EUROPEAN PARLIAMENT

2004 *2009*

Committee on Industry, Research and Energy

2005/0263(COD)

13.7.2006

OPINION

of the Committee on Industry, Research and Energy

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a directive of the European Parliament and of the Council amending Council Directives 90/385/EEC and 93/42/EEC and Directive 98/8/EC of the European Parliament and the Council as regards the review of the medical device directives
(COM(2005)0681 – C6-0006/2006 – 2005/0263(COD))

Draftsman: Šarūnas Birutis

PA_Leg

SHORT JUSTIFICATION

This proposal aims at strengthening the competitiveness and safety of the medical devices sector. Medical devices form an increasingly important health-sector segment, with a major impact on both public health and healthcare expenditure. The term "medical device" covers a wide range of products. Approximately 400.000 different medical devices can be distinguished on the market, ranging from simple devices (such as syringes and glasses), through equipment to screen and diagnose disease and health conditions, to the most sophisticated and complex instruments (like life-saving implantable devices, diagnostic imaging and minimal invasive surgery equipment).

The general public rightly expects all those products to meet the highest safety standards. At the same time, the sector is of significant importance to European industry - consisting of 7.000 companies, employing more than 350.000 people and regularly recording one of the highest production growth rates - and requires a coherent and clear legislative framework that fosters competitiveness and innovation.

The current legislative framework, regulating such a diverse variety of products, consists of three Directives. Together, they define the essential requirements that medical devices have to meet when they are put on the market, depending on their classification (such as risk assessment, risk management and risk/benefit analysis). Furthermore, the Directives provide for a system of risk-based conformity assessment procedures, usually performed by independent bodies (the so-called "Notified bodies"). And finally, the Directives lay obligations on national authorities to ensure the proper functioning of the market, for example by instance by market surveillance, guidance, objections to standards or reclassification of devices.

In 2002, the Commission reviewed the functioning of the regulatory framework. The conclusion of the review was that on the whole the Directives provided an appropriate legal framework. However, regarding specific points, room for improvement was possible. The current proposed Directive intends to fill in this room for improvement. The most significant proposals concern clarifications in the following areas:

- Conformity assessment, including clear rules on design documentation and design review;
- Clinical evaluation requirements;
- Post market surveillance and compliance of custom-made device manufacturers;
- The working of and coordination between Notified bodies;
- Medical devices with an ancillary human tissue engineered product;
- Increased transparency to the general public.

Your draftsman welcomes the Commission's proposal, which has long been awaited by industry in the sector. The practical proposals in this Directive will improve harmonisation in this highly complex and diversified sector, by providing clearer and simpler rules. By increasing the legal clarity, transparency and certainty for all market players and by improving the overall regulatory framework, the proposal will support fast technical progress, while guaranteeing a high level of public health protection.

Your draftsman emphasises the fact that, even if the changes at first glance might seem small

and technical, they can have a profound effect for the industry concerned. For example, reclassification of certain devices in a higher risk category could increase costs considerably. On the other hand, for devices operating on the borderline of different definitions or for combined devices, legal clarity and consistency can be very important, because it clarifies which directive and hence which procedure applies for them.

Your draftsman would like to draw attention to the fact that the scope of this revised directive should be exactly in line with the new proposed Regulation on Advanced Therapies Medicinal Products, in the sense that all products should be covered either by this directive or by the new regulation and that unnecessary overlap should be avoided. If necessary, the Commission should as soon as possible put forwards a proposal to clarify the scope of these legislative acts.

Finally, given the fact that industry in this sector operates on the global market, the process of international cooperation and harmonization of standards is a vital one. Your draftsman therefore believes that more effort should be made to promote international cooperation, both in the form of bilateral agreements (Mutual Recognition Agreements), as via more informal cooperation (eg. the Global Harmonization Task Force).

AMENDMENTS

The Committee on Industry, Research and Energy calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament
Amendment 1 RECITAL 17	
(17) To better coordinate the application and efficiency of national resources when applied to issues related to Directive 93/42/EEC the Member States should cooperate with each other and at international level.	(17) To better coordinate the application and efficiency of national resources when applied to issues related to Directive 93/42/EEC the Member States should cooperate with each other and at international level. ***In order to enable industry to compete globally on equal terms, there should be international standardisation and cooperation***.

