Fédération Européenne de l'Industrie de l'Optique et de la Mécanique de Précision

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Enhancing the health of the public European wide and world wide and
Facilitating innovation by harmonising the European and global regulatory environment

EUROM VI Medical Technology Comments

on the Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

(COM(2012) 542 final)

EUROM VI Medical Technology is the committee for Medical Technology within the European Federation of Precision Mechanical and Optical Industries and represents mainly European small and medium-sized enterprises.

The objectives of EUROM VI are:

- to represent European Medical Technology Industry;
- to promote cooperation between members but also with other European organisations;
- to encourage worldwide trade by being involved in harmonisation of legislation, standardisation, mutual recognition and certification procedures;
- to be a partner on works with the European Commission and Standardisation Bodies;
- to support European Industry views on international activities.

EUROM VI – Comments on the Proposal of the European Parliament and of the Council on medical devices (proposed MDR)

Introduction

The European medical technology is one of the mainstays of the global healthcare sector. More than 60.000 companies with over 450.000 employees are located within the European Union (EU)[1]. The industry with its high level of innovation is characterized by a small and medium-sized company structure.

EUROM VI welcomes the European Commission's (Commission) proposal to revise the EU's Medical Devices Directives with the objective to strengthen patient safety and to fix weak points of the current system. At the same time, this regulatory framework should also foster innovation and competitiveness in the medical technology industry. Further, the framework shall guarantee that innovative medical devices can be introduced fast and cost-efficiently into the market without losses in patient safety.

The current European approval system for medical devices makes sure that patients in the European Common Market may have a timely access to the medical technology innovations of medical devices manufacturers. The placement of medical devices under the European System takes place up to five years earlier than in the United States (US) without compromising patient safety. Comparative studies show that the rate of serious product recalls in the EU and the US, where a centralized authority approval is required, is in fact the same.[2]

Scrutiny Procedure (Art. 44)

The European system with its proven procedures for Conformity Assessment and CE marking of medical devices ensures that safe and effective medical devices are placed on the European Common Market. EUROM VI welcomes that the proposed MDR retains the principles of the new approach.

EUROM VI does not support the proposed scrutiny procedure for Class III devices which constitutes some kind of a premarket approval. We believe that it will be less effective than intended and will not significantly achieve an increase of patient safety, but increase the time to market of innovative devices for more than 90 days.

The reasons for this assumption are the following:

- There is no evidence that a centralized approval of medical devices by an authority (or any other centralized institution) will result in better performing and safer medical devices when placing them on the market than under a regulatory framework following the new approach.
- According to Art. 44 of the proposed MDR, the scrutiny procedure shall be executed by the MDCG on certain Class III devices. Moreover the Commission may determine, by means of implementing acts, specific categories or groups of devices, other than devices of class III, to which the scrutiny procedure shall apply. The way how these decisions are made appears not very transparent and may depend on suggestions made by an individual Member State or by the Commission. Only "generic" criteria are provided in the Commission's proposal to decide which devices should undergo a scrutiny procedure.
- The assessment of the Notified Body's preliminary evaluation shall be made by the Medical Device Coordination Group (MDCG), a committee for which each Member State shall nominate up to two

[1] Eurostat 2011
[2] EU Medical Device Approval Safety Assessment, A comparative analysis of medical device recalls 2005-2009; Davis/Gilbertson/Goodall, Boston Consulting Group, January 2011

experts (one for medical devices incl. active implantable medical devices, and one for in-vitro diagnostic devices). Because of the extremely high variety of medical devices and related therapy procedures it can be doubted that an adequate number of real experts will be available in the MDCG for specific innovative medical devices, technologies, and therapeutic or diagnostic procedures.

- Based on the experience within the Medical Device Expert Group and related working groups it appears very difficult to achieve a consensus amongst the up to 54 members of the MDCG as requested in Art. 78.4 of the proposed Regulation on medical devices.
- It remains unclear how the members of the MDCG will be qualified to achieve an expertise comparable to the Notified Bodies in all medical device technologies and related therapies, including new or emerging technologies, to adequately assess the Notified Bodies proposed evaluations.

In order to improve the current European system it appears more productive to strengthen the qualification, assessment, notification, and surveillance of the Notified Bodies, instead of implementing a redundant scrutiny procedure for single conformity assessments of medical devices by Notified Bodies. Therefore, beside the assessment of the Notified Bodies before their notification in the proposed MDR, EUROM VI suggests that the MDCG is empowered to resume a crucial role in aligning the surveillance of the Notified Bodies according to established rules.

Notified Bodies (Art. 28 – 40)

EUROM VI welcomes the Commission's proposal for more stringent and harmonised requirements regarding the designation of notified bodies as well as the proposal for a reinforced supervision of the notified bodies.

