DIRECTIVE 2000/70/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 November 2000

amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) In addition to being directed at medical devices for *in vitro* diagnosis, the Commission proposal sought to amend Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [4] in order to extend its scope to medical devices manufactured by using non-viable tissues or substances of human origin derived from those tissues. This amendment was not included in Directive 98/79/EC [5] when it was adopted.

(2) This Directive accordingly aims at amending Directive 93/42/EEC so as to include in its scope only devices which incorporate, as an integral part, substances derived from human blood or plasma. However, medical devices incorporating other substances derived from human tissues remain excluded from the scope of the said Directive.

(3) The essential aim of any rules governing the production, distribution or use of medical devices must be to safeguard public health.

(4) Furthermore, national provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices must be harmonised in order to guarantee free movement of such devices within the internal market.

(5) Medical devices incorporating, as an integral part, substances derived from human blood or plasma have the same purposes as other medical devices. There is therefore no reason to treat them differently as regards their free circulation.

(6) Medical devices incorporating, as an integral part, a substance derived from human blood or plasma and which is liable to act upon the body with action ancillary to that of the device must comply with the provisions of Directive 93/42/EEC and other instruments supplementing the said Directive.

(7) A human blood derivative, if used separately, may be considered to be a medicinal product constituent within the meaning of Council Directive 89/381/EEC [6]. When it is incorporated into a medical device, the substance must be subject to appropriate checks by analogy with Council Directives 75/318/EEC [7] and 89/381/EEC. These checks will be carried out by the authorities empowered to implement the aforesaid Directives,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 93/42/EEC is hereby amended as follows:

1. Article 1 shall be amended as follows:

(a) the following paragraph shall be inserted:

'4 a. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma within the meaning of Article 1 of Directive 89/381/EEC (*) and which is liable to act upon the human body with action ancillary to that of the device, hereinafter referred to as a "human blood derivative", that device must be assessed and authorised in accordance with this Directive.

(*) Council Directive 89/381/EEC 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 (OJ L 181, 28.6.1989, p. 44).';

[1] OJ C 172, 7.7.1995, p. 21 and OJ C 87, 18.3.1997, p. 9.
[2] OJ C 18, 22.1.1996, p. 12.
[3] Opinion of the European Parliament of 12 March 1996 (OJ C 96, 1.4.1996, p. 31), Council Common Position of 29 June 2000 (OJ C 245, 25.8.2000, p. 19) and European Parliament Decision of 24 October 2000.
[4] OJ L 169, 12.7.1993, p. 1. Directive as amended by Directive 98/79/EC of the European Parliament and of the Council (OJ L 331, 7.12.1998, p. 1).
[5] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).
[6] Council Directive 89/381/EEC 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 (OJ L 181, 28.6.1989, p. 44).
[7] Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of medicinal products (OJ L 147, 9.6.1975, p. 1). Directive as last amended by Commission Directive 1999/83/EC (OJ L 243, 15.9.1999, p. 9).