[1] Not yet published in OJ.

Justification

The European medical devices industry sells its products world wide. European standards, based on an international standardisation process, are therefore preferable. More effort should be made to promote international cooperation, both in the form of bilateral agreements, as via more informal cooperation (eg. the Global Harmonization Task Force).

Amendment 2
RECITAL 21 A (new)

(21a) Reprocessing medical devices is a sector that promises costs savings. Taking into account the current lack of a level playing field in the EU and the need to ensure patient safety, the Commission should come forward with a proposal on medical device reprocessing, based on an impact assessment and a study of the market.

Justification

Currently, the reprocessing of medical devices is not regulated on EU level. According to figures of EAMDR, cost savings of about 3 billion EUR a year could be achieved in the EU by making full use of the potential of medical device reprocessing. To ensure patient safety, the legislation should focus on the quality of reprocessing. Any proposal should be based on a proper impact assessment, focusing on existing regulation in Member States, and a study of the market.

Amendment 3
ARTICLE 2, POINT 1, POINT (A), POINT (I A) (new)
Article 1, paragraph 2, point (a) (Directive 93/42/EEC)

(ia) in point (a) the following closing phrase is added:

Under this Directive, all contact lenses should be deemed to be medical devices;

Justification

Cosmetic lenses are not currently regulated as medical devices in Europe, even though they have the same effects and potential health risks on the eye if improperly manufactured or used

without the consultation and supervision of an eye care specialist.

Amendment 4
ARTICLE 2, POINT 1, POINT (F), POINT (I)
Article 1, paragraph 5, point (c) (Directive 93/42/EEC)

"(c) 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;"	"(c) medicinal products covered by Directive 2001/83/EC. In deciding whether a product falls under that Directive ***by virtue of the application of the definition laid down in point (b) of Article 1(2) of Directive 2001/83/EC*** or ***under*** the present Directive, particular account shall be taken of the principal mode of action of the product;"

Justification

The proposed directive has to be altered in order to render more stringent the definition of medical devices. This would make it more difficult to have medication registered as medical devices. The draft Commission proposal for revision of the Directive includes amendments to the definitions section in Article 1. However, the definition of "medical device" at Article 1.2(a) is substantially the same as that set out in the existing Directive.

Amendment 5
ARTICLE 2, POINT 1, POINT (F), POINT (I A) (new)
Article 1, paragraph 5, point (d) (Directive 93/42/EEC)

	(ia) point (d) is replaced by the following:
	"(d) cosmetic products covered by Directive 76/768/EEC. In deciding whether a product falls under Directive 76/768/EC or this Directive, particular account shall be taken of the principal intended purpose of the product and the relevant mechanism of action;"

Justification

In some cases cosmetic products have a medical intention (i.e. treatment of a disease) and should therefore be classified as medical devices. The decision which directive applies should thus be taken case by case on the basis of the intended purpose.

Amendment 6
ARTICLE 2, POINT 1, POINT (G)
Article 1, paragraph 6 (Directive 93/42/EEC)

(g) Paragraph 6 is deleted.	***deleted***

Justification

This amendments seeks to reinstate the exemption of personal protective equipment from this Directive. These products are sufficiently covered by the Directive 89/686/EEC. Unnecessary application of two directives with different conformity assessment procedures should be avoided.

Amendment 7
ARTICLE 2, POINT 1 A (new)
Article 2, paragraph 1 a (new) (Directive 93/42/EEC)

	(1a) The following paragraph is added to Article 2:
	"Member States shall take all necessary steps to ensure that medical devices sold via the Internet, by mail order and other distribution channels do not put the health and safety of consumers at risk, and that they comply with all the provisions laid down in this Directive."

Justification

Sales of medical devices over the internet, by mail order and other alternative distribution channels are becoming more and more common in many European countries and have potential health risks for European citizen since they are not subject to any consultation or counsel by appropriate specialists.

