Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	1995/0013(COD)
In vitro diagnostic medical devices: security requirements Repealed by 2012/0267(COD) Subject 2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance 4.20.02 Medical research 4.20.04 Pharmaceutical products and industry 4.60.02 Consumer information, advertising, labelling	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ECON Economic and Monetary Affairs, Industrial Policy	RDE POMPIDOU Alain	24/05/1995
Former committee responsible		
ECON Economic and Monetary Affairs, Industrial Policy	RDE POMPIDOU Alain	24/05/1995
Former committee for opinion		
BUDG Budgets		
ENER Research, Technological Development and Energy	The committee decided not to give an opinion.	
RELA External Economic Relations	The committee decided not to give an opinion.	
ENVI Environment, Public Health and Consumer Protection	PPE TRAKATELLIS Antonios	19/04/1995
CONT Budgetary Control	The committee decided not to give an opinion.	

Council of the European Union

Council configuration	Meeting	Date
General Affairs	2120	05/10/1998
Environment	2076	23/03/1998
Competitiveness (Internal Market, Industry, Research and Space)	2051	27/11/1997
Competitiveness (Internal Market, Industry, Research and Space)	2007	21/05/1997

Key events

24/10/1994	Additional information		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	
12/03/1996	Debate in Parliament		Summary
12/03/1996	Decision by Parliament, 1st reading	T4-0115/1996	Summary
20/12/1996	Modified legislative proposal published	COM(1996)0643	Summary
21/05/1997	Debate in Council	2007	
23/03/1998	Council position published	05255/1/1998	Summary
02/04/1998	Committee referral announced in Parliament, 2nd reading		
03/06/1998	Vote in committee, 2nd reading		Summary
03/06/1998	Committee recommendation tabled for plenary, 2nd reading	A4-0225/1998	
17/06/1998	Debate in Parliament		Summary
18/06/1998	Decision by Parliament, 2nd reading	T4-0362/1998	Summary
05/10/1998	Act approved by Council, 2nd reading		
27/10/1998	Final act signed		
27/10/1998	End of procedure in Parliament		
07/12/1998	Final act published in Official Journal		

Technical information

Procedure reference	1995/0013(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
	Repealed by 2012/0267(COD)
Legal basis	EC before Amsterdam E 100A
Stage reached in procedure	Procedure completed
Committee dossier	ECON/4/09931

Documentation gateway

Legislative proposal		COM(1995)0130 OJ C 172 07.07.1995, p. 0021	19/04/1995	EC	Summary
Economic and Social Committee: opinion, report		CES1153/1995 OJ C 018 22.01.1996, p. 0012	25/10/1995	ESC	Summary

Committee report tabled for plenary, 1st reading/single reading	A4-0031/1996 OJ C 078 18.03.1996, p. 0002	06/02/1996	EP	
Text adopted by Parliament, 1st reading/single reading	T4-0115/1996 OJ C 096 01.04.1996, p. 0017-0031	12/03/1996	EP	Summary
Modified legislative proposal	COM(1996)0643 OJ C 087 18.03.1997, p. 0009	20/12/1996	EC	Summary
Council position	05255/1/1998 OJ C 178 10.06.1998, p. 0007	23/03/1998	CSL	Summary
Commission communication on Council's position	SEC(1998)0555	26/03/1998	EC	Summary
Committee recommendation tabled for plenary, 2nd reading	A4-0225/1998 OJ C 210 06.07.1998, p. 0009	03/06/1998	EP	
Text adopted by Parliament, 2nd reading	T4-0362/1998 OJ C 210 06.07.1998, p. 0170-0194	18/06/1998	EP	Summary
Commission opinion on Parliament's position at 2nd reading	COM(1998)0548	02/10/1998	EC	Summary
Implementing legislative act	32002D0364 OJ L 131 16.05.2002, p. 0017-0030	07/05/2002	EU	

Additional information

European Commission	EUR-Lex

Final act

Directive 1998/79
OJ L 331 07.12.1998, p. 0001 Summary

In vitro diagnostic medical devices: security requirements

CATEGORY OF REFERRAL: Proposal for Directive 2. Expected date of referral: December 1994 3. Previous Community legislation: Directive 93/42 of 14 June 1993 on medical devices excluding devices used for in-vitro diagnosis and active implantable devices. Related legislation 73/23, 87/404, 88/378, 89/106, 89/336, 89/392, 89/684, 90/384, 90/385 amended by 93/68, 90/396, 91/263, and 92/42. PREVIOUS POSITION OF EP: Amendments and legislative Resolution A3-0178/92 on medical devices (OJ C150 of 15/06/1992) and EP decision on medical devices (OJ C150 of 31/05/1993). The EP found the general tenor of the proposal satisfactory but adopted a number of amendments, especially in regard to restricting administrative formalities, increasing consultation opportunities for manufacturers, and making some of the definitions more precise. SITUATION IN THE MEMBER STATES: no national legislation available.

