Eucomed
Medical Technology

POSITION PAPER
30 January 2013

Towards a regulation that guarantees patient safety, ensures patient access and keeps innovation in Europe

Eucomed's response to the Commission's proposal for the revision of the EU Medical Devices Directives

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Executive Summary

Towards a regulation that guarantees patient safety, ensures patient access and keeps innovation in Europe

The European medical device industry is a critical provider of innovative, effective and safe healthcare solutions for an increasing number of patients in Europe. Through its healthcare innovations, the industry contributes to ensuring sustainable and accessible healthcare systems throughout Europe.

The European Medical Device industry recognizes that the system needs an overhaul due to increased expectations and technological advances, and acknowledges that change is necessary to improve Europe's Medical Device regulatory framework. In particular, the European Medical Device industry unanimously agrees that incidents like the fraudulent PIP breast implant case should never happen again.

In the global context, let us not forget that Europe has been known for providing its citizens with timely access to safe technology thanks to the effective decentralised approval system. The European system (see also Appendix 1) forms a significant basis for other national regulatory frameworks around the globe (e.g. Japan, Australia, Canada) because of its efficiency in providing lifesaving and life-enhancing technologies to patients and doctors while guaranteeing a high level of safety.

Various recent reports[i] from respected academics and researchers have shown that lifesaving and life-enhancing medical technologies are made available to European patients on average of three to five years earlier than those in the United States - and this without compromising safety.

We are convinced that Europe can remain in this leading situation with the support of an improved decentralised, device-specific regulatory framework that assures safety, encourages cost-effective innovation and ensures that an incident such as the PIP case will not happen again.

We strongly believe that it is in Europe's best interest to have a clear, predictable and effective regulatory system that:

- guarantees the highest level of **safety** for patients;
- ensures timely **access** to the latest innovative technologies;
- enjoys the **trust** of its stakeholders;
- contributes to the **sustainability** of national healthcare systems;
- maintains an environment that encourages and keeps **research** and **innovation** in Europe.

We welcome the majority of the recommended measures in the Commission's proposal for the revision of the EU Medical Devices Directives (MDD), and acknowledge their importance in achieving the above mentioned objectives.

Getting the regulation right: 7 key focal areas

The Commission's proposal represents a step in the right direction and the majority of the recommended measures are welcomed by industry as they: (1) improve patient safety, (2) do not unnecessary delay patient access to medical devices that save or improve lives and (3) do not hamper innovation.

However, further improvements to the Commission's proposal are necessary and should be brought to seven key focal areas to improve the delivery of safe, innovative medical technology that Europe's patients need:

1. **Only the best Notified Bodies** should be allowed to approve medical devices to the market in order to ensure that the backbone of Europe's decentralised system meets the highest safety and quality standards.

2. **A systematic control procedure** is necessary to improve the system and increase patient safety. The proposed 'Commission scrutiny procedure' (article 44) is inappropriate because it is not systematic and will not lead to increased patient safety. It should be replaced with a systematic control procedure (that goes beyond the current proposed measures). Only then will we reach the outcome that is desired by all stakeholders: maximum safety for all Europeans without unnecessary delay or duplication of work.

3. **Increase stakeholder involvement** to ensure that the opinions of essential healthcare actors are heard.

4. **Greater transparency and traceability** is critical to ensure that patients, doctors, industry and other stakeholders have access to clear information about the medical devices they use.

5. **Clinical evidence needs more clarity** as clear, appropriate requirements for clinical evidence are paramount to demonstrate that devices perform well and are safe for patients when used by a well-trained healthcare professional and as intended by the manufacturer.

6. **Enhance vigilance and market surveillance** to allow for rapid identification of adverse events and to ensure coherent and timely action by Member States.

7. **Clear science based classifications** are needed to avoid the currently proposed arbitrary reclassification of families of medical devices without any scientific or other justification, which will lead to global confusion. Clear and science based procedures must be followed to ensure that devices are appropriately classified.

Additional issues

The Medical Devices Directives are broad in scope and cover several important areas. Eucomed believes the following areas also need considerable attention because, although the topics may seem very technical, if not thought through correctly their impact can be very detrimental to Europe's patients and on-going innovation:

1. Scope
2. Economic operators
3. Reprocessing
4. Standards, guidelines and specifications
5. Early scientific advice
6. Governance
7. Funding
8. Transition periods
9. Hazardous substances
10. Delegated and implementing acts

Eucomed's detailed position per issue is available in a series of fact sheets available on our website eucomed.org.

