma;

Whereas in accordance with Article 5 of Council Directive 87/22/EEC of 22 December 1986 on the approximation of national provisions relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology (8); the Commission is required to submit proposals to harmonize, along the lines of Directive 75/319/EEC, the conditions for authorizing the manufacture and placing on the market of medicinal products derived from human blood or human plasma;

Whereas the Community entirely supports the efforts of the Council of Europe to promote voluntary unpaid blood and plasma donation to attain self-sufficiency throughout the Community in the supply of blood products, and to ensure respect for ethical principles in trade in therapeutic substances of human origin;

Whereas the rules designed to guarantee the quality, safety and efficacy of medicinal products derived from human blood or human plasma must be applied in the same manner to both public and private establishments, and to blood and plasma imported from third countries;

Whereas, before an authorization to market a medicinal product derived from human blood or human plasma can be granted, the manufacturer must demonstrate his ability to guarantee batch-to-batch consistency and the absence of specific viral contamination, to the extent that the state of technology permits;

(1) OJ No C 308, 3. 12. 1988, p. 21.
(2) OJ No C 290, 14. 12. 1988, p. 134 and OJ No C 120, 16. 5. 1989.
(3) OJ No C 208, 8. 8. 1988, p. 64.
(4) OJ No 22, 9. 2. 1965, p. 369/65.
(5) OJ No L 15, 17. 1. 1987, p. 36.
(6) OJ No L 147, 9. 6. 1975, p. 13.
(7) OJ No L 332, 28. 11. 1983, p. 1.
(8) OJ No L 15, 17. 1. 1987, p. 38.