Basic information

2005/0263(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Medical devices and active implantable medical devices Amending Directive 98/8/EC 1993/0465(COD) **Subject** 4.20.02 Medical research 4.20.04 Pharmaceutical products and industry 4.60.04 Consumer health	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	ULMER Thomas (PPE-DE)	21/02/2006

Committee for opinion	Rapporteur for opinion	Appointed
ITRE Industry, Research and Energy	BIRUTIS Šarūnas (ALDE)	21/02/2006
IMCO Internal Market and Consumer Protection (Associated committee)	JÄÄTTEENMÄKI Anneli (ALDE)	02/05/2006

Council of the European Union

Council configuration	Meetings	Date
General Affairs	2816	2007-07-23
Employment, Social Policy, Health and Consumer Affairs	2733	2006-06-01

European Commission

Commission DG	Commissioner
Internal Market, Industry, Entrepreneurship and SMEs	VERHEUGEN Günter

Key events

Date	Event	Reference	Summary
22/12/2005	Legislative proposal published	COM(2005)0681	Summary
01/02/2006	Committee referral announced in Parliament, 1st reading		

18/05/2006	Referral to associated committees announced in Parliament		
01/06/2006	Debate in Council		
04/10/2006	Vote in committee, 1st reading		
11/10/2006	Committee report tabled for plenary, 1st reading	A6-0332/2006	
29/03/2007	Decision by Parliament, 1st reading	T6-0091/2007	Summary
29/03/2007	Results of vote in Parliament		
23/07/2007	Act adopted by Council after Parliament's 1st reading		
04/09/2007	End of procedure in Parliament		
05/09/2007	Final act signed		
21/09/2007	Final act published in Official Journal		

Technical information

Procedure reference	2005/0263(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Amendments and repeals	Amending Directive 98/8/EC 1993/0465(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/32996

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE374.188	22/06/2006	
Committee opinion	ITRE	PE374.018	13/07/2006	
Amendments tabled in committee		PE376.778	12/09/2006	
Committee opinion	IMCO	PE376.323	18/09/2006	
Committee report tabled for plenary, 1st reading/single reading		A6-0332/2006	11/10/2006	
Text adopted by Parliament, 1st reading/single reading		T6-0091/2007	29/03/2007	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	03612/2007/LEX	05/09/2007	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2005)0681	22/12/2005	Summary
Document attached to the procedure	SEC(2005)1742	22/12/2005	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0732/2006	17/05/2006	

Additional information		
Source	**Document**	**Date**
European Commission	EUR-Lex	

Final act	
Directive 2007/0047 OJ L 247 21.09.2007, p. 0021	Summary

Medical devices and active implantable medical devices

2005/0263(COD) - 05/09/2007 - Final act

PURPOSE: to amend provisions relating to: active implantable medical devices; medical devices and the placing of biocidal products on the market.

LEGISLATIVE ACT: Directive 2007/47/EC of the European Parliament and of the Council amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

BACKGROUND: in 2003 the Commission prepared and presented a Communication on the application of EU provisions relating to active implantable medical devices, medical devices and biocidal products. The conclusions of this Communication, which found support in both Council and Parliament, were that there is an urgent need to revise and amend existing legislation in order to take account of new developments.

CONTENT: the purpose of this Directive, therefore, is to amend existing Community provisions in the field of active implantable medical devices, medical devices and the placing of biocidal products on the market. The three Directives subject to amendment are:

- Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices.;
- Council Directive 93/42/EEC concerning medical devices; and
- Directive 98/8/EC concerning the placing of biocidal products on the market.

To ensure consistency of interpretation and implementation between provisions relating to “active implantable medical devices” and “medical devices”, the legal framework relating to:

- authorised representative;
- the European databank;
- health protection measures; and
- medical devices incorporating stable derivates of human blood or human plasma has been extended. In addition, provisions set out in Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, has been extended to the Directive on active implantable medical devices.

The status of “software” in medical devices has been clarified. The amending Directive specifies that software specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical devices, is indeed a medical device. Software, when used for general purposes such as healthcare setting, is not.

