Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2001/0186(COD)	Procedure completed
Medical devices incorporating stable derivates of human blood or human plasma See also Directive 2000/70/EC 1995/0013B(COD) Subject 4.20.04.02 Safety of blood and transfusion 4.60.02 Consumer information, advertising, labelling		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health, Consumer Policy		
Council of the European Union	Council configuration	Meeting	Date
	Employment, Social Policy, Health and Consumer Affairs	2392	03/12/2001
European Commission	Commission DG	Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs		

Key events

21/08/2001	Legislative proposal published	COM(2001)0480	Summary
03/09/2001	Committee referral announced in Parliament, 1st reading		
08/10/2001	Vote in committee, 1st reading		
23/10/2001	Decision by Parliament, 1st reading	T5-0526/2001	Summary
03/12/2001	Act adopted by Council after Parliament's 1st reading		
07/12/2001	Final act signed		
07/12/2001	End of procedure in Parliament		
10/01/2002	Final act published in Official Journal		

Technical information

Procedure reference	2001/0186(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation

Legislative instrument	Directive
	See also Directive 2000/70/EC 1995/0013B(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095; Rules of Procedure EP 52-p1
Stage reached in procedure	Procedure completed

Documentation gateway

Legislative proposal		COM(2001)0480 OJ C 304 30.10.2001, p. 0334 E	22/08/2001	EC	Summary
Text adopted by Parliament, 1st reading/single reading		T5-0526/2001 OJ C 112 09.05.2002, p. 0026-0094 E	23/10/2001	EP	Summary
Economic and Social Committee: opinion, report		CES1484/2001 OJ C 048 21.02.2002, p. 0069	28/11/2001	ESC	

Additional information

European Commission	EUR-Lex

Final act

Directive 2001/104
OJ L 006 10.01.2002, p. 0050-0051 Summary

Medical devices incorporating stable derivates of human blood or human plasma

PURPOSE:To propose a new Directive on human blood or human plasma in order to clarify a mis-transcription in the original text. CONTENT: Directive 2000/70/EC regulates devices incorporating stable derivatives of human blood or human products. Following agreement on the Directive, it was brought to the Commission's attention by the Member States that there was a mis-transcription in the wording as agreed by the Council. The existence of the anomaly was confirmed by experts in the European Parliament, the Council and the Commission. It was decided that this situation could lead to confusion should the legislation require interpretation. All parties therefore agree that the simplest solution would be for the Commission to propose the Directive anew whilst at the same time incorporating the agreed, rather than mis-transcribed text. This, it is believed is the quickest way to implement the requirements of the Directive. This proposal effectively gives expression to what had originally been agreed.?

Medical devices incorporating stable derivates of human blood or human plasma

The European Parliament approved this proposal, which amends Directive 93/42/EEC, by extending its scope to devices incorporating stable derivates of human blood or blood products. It was agreed not to table amendments since this would imply the opening of a second reading under the co-operation procedure.?

Medical devices incorporating stable derivates of human blood or human plasma

PURPOSE : to amend Council directive 93/42/EEC to include medical devices incorporating substances derived from human blood or plasma. COMMUNITY MEASURE : Directive 2001/104/EC of the European Parliament and of the Council amending Council Directive 93/42/EEC concerning medical devices. CONTENT : This directive aims at including in the scope of directive 93/42/EEC only medical devices which incorporate as an integral part, substances derived from human blood or human plasma. Medical devices incorporating other substances derived from human tissues remain excluded from the scope of the Directive. DATE OF APPLICATION : 13 June 2002 ENTRY INTO FORCE : 10 January 2002.?