Amendment 8
ARTICLE 2, POINT 3
Article 9, paragraph 3 (Directive 93/42/EEC)

3 Where a Member State considers that the classification rules set out in Annex IX require adaptation in the light of technical progress and any information which becomes available under the information system provided for in Article 10, it shall	3 Where a Member State considers that the classification rules set out in Annex IX require adaptation in the light of technical progress and any information which becomes available under the information system provided for in Article 10, it shall

submit a duly substantiated request to the Commission and ask it to take the necessary measures. The Commission shall adopt these measures in accordance with the procedure referred to in Article 7 (2).	submit a duly substantiated request to the Commission and ask it to take the necessary measures. The Commission shall adopt these measures in accordance with the procedure referred to in Article 7 (2). ***The Commission shall ensure that relevant information about envisaged measures is made available to interested parties without delay.***

Justification

Changes in the classification can be of great importance for industry because the different requirements in the different classes. In order for industry to be able to make well-planned and cost-effective investments in R&D and production, relevant information about envisaged changes to the classification should be made known as quickly as possible.

Amendment 9
ARTICLE 2, POINT 5, POINT (A)
Article 12, paragraph 3 (Directive 93/42/EEC)

(a) In paragraph 3, the words “Annex IV, V or VI” are replaced by “Annex II, IV, V or VI”.	(a) In paragraph 3, the words “Annex IV, V or VI” ***and the words "the obtaining of sterility" are replaced by "the obtaining and maintaining of sterility for the shelf life of the device or until the sterile package is opened or damaged"***.

Amendment 10
ARTICLE 2, POINT 10
Article 15, paragraph 2, subparagraph 1 (Directive 93/42/EEC)

2. In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy. Such decisions shall be communicated by the competent authority to the other Member States.	2. In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy. Such decisions***, and the justifications for the decisions,*** shall be communicated by the competent authority to

	the other Member States ***and to the interested parties***.

Amendment 11
ARTICLE 4, PARAGRAPH 1, SUBPARAGRAPH 2

They shall apply those provisions from [***12 months*** from the transposition].	They shall apply those provisions from [***18 months*** from the transposition].

Justification

The transitional period should be sufficiently long to ensure that manufacturers will have enough time to perform the necessary tests and applications in order not to stop on-going production unnecessarily.

Amendment 12
ANNEX I, POINT 1, POINT (B)
Annex I, Section 10, paragraph 4 a (new) (Directive 90/385/EEC)

	The notified body shall verify the usefulness of the substance. The sole role of the EMEA and the competent authorities designated by the Member States is to provide a scientific opinion on the quality and safety of the substance.

Justification

Clarification of the role of notified bodies and EMEA/competent authorities will prevent that approval of medicinal devices with fully documented medicinal substances integrated in practice will be handled as a pharmaceutical, which would add disproportional costs and time without offering any benefits to patients.

Amendment 13
ANNEX II, POINT 1, POINT (B)
Annex I, Section 7.4, paragraph 2, final part (Directive 93/42/EEC)

the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a	the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a

scientific opinion from the ***European Medicines Agency (***EMEA***)*** on the quality and safety of the substance. When issuing its opinion, the EMEA shall take into account the manufacturing process and the ***data*** related ***to*** the incorporation of the substance into the device.	scientific opinion ***from the national competent authority, designated by a Member State in accordance with Directive 2001/83/EC or*** from the EMEA on the quality and safety of the substance. When issuing its opinion, ***the competent authority or*** the EMEA shall take into account the manufacturing process and the related ***data as well as*** the ***usefulness of*** incorporation of the substance into the device ***as determined by the notified body.***

Justification

The current system, which allows Notified Bodies to seek the opinion from any of the relevant national authorities, should be maintained in order to ensure timely and cost effective consideration of the safety and quality of the substance in question. The duty to evaluate the usefulness of including the medicinal substance in the medical device should remain in the hands of the evaluation body responsible for the overall assessment of the device.