Furthermore, it should be guaranteed that the audits conducted by notified bodies follow the same defined standards and are performed with the same thoroughness within and outside the EU in order to keep up with global competition.

Moreover, national authorities shall apply adequate and identical means to monitor and approve the qualification of the notified bodies before and after their notification.

In order to eliminate the flaws related to the assessment of the manufacturers' Technical Documentations (especially of Class III medical devices, where an examination of the design dossier by the Notified Body is a mandatory part in a manufacturer's conformity assessment procedure), it is necessary that the Notified Body has a sufficient number of own experts available. Demonstration of the qualification of these experts should play a major role in the designation of Notified Bodies for a specific product scope.

EUROM VI supports the proposals made by Eucomed[3] that Notified Bodies for high risk medical devices should specialize in certain product categories in order to provide unique expertise in given product categories. This may lead to the result, that not all currently existing Notified Bodies will be accredited for all medical device categories.

Scope of the Medical Device Regulation (MDR)

Products that contain or consist of biological substances

According to Art. 1 (f) the proposed regulation shall not apply to products that contain or consist of biological substances. Biological substances represent an umbrella term for different products. Some of them exhibit a

[3] Eucomed Position Paper "Towards a regulation that guarantees patient safety, ensures patient access and keeps innovation in Europe"; Brussels, 2013-01-30

physical mode of action, for example, *Lactobacillus gasseri* for the treatment of bacterial vaginosis. This lactobacillus has a GRAS status (i. e. Generally Recognized As Safe) and the intended purpose is not achieved by pharmacological, immunological, or metabolic means. Such products clearly fit into the definition of a medical device and cannot be approved as medicinal products because they have no medicinal mode of action. The general exclusion of biological substances from the scope of the proposed MDR would lead to the loss of efficient and safe medical devices and a reduction of the respective sales volumes in this growing medical device niche.

Consequently, EUROM VI proposes not to exclude products that contain or consist of biological substances from the scope of the MDR as long as their mode of action is purely physical and shows absence of pharmacological, immunological or metabolic interactions with the patient.

Classification of Medical Devices (Annex VII – Classification Rules)

Medical devices are divided into risk classes – from Class I (low risk) to Class III medical devices or Active Implantable Medical Device (AIMD, high risk) – dependent on their potential risk for the human body.

The Commission has proposed to reclassify some device categories, which have a low risk-profile and have no history of safety issues, into the higher risk Class III.

EUROM VI suggests to delete the new classifications or to reclassify the device categories based on scientific data.

Classification Rule 6 – Surgically invasive devices for transient use

In Rule 6 first indent, for the use at the heart or circulatory system, the word ‘specifically’ has been deleted. As a result, many products like surgical instruments not intended to be used specifically in the cardiac field will then be in class III instead of class I. The possibility may be that every product which may be in contact with the heart or circulatory system will be required to be Class III. We therefore suggest to reinstate the word ‘specifically’ in Rule 6 first indent.

Note: The German translation of Rule 7 differs from the English version, as the word ‘specifically’ has been deleted in the first indent of the German translation of Rule 7.

Classification Rule 19 – Devices incorporating nano-material

The new classification Rule 19 of the proposed MDR requires that all medical devices incorporating or consisting of nanomaterial are in Class III unless the nanomaterial is encapsulated or bound in such a manner that it cannot be released into the patient’s or user’s body when the device is used within its intended purpose.

Many parts, components or colour coatings used in medical devices contain nanoparticles, e.g. as fillers in elastomers like carbon black in O-ring seals, or Aerosils in silicone hoses, or paint particles in colour coatings. A “zero emission” of such particles falling under the definition of nanoparticles, cannot be guaranteed and is physically impossible; also abrasive wear of common material may lead to nanoparticles and must be taken into account. Consequently, a high amount of low risk medical devices currently in use for many years without any problems would have to be reclassified into Class III due to the current wording of Rule 19. As a consequence, the reclassification of such devices would result in major regulatory efforts and significantly higher costs without increasing the safety of patients or users.

With regard to Rule 19 EUROM VI therefore supports the comment of the association of the European Dental Industry – FIDE dated September 2012[4].

Rule 21 – Substances intended to be ingested, inhaled or administered rectally or vaginally

According to the proposed MDR products containing substances or combinations of substances that are intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body shall be classified in the highest risk class (class III – Rule 21 of Annex VII) and must comply with the relevant requirements of Annex I of Directive 2001/83/EC on medicinal products for human use (Point 9.2 of Annex I in the proposed MDR).

However, if absorption or a subsequent systemic dispersion is not intended, biodistribution as well as pharmacodynamic and pharmacokinetic studies as required by Annex I of Directive 2001/83/EC are not feasible. Thereby, it will per se not be possible to obtain all relevant clinical data in accordance with Annex I of Directive of 2001/83/EC. Therefore, without absorption or systemic dispersion in the human body, these products cannot comply with the proposed requirements laid down in Point 9.2. of Annex I in the proposed MDR and will consequently fail the conformity assessment procedure.