A clear, predictable and effective regulatory framework for Europe

Eucomed recognises the need to modernise and strengthen the current medical devices legislation in Europe, in particular, by strengthening the decentralised Notified Body system and increasing EU Member State co-ordination. The overarching objective should be to achieve a clear, predictable and effective legislative framework that is consistently implemented across the EU and increases patient safety, maintains timely access to the latest medical technologies and keeps Europe's "medtech research and innovation engine" running.

This legislative framework should inspire trust in its stakeholders by addressing current systemic weaknesses and building on the strengths of what has proven to be the world's best system for patients and medical progress. Europe has emerged as a leader in medical technology and we are convinced that we can remain in this privileged situation with the support of a decentralised, device-specific regulation that works for patients and innovation – a regulation that works for Europe.

In September 2012 former surgeon and Eucomed Chairman Dr. Guy Lebeau M.D. stated what remains paramount in the current process of revising the regulatory framework for devices:

"I know from first-hand experience that European patients and European medical research and innovation are benefitting heavily from our current system that is the world's fastest in providing patients with lifesaving technologies while guaranteeing the highest level of safety.

As a surgeon first and as a business executive second, I fully agree that changes need to be made to the current regulatory framework but let's make sure we keep the best system for patients and medical progress in Europe".

Introduction

Aiming for a regulation that keeps Europeans healthy and safe

The European medical device industry is a critical provider of innovative, effective and safe healthcare solutions for an increasing number of patients in Europe. Through its healthcare innovations, the industry contributes to ensuring sustainable and accessible healthcare systems throughout Europe.

The European Medical Device industry recognizes that the system needs an overhaul due to increased expectations and technological advances and acknowledges that change is necessary to improve Europe's Medical Device regulatory framework. In particular, the European Medical Device industry unanimously agrees that incidents like the fraudulent PIP breast implant case should never happen again.

In the global context, let us not forget that Europe has been known for providing its citizens with timely access to safe technology thanks to the effective decentralised approval system. The European system (see also Appendix 1) forms a significant basis for other national regulatory frameworks around the globe (e.g. Japan, Australia, Canada) because of its efficiency in providing lifesaving and life-enhancing technologies to patients and doctors while guaranteeing a high level of safety.

Various recent reports[ii] from respected academics and researchers have shown that lifesaving and life-enhancing medical technologies are made available to European patients on average of three to five years earlier than those in the United States - and this without compromising safety.

We are convinced that Europe can remain in this leading situation with the support of an improved decentralised, device-specific regulatory framework that assures safety, encourages cost-effective innovation and ensures that an incident such as the PIP case will not happen again.

We strongly believe that it is in Europe's best interest to have a clear, predictable and effective regulatory system that:

- guarantees the highest level of **safety** for patients;
- ensures timely **access** to the latest innovative technologies;
- enjoys the **trust** of its stakeholders;
- contributes to the **sustainability** of national healthcare systems;
- maintains an environment that encourages and keeps **research** and **innovation** in Europe.

The Commission's proposal represents a step in the right direction and the majority of the recommended measures are welcomed by industry as they: (1) improve patient safety, (2) do not unnecessary delay patient access to medical devices that save or improve lives and (3) do not hamper innovation. Further improvements can be brought to seven key focal areas to improve the delivery of safe, innovative medical technology that Europe's patients need. These seven key focal areas, and ten additional technical topics, will be discussed in the following chapters.

1. Only the best Notified Bodies

EC Proposal: Chapter IV (Art. 28-40, Annex VI) & Chapter V (Art. 42)

The European decentralised approach of Members State control and use and oversight of Notified Bodies forms a significant basis for other national regulatory frameworks around the globe (e.g. Japan, Australia, Canada) because it is recognised as the best system in terms of providing safety and efficiency. Evidence shows that the European system delivers the same high level of safety as the US system[iii]. In addition, the European system enables timely access of the latest lifesaving and life-enhancing medical technology innovations for patients and healthcare professionals (between 3-5 years earlier than in the US[iv]) and furthermore represents an effective and efficient use of government resources and tax-payers' money.