In vitro diagnostic medical devices: security requirements

The rapporteur, Mr Pompidou (UPE, F), referred to the problems associated with this proposal, which had to reconcile two essential requirements, namely to ensure the free movement of products while at the same time protecting the health and safety of EU citizens. He thought that the ?new approach? was not appropriate for dealing with the problems posed by the stability of biological reactants, which in 35% of cases could lead to serious errors in diagnosis. For this reason he called for a quality control system to be introduced before and after the product was placed on the market, as this was the only way in which public health and safety could be guaranteed. Finally, the rapporteur stressed that a centralised database was needed in order to ensure consistency in the information being supplied to this sector. Commissioner Bangemann said that everyone was in favour of providing better protection for patients and declared that the Commission could accept 47 of the 78 amendments tabled. These were Amendments Nos 1 to 6, 8, 10 to 16, 19 and 21 in part, 22 to 29, 32 to 34, 36 to 39, 41, 42, 44 and 45 to 47 in part, 48 to 52, 56 in part, 58 to 60, 68 in part and 74. However, the Commission could not accept the compulsory use of labels in the national language of the country in which the product was marketed. The Commissioner went on to explain that most of the products were used by professionals who had a knowledge of foreign languages and that the cost of such a measure would be excessive, especially for smaller countries. However, he did not rule out the possibility of Member States introducing this requirement on a national basis. Finally, Mr Bangemann expressed his support for a regulatory committee.

In vitro diagnostic medical devices: security requirements

The modified Commission proposal on in vitro diagnostic medical devices incorporates a number of amendments adopted by Parliament, and in particular those concerning: - clearer demarkation of the scope in comparison with Directive 89/392/EEC relating to machinery; - the clarification that the aspects concerning medical prescriptions for devices are not affected by the harmonizations; - the tightening-up of the protection requirements with a view, in particular, to minimizing the risks, including the risks relating to the packaging; - the clarification of the powers of the Member States' authorities and the strengthening of their market surveillance powers; - the establishment of a European Union database on the products placed on the market; - extension of the group of in vitro diagnostic devices which must be submitted to third-party certification before they are placed on the market; - the inclusion in the scope of Directive 93/42/EEC of certain medical devices manufactured using products derived from human tissues or cells; - the amendments to Directive 93/42/EEC to bring it closer into line with this Directive. The Commission has not approved the amendments concerning: the obligation that the information accompanying the products placed on the market must be available in the national language(s); the type of committee; application of the transitional system for notification of devices placed on the market to all Member States. ?

In vitro diagnostic medical devices: security requirements

The Council common position is based on the amended Commission proposal and incorporates in full or in part most of the amendments put forward by Parliament and accepted by the Commission. The one significant exception is the amendments concerning the inclusion of certain medical devices manufactured using substances derived from human tissue or cells in the scope of Directive 93/42/EEC. In fact the common position covers only the section on in vitro diagnostic medical devices, including in vitro diagnostic devices manufactured using substances of human origin. It does not incorporate the section of the proposal aiming to modify Directive 93/42/EEC to include medical devices other than those for in vitro diagnosis which have been manufactured from human tissues. This section of the proposal is still at the first reading stage in the Council and is to be the subject of separate legislation. The main changes to the Commission proposal to increase the safety of in vitro diagnostic medical devices are: (a) field of application: the directive does not affect national laws requiring devices to be issued only on a medical prescription; it also covers devices designed to monitor therapeutic treatment; (b) essential requirements: these are also concerned with the packaging of devices in so far as such packaging is related to the safety and performance aspects of the device; (c) devices subject to certification by a third party: Annex II of the common position lists, in addition to the extension already provided by the amended proposal, a number of devices for which certification by a third party will be required; this annex makes a distinction between products used in particular for blood transfusions (list A tests for blood groups, HIV and Hepatitis B, C and D) and products regarded as sensitive which require the intervention of a third party before they are placed on the market (list B); the list at Annex II has been extended to take account in particular of the medical conditions under which they are used, the consequences of false negative or positive results and the experience of the Member States; (d) market monitoring measures: the common position provides for a European databank to be set up containing data relating to registration of manufacturers and devices, certificates and data obtained in accordance with the vigilance procedure; it states that Member States have an obligation to monitor the safety and quality of devices placed on the market. The Council has also introduced new provisions with regard to the following aspects: (a) technical specifications: the common position provides that for devices listed at Annex II list A and if necessary for those on list B, 'common technical specifications' should be drawn up; these specifications would establish appropriate performance evaluation and re-evaluation criteria and replace national documents on these subjects. (b) strengthening evaluation and conformity procedures: in order to ensure an optimal level of safety for devices normally used for blood transfusions, Annex IV (full quality assurance system) requires for devices on list A of Annex II a particular assessment of the products' design; in addition, each batch of manufactured products is subject to additional checks on samples of the manufactured products; (c) rules applicable to the notified bodies: the common position states that the notified bodies have an obligation to suspend or withdraw certificates in given circumstances; the designation criteria for these bodies are also set out in greater detail; (d) particular health monitoring measures: a new provision makes it possible to take transitional national measures or Community measures to prohibit or restrict the availability of certain products or groups of products or to subject them to particular requirements. ?