EUROM VI suggests either to delete Rule 21 or to state Rule 21 precisely by referral to "*substances or combinations of substances that are intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by* ***and*** *dispersed in the human body* ***in order to achieve the intended purpose*****".**

Clinical evaluation (Annex XIII)

Annex XIII, part A, section 4 of the proposed MDR allows to refer to existing clinical data of another medical device if 'equivalence' of the other device with the device in question can be demonstrated, and lists the prerequisites for demonstration of equivalence:

'Clinical data relating to another device may be relevant where equivalence is demonstrated of the device subject to clinical evaluation to the device to which the data relates. Equivalence can only be demonstrated when the device that is subject to clinical evaluation and the device to which the existing clinical data relates have the same intended purpose and when the technical and biological characteristics of the devices and the medical procedures applied are similar to such an extent that there would be not a clinically significant difference in the safety and performance of the devices.'

Annex XIII, part A, section 5 amends these requirements with regard to implantable devices and devices falling within Class III:

'In the case of implantable devices and devices falling within class III, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone. Demonstration of equivalence in accordance with Section 4 shall generally not be considered as sufficient justification within the meaning of the first sentence of this paragraph.'

However, the underlined sentence in Annex XIII, part A, section 5 is contradictory to the first sentence of this section, where referring to existing clinical data (own, previous and/or external data) related to another device is generally justified also in case of implantable devices and devices in Class III. It appears unclear why the prerequisites listed in section 4 shall be insufficient for implantable devices and devices falling within Class III to demonstrate 'equivalence' although these prerequisites can be used for all other devices.

[4] Statement on the risk classification of medical devices containing nano-materials on the basis of an assessment of their health effects; FIDE – European Dental Industry, Cologne, September 2012

Furthermore, EUROM VI would like to emphasize:

- 'Demonstration of equivalence' serves to protect resources and to avoid redundant investigations.
- By referring to existing clinical data of equivalent products, redundant and often cumbersome and physically stressing tests on patients can be avoided.
- Referring to existing clinical data of equivalent products is best-practice also in other jurisdictions – even in the case of high-risk devices.

Single-Use Devices and Reprocessing (Art. 15)

EUROM VI welcomes that the Commission proposed the same rights and responsibilities for reprocessors of *single-use devices* as for manufacturers. Concerning the reprocessing of *single-use devices,* only reprocessing that is considered safe according to the latest scientific evidence should be carried out.

Refurbishment

EUROM VI proposes to integrate clear regulations in the MDR for companies refurbishing (repairing) medical devices. Stronger requirements for these companies are necessary to ensure an identical level of safety of the refurbished devices. Any natural or legal person, who refurbishes a device according to the specifications provided by the manufacturer of the device, shall ensure that the repair does not adversely affect the safety and performance of the device. Any repair not in compliance with the requirements provided by the manufacturer, or using spare parts for which the refurbisher cannot demonstrate evidence that the refurbished device achieves an identical level of safety as the original device, should not be regarded as a repair, but as a placing on the market of a new product, and require a new conformity assessment.

Delegated and Implementing Acts

In more than 50 cases the Commission is empowered in the proposed Regulation on medical devices to adopt delegated or implementing acts. By means of these empowerments the Commission reserves the exclusive right to amend the proposed legislation, vary its scope etc. – without requiring to make use of the expertise of stakeholders in the healthcare sector, e.g. Member States, healthcare industry and healthcare facilities.

Implementing acts can be considered as "legislative measures" where no effective legal remedy exists for a manufacturer to challenge an unjustified decision.

This high number of empowerments of the Commission will result in a lack of predictability of requirements, hamper a strategic planning of industry and other stakeholders, and may result in major business impacts especially to SMEs.

EUROM VI therefore applies to

- develop the respective processes in the MDR instead of referring to delegated and implementing acts for currently undefined and non-harmonized processes;
- install a comitology process and ensure the mandatory involvement of affected stakeholders in order to include their expertise in decisions with regulatory impact.

The above listed comments are made with respect to the objectives communicated by the European Commission:

- To guaranty patient safety
- To foster innovation
- To support competitiveness
- To allow for a fast and cost-efficient placing of medical devices on the market, and
- To ensure a fast access of patients to the benefits of innovative devices.

EUROM VI strongly supports the intention to strengthen the advantages of the current system and to try to diminish its weaknesses without creating a cumbersome new system. However, as the current version of the proposed MDR contains too many discrepancies and undefined procedures, it will not achieve these objectives. Therefore, EUROM VI suggests amending the proposed MDR accordingly before its adoption.

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