In other provisions the amendments introduce the following new elements:

- Clarification of the term “single use” and uniform labelling in order to ensure that medical devices do not endanger the safety or health of patients.
- Enhanced provisions on clinical evaluation, including clarification that clinical data is generally required for all devices regardless of classification. There is the possibility to centralise data on clinical investigations in the European data bank.
- An explicit requirement for a post market production review system, involving incident reporting to authorities.
- Offering manufacturers of Class I sterile and/or measuring medical devices the option of using the full quality assurance conformity assessment module in order to provide them with more flexibility in the choice of compliance modules.
- Extended time period (to 15 years) for the retention of documents concerning implantable devices.
- Establishment of a procedure on whether or not a product falls under the definition of “medical devices”.
- Obliging manufacturers to designate an “authorised representative” for their devices.
- Emphasising the level of training and knowledge of the uses within the essential requirements. Manufacturers should place particular emphasis on the consequences of a product’s misuse and its adverse effects on the human body.
- Requiring manufacturers to apply adequate controls to third parties carrying out the design and manufacture of devices on their behalf.
- Specification of implementation procedures in accordance with the “regulatory procedure” as set out in Decision 1999/468/EEC.
- Mandating, within 12 months after the entry into force of this Directive, CEN and/or CENELEC to specify technical requirements and a suitable specific label for phthalate containing devices.
- Requiring devices that contain critical phthalates and which are used on children, pregnant and nursing women and other patients at risk, to be labelled accordingly.
- Requiring manufacturers to avoid the use of substances that may possibly compromise the health of patients, in particular substances which are carcinogenic, mutagenic or toxic to reproduction. They should strive to develop alternative substances or products with a lower risk potential.
- Excluding, from the scope of this Directive, provisions relating to in vitro diagnostic medical devices and vitro diagnostic medical devices.

ENTRY INTO FORCE: 10 October 2007.

TRANSPOTION: 21 December 2008.

APPLY: from 21 March 2010.

Medical devices and active implantable medical devices

2005/0263(COD) - 29/03/2007 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted the resolution drafted by Thomas **Ulmer** (EPP-ED, Germany) and amended the proposal put forward by the Commission amending Directive 93/42/EEC concerning medical devices and Directive 90/385/EEC concerning active implantable medical devices. The report was adopted by 645 votes in favour to 15 against with 4 abstentions.

The key amendments relate to the following:

- **safety:** a new recital states that particular care should be taken to ensure that the reprocessing of medical devices does not endanger patients" safety or health. It is therefore necessary to provide clarification on the definition of the term "single use", uniform labelling and instructions for use. Moreover, the Commission should engage in further analysis in order to see if additional measures are appropriate to ensure a high level of protection for patients;
- the manufacturer should place particular emphasis on the consequences of misuse of the product and its adverse effects on the human body;
- **differentiation from other directives:** in order to ensure that the Directive could be transposed smoothly, it was crucial to distinguish clearly between this and other laws, such as the Advanced Therapies Directive, and for there to be an unambiguous definition of medical devices. The definition of the latter now includes a phrase stating that the software must be intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes. The issue of combined products, i.e. devices which contain both human or animal tissue and material components, has been addressed. The Directive will not apply to medicinal products covered by Directive 2001/83/EC. In deciding whether a product falls under that directive or the present Directive, particular account shall be taken of the principal mode of action of the product. Nor will the directive apply to transplants or tissues or cells of human origin or to products incorporating tissues or cells of human origin, with certain prescribed exceptions;
- **software:** one very vital issue was whether 'software in its own right' should be defined as a medical device or not. Parliament inserted clarification on this point in a recital stating that it is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. Software for general purposes when used in a healthcare setting is not a medical device. “Medical device” is redefined to include the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application intended by the manufacturer to be used for human beings for the prescribed purposes;
- **reprocessing:**the Commission shall, at the latest three years after the adoption of the Directive, submit a report to the European Parliament and to the Council on the issue of the reprocessing of medical devices in the Community. In the light of the findings of this report, the Commission shall submit any additional proposal it may deem appropriate in order to ensure a high level of health protection;

- **comitology:** the Commission will need to adapt classification rules for medical devices, to adapt the means by which the information needed to use medical devices safely and properly may be set out, to determine conditions for making certain information publicly available, to adapt the provisions on clinical investigations set out in certain Annexes, to adopt particular requirements for placing certain medical devices on the market or putting them into service, and to take decisions to withdraw such devices from the market for reasons of protection of health or safety. Those measures are of general scope and are designed to amend or supplement Directive 90/385/EEC and Directive 93/42/EEC by the modification or addition of non-essential elements, and they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EEC. In urgent cases, the Commission should be able to use the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for taking decisions on withdrawal of certain medical devices from the market and for the adoption of particular requirements for placing such devices on the market or putting them into service for reasons of protection of health or safety.

Medical devices and active implantable medical devices

2005/0263(COD) - 22/12/2005 - Legislative proposal

PURPOSE : to amend Directives 93/42/EEC on medical devices and 90/385/EEC on active implantable medical devices.

PROPOSED ACT : Directive of the European Parliament and of the Council.

CONTENT : this proposal amends Directive 93/42/EEC on medical devices by modifying current

provisions, to bring about clarity, or by introducing new provisions, seen as necessary to continue to support the protection of human health. Also, the proposal updates Directive 90/385/EEC on active implantable medical devices to make it coherent with the other Directives on medical devices.