In vitro diagnostic medical devices: security requirements

The Commission accepts the common position. It calls on Parliament and the Council to conclude the legislative procedure as quickly as possible in order to bring about the necessary improvement in health protection in the in vitro diagnostic devices sector. The Commission stresses that legislation on medical devices manufactured using substances of human origin should be produced as soon as possible and will contribute to this accordingly. ?

In vitro diagnostic medical devices: security requirements

Reporting for the Committee Mr Alain POMPIDOU (UFE, F) recommends that Parliament makes a few changes to the Council Common Position on a Directive on safety requirements for in vitro medical devices. Unlike medicines which are administered to the human body, in vitro diagnostics is carried out outside the human body on samples taken form patients. This include methods for the diagnosis of illnesses and screening of blood. The rapporteur notes that Council has accepted most of those amendments adopted by Parliament at first reading which were supported by the Commission. He therefore proposes only a small number of amendments seeking to strengthen the Common Position. In particular, while it is up to each Member State to decide whether instructions for use must be translated into its language or not, the rapporteur considers that this must be mandatory for self-testing devices such as pregnancy tests.?

In vitro diagnostic medical devices: security requirements

Commissioner Bangemann accepted all the rapporteur?s amendments, which contained welcome clarifications and additions. He was also in favour of setting up a European database in this area.

In vitro diagnostic medical devices: security requirements

In adopting the recommendation for second reading by Mr Alain POMPIDOU (UPEF) European Parliament stressed the need. - to draw up as quickly as possible legislation concerning medical devices manufactured from substance of human origin; - avoid distortion of competition concerning self testing devices; - translate into the language of the final user the instructions for use and the labelling of self test devices; - include screening methods by serum tests of chromosome 21; - development market DNA microchips with a view to screening for genetic diseases or the predisposition to certain genetic diseases (concerning which manufacture should inform the relevant authorities of the introduction of new products onto the market with regard to both the technology used and the substances to be analysed or other parameters; - preserve the confidentiality of information concerning persons undergoing diagnosis or tests and protect individuals against any discrimination based on inherited genetic characteristic of men and women.?

In vitro diagnostic medical devices: security requirements

The Commission can accept the six amendments adopted by Parliament at second reading. ?

In vitro diagnostic medical devices: security requirements

OBJECTIVES: to harmonise and improve the safety standards of in vitro diagnostic medical devices with a view to completing the internal market in this sector; to safeguard the health and safety of patients, users of the products in question and third parties.

COMMUNITY MEASURE: European Parliament and Council Directive 98/79/EC on in vitro diagnostic medical devices.

CONTENT: in vitro diagnostic medical devices are a sub-category of the medical devices defined in Directive 93/42/EEC. These devices are used in medicine for in vitro analysis of samples taken from the human body. The medical applications include analyses to evaluate the state of health (e.g. cholesterol, pregnancy), diagnose congenital diseases or anomalies, check the progress of a course of treatment (e.g. dosage and effect of drugs) or determine safety and compatibility in the case of organ or blood donations (e.g. to check for HIV or hepatitis).

The directive lays down the conditions under which in vitro diagnostic medical devices may be placed on the market. It sets out the main requirements in terms of reliability of the devices, taking account of their purpose, and in terms of the protection of users and third parties. In addition, it harmonises the procedures for evaluating compliance to be applied by manufacturers before placing devices on the market.

The directive requires Member States to implement a vigilance procedure so that any information which comes to their attention in relation to incidents involving devices carrying the CE mark is registered and evaluated centrally.

In order to monitor the market, the directive makes provision for the implementation of a European database containing data relating to registration of manufacturers and devices, certificates and data obtained in accordance with the vigilance procedure. It states that Member States have an obligation to monitor the safety and quality of devices placed on the market.

Finally, the directive makes it possible to take transitional national measures or Community measures to prohibit or restrict the placing on the market of certain products or groups of products on grounds of public health.

ENTRY INTO FORCE: 7 December 1998.

DEADLINE FOR TRANSPOSITION: 7 December 1999. Provision applicable from 7 June 2000.