However, fair criticism has been raised that not all Notified Bodies across Europe work at the same high standard that is expected and needed, which has led to questions of transparency, trust and legal certainty. For patient safety and the credibility of the Notified Body system this criticism has to be addressed by improving three key elements:

1. **Competency**
   Ensure that all Notified Bodies have a consistent, mandatory and transparent high level of competency and expertise for reviewing the broad range of different medical technologies;

2. **Oversight and control**
   Change today's largely voluntary and national approaches of authority control into a binding system of strict and coherent authority oversight and control. This must be based on consistent, mandatory European rules and standards, with rapid de-accreditation where the necessary standards are not sustained and made transparent.

3. **Binding obligations**
   Enhance and clarify the mandate of Notified Bodies which enable them to fulfill their expected role and duties. E.g. the unannounced manufacturing site visits should be a legally binding obligation in order to be sure it happens.

Addressing known weaknesses

The Commission's proposal replaces 2 pages in today's legal text into16 full pages of new detailed and stringent legal requirements for the quality and competence of Notified Bodies and their strict control by the Member States and the European Commission. In particular it addresses specific known weaknesses by the following measures (Chapter IV& V):

- More rigorous designation and competence criteria (Art. 28, 29 & Annex VI);
- A new EU level of audit, control and surveillance powers given to Member States and the Commission to ensure the quality and expertise of Notified Bodies (Art. 35);

- The power for the Commission to challenge the competence of a Notified Body and if necessary suspend, restrict or withdraw notification (Art. 37);

- The ability for the Commission to further specify the required mandatory testing and regular checks of manufacturers by Notified Bodies, including frequency of sampling and testing, frequency of unannounced factory inspections and the required physical laboratory or other tests to be carried out. (Art. 42).

INDUSTRY POSITION

More stringent control measures on Notified Bodies are necessary

Industry fully supports the European Commission's proposed measures as they are absolutely essential to identify and address potential safety and quality issues at the earliest possible stage.

In addition industry believes that more stringent measures are necessary to ensure the highest safety of medical technology for Europeans. However, this should be done through additional systematic control procedures on the work undertaken by Notified Bodies. Our suggestions can be found in the following chapter (2).

2. A systematic control procedure

EC Proposal: Chapter V

To cater for the enormous diversity of life-improving medical treatments and technologies provided to patients (over 500,000 different types) Europe's current medical devices legislation makes a clever and effective use of authority and regulator's resources. The competent authorities are in control of two main elements. Firstly, they set the public safety requirements and intervention mechanisms. And secondly, they select and control competent, scientific certification bodies to do the technical and scientific review (Notified Body). Ultimate control remains under the jurisdiction of the Competent Authority. This concept translates in the legislation where the Member States' authorities have two broad tasks:

1. Setting and monitoring public health and safety requirements such as essential safety and performance requirements, clinical investigation, product classifications, product, technical and manufacturing standards, vigilance and market surveillance;

2. Selecting, empowering, monitoring and evaluating competent testing and certification organizations, called Notified Bodies, who must have the latest in scientific and technical competence, and be capable of checking both manufacturers and their medical devices in accordance with the regulations.

This resource allocation safeguards public health and sets high standards while allowing swift market intervention where and when needed.

Furthermore, this approach fosters medical progress and innovation as the science and technical aspects are left in the domain of clinical and technical experts, peer review and internationally recognised clinical and technical standards and thus free from needless bureaucratic burdens.

The decentralised device-specific Notified Body system has been in place and proved successful for nearly twenty years. Indeed, Europe's Notified Body system forms a significant basis for other national regulatory frameworks around the globe (e.g. Japan, Australia, Canada).

'Scrutiny procedure' does not increase safety and leads to unnecessary delays

The Commission has proposed a series of improvements to address known weaknesses in the system aimed at optimizing the designation and monitoring of Notified Bodies. In particular, the proposal creates a Member State authority body, the Medical Device Coordinating Group (MDCG), to work together with the Commission to improve oversight of the Notified Bodies.

The MDCG together with the Commission would carry out three key activities to strengthen oversight of Notified Bodies:

1. Review applications of entities proposing to become Notified Bodies ("Initial Qualification", Art. 32);

2. Periodically audit existing Notified Bodies ("Ongoing Monitoring"(Art. 35);

3. Select random products under Notified Body review, to undergo an additional "scrutiny" procedure by the MDCG (Art. 44). The policy objective of this procedure is to increase patient safety by ensuring that:

    - Notified Bodies are doing a good and consistent job;

    - Clinical evidence being presented by manufacturers is being properly reviewed by independent clinical experts.