Amendment 14
ANNEX II, POINT 1, POINT (F)
Annex I, Section 13.1, paragraph 1 (Directive 93/42/EEC)

13.1. ***Each*** device must be ***accompanied by*** the information needed to use it safely and ***properly***, taking account of the training and knowledge of the potential users, and to identify the manufacturer.	13.1. ***For each*** device***,*** the information needed to use it safely and ***as intended***, taking account of the training and knowledge of the potential users, and to identify the manufacturer***, must be provided***.

Justification

Creates legal clarity by introducing the generally accepted term of "Intended use".

Amendment 15
ANNEX II, POINT 1, POINT (G), POINT (II)
Annex I, Section 13.3, point (b) (Directive 93/42/EEC)

(ii) point (b) is replaced by the following:	***deleted***
"(b) the details strictly necessary for the user to identify the device and the contents of the packaging including the respective code of an internationally recognized	

generic medical device nomenclature;"

Justification

Adding more codes to products, packaging and instructions for use will only add administrative costs without offering any benefits to patients. GMDN codes are already being used for vigilance reporting, hence allowing authorities to asses potential risk issues.

Amendment 16
ANNEX II, POINT 7, POINT (B), POINT (III)
Annex VII, Section 3, indent 7 a (new) (Directive 93/42/EEC)

— the clinical evaluation in accordance with Annex X,	— ***where appropriate,*** the clinical evaluation in accordance with Annex X,

Justification

This annex is applicable to Class I products, such as tongue depressors, cotton gauzes, walking sticks and spectacles frames. It is not necessary to gather all the information for a clinical evaluation for this kind of products.

Amendment 17
ANNEX II, POINT 9, POINT (C), POINT (VII)
Annex IX, Section 4.4 (Directive 93/42/EEC)

(vii) ***in*** Section 4.4. ***the words 'Non active devices' are*** replaced by the ***word 'Devices'***	(vii) Section 4.4. ***is*** replaced by the ***following: "Devices intended for recording X-rays to generate diagnostic images are in Class IIa."***

Justification

Clarification. The original text could unintentionally cover other devices (eg. recording of diagnostic X-ray images on digital media) for which the classification into Class IIa seems to be disproportionate.

PROCEDURE

Title	Proposal for a directive of the European Parliament and of the Council amending Council Directives 90/385/EEC and 93/42/EEC and Directive 98/8/EC of the European Parliament and the Council as regards the review of the medical device directives
References	COM(2005)0681 – C6-0006/2006 – 2005/0263(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	ITRE 16.3.2006
Enhanced cooperation – date announced in plenary	no
Drafts(wo)man Date appointed	Šarūnas Birutis 21.2.2006
Previous drafts(wo)man	
Discussed in committee	19.4.2006 29.5.2006 13.7.2006
Date adopted	13.7.2006
Result of final vote	+: 37 –: 0 0: 6
Members present for the final vote	Šarūnas Birutis, Jan Březina, Philippe Busquin, Jerzy Buzek, Joan Calabuig Rull, Pilar del Castillo Vera, Jorgo Chatzimarkakis, Giles Chichester, Den Dover, Lena Ek, Nicole Fontaine, Adam Gierek, Norbert Glante, Umberto Guidoni, Fiona Hall, David Hammerstein Mintz, Rebecca Harms, Erna Hennicot-Schoepges, Romana Jordan Cizelj, Werner Langen, Anne Laperrouze, Vincenzo Lavarra, Eugenijus Maldeikis, Eluned Morgan, Reino Paasilinna, Vladimír Remek, Herbert Reul, Teresa Riera Madurell, Paul Rübig, Andres Tarand, Britta Thomsen, Catherine Trautmann, Claude Turmes, Nikolaos Vakalis, Alejo Vidal-Quadras Roca
Substitute(s) present for the final vote	María del Pilar Ayuso González, Etelka Barsi-Pataky, Ivo Belet, Gunnar Hökmark, Peter Liese, Lambert van Nistelrooij, Vittorio Prodi, Esko Seppänen
Substitute(s) under Rule 178(2) present for the final vote	
Comments (available in one language only)	