Since its adoption in 1993, a great deal of experience has been gained on the implementation of the Directive 93/42/EEC concerning medical devices. Whilst overall the experience has been extremely positive, some experience reveals that the Directive requires improved implementation by all parties concerned. A Report on the functioning of the Medical Devices Directives was published in June of 2002 and brought forward by the Commission in its Communication (COM(2003)0386). The most important areas where improvement should be made concern:

- conformity assessment, where questions arose as to the absence of clear rules on design examination by notified bodies;

- the sufficiency and adequacy of clinical data for all classes of devices;

-post market surveillance, where better coordination of activities in the area of post market surveillance are needed;

- Notified Bodies - in relation to their competence for the tasks for which they are designated, differences in interpretation between Notified Bodies and lack of transparency in the performance, and control, of their activities;

- increased transparency to the general public in relation to the approval of devices;

- modification of Directive 90/385/EEC relating to active implantable medical devices in order to align it with the other framework Directives on medical devices.

The proposed legislative modification brings forth either additional or replacement text regarding, in particular:

Conformity assessment modules: it has been further clarified that, for the conformity assessment of class IIa and class IIb devices under Annex II notified bodies are required to assess, on a representative basis, the design documentation for the device concerned.

Clinical data and evaluation: in order to clarify and enhance the provisions on clinical evaluation, significant modification was required of Annex X concerning clinical data and its evaluation and to various references to clinical data within the provisions of the Directive, including the definition of clinical evaluation and provision for the possibility to centralise data on clinical investigations in the

European databank.

Legal certainty regarding scope: to provide a method to make binding decisions on issues arising at national level, in relation to the misinterpretation of a product as being or not being a medical device, a procedure, based on comitology, has been added to Article 13. Also, in order to clarify that it is possible for both the Directive on medical devices and the Directive on personal protective equipment to simultaneously apply to a product, such as a surgical glove, it is necessary to delete the reference in Article 1 to the Directive on personal protective equipment to allow both apply.

Measures to increase transparency: the Article on confidentiality, which previously maintained all information available under the Directive as being confidential, has been relaxed, to allow certain information on all devices to be publicly available and to allow, by comitology, a method of making other information non-confidential, such as summary information on the approval of high risk devices.

Legal basis for better coordination and communication of market surveillance activities: the market for medical devices is a global market, with a significant number of devices being imported into the EU. This has led to an increasing need to coordinate activities of national authorities when applied to issues related to the directive taking place across a number of Member States and/or third countries. Thus it is necessary to introduce a new provision on cooperation to provide a legal basis for this coordination and international activities.

Clarification regarding medicinal products/medical device provisions: devices that incorporate as an integral part a medicinal product or blood plasma derivative are required to be reviewed by a notified body in consultation with a national authority for medicines or the European Medicines Agency (EMEA) as appropriate. These provisions, which are currently contained in Annex I Section 7.4 of the Directive needed modification to reflect the experience gained over the years in their implementation, clarifying both the role of the notified body and the relevant authority.

Devices with an ancillary human tissue engineered product: provisions are made to include these devices in the scope. This mirrors the proposed Community legislation on Advanced Therapies and fills

a potential regulatory gap.

Custom-made devices: in order to better evidence the compliance of custom made device manufacturers there is now an explicit requirement for a post market vigilance system reporting to authorities, as already in place for other devices. In order to enhance patient information a requirement is introduced that the 'Statement' under Annex VIII should be also given to the patient and that it must contain the name of the manufacturer.

Amendment of other Directives: Directive 90/385/EEC on active implantable medical devices requires alignment of text on certain aspects across all three medical device directives. The Directive was the first in the series of directives on medical devices but it has not benefited to the same extent from the market experiences and developments as the Directive 93/42/EEC and the Directive 98/79/EC on in vitro diagnostic medical devices, which were adopted in later years.

To ensure consistency of interpretation and implementation of the medical device Directives and to update the Directive 90/385/EEC on active implantable medical devices in terms of health protection measures, certain aspects, such as authorised representative, the European Databank, health protection measures, and the application of the Directive 2000/70/EC on medical devices incorporating stable derivates of human blood or human plasma have to be added to Directive 90/385/EC. The latter alignment, on human blood or plasma, results in a significant body of text being inserted into the Directive.

Finally, under this regulatory reform, Directive 98/8/EC concerning the placing of biocidal products on the market needs to be modified in order to clarify that, alongside the active implantable medical devices and medical devices, in vitro diagnostic medical devices, now subject of a specific Directive, will be excluded from the scope of the biocides Directive.