Basic information

1995/0013B(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Medical devices including blood and plasma derivates See also 2001/0186(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 and Consumer Protection	TRAKATELLIS Antonios (PPE-DE)	12/07/2000

Former committee responsible	Former rapporteur	Appointed
ECON Economic and Monetary Affairs, Industrial Policy	POMPIDOU Alain (RDE)	24/05/1995

Former committee for opinion	Former rapporteur for opinion	Appointed
ENVI Environment, Public Health and Consumer Protection	TRAKATELLIS Antonios (PPE)	19/04/1995

Council of the European Union

Council configuration	Meetings	Date
Health	2281	2000-06-29

Key events

Date	Event	Reference	Summary
19/04/1995	Legislative proposal published	COM(1995)0130	Summary
15/05/1995	Committee referral announced in Parliament, 1st reading		
06/02/1996	Vote in committee, 1st reading		Summary
06/02/1996	Committee report tabled for plenary, 1st reading	A4-0031/1996	
29/06/2000	Council position published	13561/1/1999	Summary

06/07/2000	Committee referral announced in Parliament, 2nd reading		
10/10/2000	Vote in committee, 2nd reading		Summary
10/10/2000	Committee recommendation tabled for plenary, 2nd reading	A5-0268/2000	
24/10/2000	Decision by Parliament, 2nd reading	T5-0451/2000	Summary
16/11/2000	Final act signed		
16/11/2000	End of procedure in Parliament		
13/12/2000	Final act published in Official Journal		

Technical information

Procedure reference	1995/0013B(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Amendments and repeals	See also 2001/0186(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/12916

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A4-0031/1996 OJ C 078 18.03.1996, p. 0002	06/02/1996	
Text adopted by Parliament, 1st reading/single reading		T4-0115/1996 OJ C 096 01.04.1996, p. 0017-0031	12/03/1996	
Committee recommendation tabled for plenary, 2nd reading		A5-0268/2000 OJ C 197 12.07.2001, p. 0009	10/10/2000	
Text adopted by Parliament, 2nd reading		T5-0451/2000 OJ C 197 12.07.2001, p. 0023-0074	24/10/2000	Summary

Council of the EU

Document type	Reference	Date	Summary
Council position	13561/1/1999 OJ C 245 25.08.2000, p. 0019	29/06/2000	Summary

European Commission

Document type	Reference	Date	Summary
	COM(1995)0130		

Legislative proposal	OJ C 172 07.07.1995, p. 0021	19/04/1995	Summary
Commission communication on Council's position	SEC(2000)1134	30/06/2000	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1153/1995 OJ C 018 22.01.1996, p. 0012	25/10/1995	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Directive 2000/0070
OJ L 313 13.12.2000, p. 0022 Summary

Medical devices including blood and plasma derivates

1995/0013B(COD) - 16/11/2000 - Final act

PURPOSE : to amend Directive 93/42/EEC, as regards medical devices incorporating stable derivates of human blood or human plasma. COMMUNITY MEASURE : Directive 2000/70/EC of the European Parliament and of the Council. CONTENT : the Directive 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 tissue remain excluded from the scope of the Directive. ENTRY INTO FORCE : 13 /12/2000. DEADLINE SET FOR TRANSPOSITION : 13/12/2001.

Medical devices including blood and plasma derivates

1995/0013B(COD) - 24/10/2000 - Text adopted by Parliament, 2nd reading

The European Parliament adopted the report, drafted by Mr Antonios TRAKATELLIS (EPP/ED, Gr) without amendment.

Medical devices including blood and plasma derivates

1995/0013B(COD) - 30/06/2000 - Commission communication on Council's position

The Commission's proposal, resulting from the COREPER decision of October 1997 and based on Article 95 of the Treaty seeks to harmonise national provisions governing the placing on the market of medical devices incorporating tissues of human origin. During the discussions in the Council, it emerged that it would be advisable to restrict the scope of the proposal to devices containing derivatives of human blood and human plasma, and that devices incorporating other derivatives of human tissues should be the subject of a specific directive. The common position is consequently restricted to amending Directive 93/42/EEC with a view to introducing provisions concerning derivatives of blood and plasma. The Commission accepts the constituent parts of the common position. It notes that the latter is in line with the amendments proposed by the European Parliament. It therefore calls on the two institutions to conclude the legislative procedure as quickly as possible so that the necessary improvement in health protection in the sector concerned can be achieved. In addition, the Commission will begin preliminary work in order to consider the advisability of submitting a proposal for a directive concerning substances other than those derived from human blood and human plasma.

Medical devices including blood and plasma derivates

1995/0013B(COD) - 19/04/1995 - Legislative proposal

Following the splitting of the initial Commission proposal and the adoption of Directive 98/79/EC concerning in vitro diagnostic medical devices, the proposed amendment seeks to extend the scope of application of Directive 93/42/EEC to medical devices incorporating derivatives of human blood and human plasma only.

Medical devices including blood and plasma derivates

1995/0013B(COD) - 29/06/2000 - Council position

The Commission included in its amended proposal almost all of the amendments suggested by the Parliament. More importantly, during the legislative procedure on the proposal, the Council in agreement with the Commission, decided to make a split and initially to draw up a common position only on in vitro diagnostic medical devices. For that part of the proposal, all the amendments proposed by the Parliament were adopted by the Council. The European Parliament approved the split and proposal at second reading an amendment to that effect, stressing the need to legislate rapidly on medical devices manufactured from substances of human origin. That amendment was incorporated in Recital no 35 of Directive 98/79/EC on in vitro diagnostic medical devices, adopted on 27 October 1998. The text of the present common position is the result of the continuation of work at Council level on the part of the proposal still outstanding. However, agreement could be reached only on a Directive limited to devices containing derivatives of human blood or plasma. Devices incorporating other substances derived from human tissue will have to be the subject of a specific Directive. Accordingly, the text of the common position is limited to amending Directive 93/42/EEC to incorporate provisions on substances derived from human blood or plasma. Consequently, two of the five amendments relating to the inclusion of medical devices made from products derived from tissues and cells from the human body in Directive 93/42/EEC, proposed by the Parliament and adopted by the Commission have become irrelevant because the scope of the common position is limited. Furthermore, amendments concerning an addition to the labelling requirements, requirements on the EU conformity declaration and the addition of medical devices covered by this Directive to class III of the classification system were all adopted by the Council with necessary adjustment to take account of the fact that the scope is limited to devices incorporating stable derivatives of human blood or plasma. Since derivatives of human blood are considered to be a medicinal product within the meaning of Directive 89/381/EEC on special provisions for medicinal products derived from human blood or plasma, and, accordingly, medical devices containing those derivatives must guarantee the same level of quality and safety as medicinal products when used, they must be subject to the existing Community evaluation and verification procedures for medicinal products.