Whereas the first two measures are meaningful improvements to strengthen the Notified Body qualification and oversight, the third measure, the individual product scrutiny procedure (outlined in Article 44, see also Appendix 2 of this document), does not contribute to patient safety nor does it make best use of the competent authority and Commission resources and is essentially a random duplication of the aforementioned measures. Rather, this approach creates a false sense of security and leads to an unnecessary delay to new and improved products and treatments for patients as follows:

- It is a random sampling process of certain class III medical devices rather than a systematic strengthening of the system for all class III medical devices, and only applies to products that are selected for scrutiny (therefore the vast majority of files by-pass the system);

- There is great uncertainty about which products are to be selected for scrutiny, how the scrutiny process would be conducted and how long the process would take;

- National policy could be a factor in the file selection process, to the detriment of Europe's patients;

- Scrutiny occurs very late, namely after the view of a Notified Body has finished, and thus creates an additional unnecessary bureaucratic burden by duplicating the review of a Notified Body a second time;

- The MDCG will most likely lack the appropriate high level technical expertise;

Only a systematic control procedure will deliver on the promise of increasing safety

The objective of all stakeholders, including industry, is to increase safety for patients. Industry will consider all proposed measures if they improve patient safety and do not unnecessarily delay medical devices reaching patients. Unfortunately the proposed scrutiny procedure has the opposite effect and is therefore inappropriate: it unnecessarily delays important medical devices reaching patients and does not increase safety for them. We believe that only a truly systematic control procedure, and not the proposed scrutiny mechanism, will achieve the common, objective of increased patient safety.

The random, “needle-in-a-haystack” approach to scrutiny proposed by the Commission must be replaced by a meaningful approach: a systematic control procedure applicable to all class III devices. The system should not be “looking for a needle in a haystack” through random checks at the end of a review process but should prevent the “needle landing in the haystack in the first place” and do so in a systematic way. Only then will patient safety be successfully increased and unnecessary delays of devices reaching patients be prevented.

Eucomed finds the scrutiny procedure inappropriate as it is ineffective and inappropriate and strongly urges that it is replaced it with a comprehensive, systematic control procedure that tackles the policy objective and applies to all Notified Bodies and all independent clinical expert reviews for all class III medical devices. The procedure would consist of the following:

1. Measures to ensure notified bodies are doing a good and consistent job:

a) **Develop and implement more rigorous criteria for class III Notified Body designation** to ensure that Notified Bodies evaluating class III products meet the highest quality standards;

b) **Encourage further specialization of Notified Bodies** to ensure that Notified Bodies have the unique expertise to guarantee sound assessments in a given product category;

c) **Undertake regular audits of Notified Bodies** which can be conducted jointly by the Commission and its proposed MDCG.

2. Measures to ensure that the clinical evidence for medical devices is being properly reviewed by independent clinical experts:

d) **MDCG to vet and maintain a list of clinical experts, including their specialty for class III devices.** Those experts can be nominated by all stakeholders including Notified Bodies for inclusion into the list.

e) **Require Notified Bodies to engage only these vetted clinical experts in their file reviews** to ensure that clinical evidence presented by manufacturers is being properly reviewed;

f) **Require Notified Bodies to publicly disclose their roster of internal and external technical experts**.

g) **Allow manufacturers and authorities access to the vetted clinical experts** early in the design of class III medical devices and receive recommendations on the clinical aspects.

The systematic control procedure consists of five measures and reflects current best practices in quality management and will lead to the desired increase in safety. Focusing on ensuring that the process is set up and operated in a manner to ensure safety and quality is more reliable than attempting to catch problems through sampling product files at the end of the process.

Unlike Commission scrutiny, systematic control procedure, as part of the system and not added to it, will also allow small and medium-sized enterprises (SME), which make up more than 80% of the medical technology industry, to continue to flourish and drive innovation in Europe. SMEs typically operate with modest resources and cannot cope with the unpredictability of a process that is not systematic. The costs of the current proposed scrutiny measure (Article 44) will be devastating to innovative young companies, resulting in fewer companies actively developing innovative technology for European patients.

INDUSTRY POSITION

Increase patient safety through replacing the inappropriate 'scrutiny procedure' with a systematic control procedure

Only a systematic control procedure will improve the system and increase patient safety. The proposed 'Commission scrutiny procedure' (article 44) is inappropriate because it will not lead to increased patient safety. It should be replaced with a systematic authority control procedure of notified bodies and clinical review (that go beyond the current proposed measures). Only then will Europe reach the desired outcome of all stakeholders: maximum safety for all Europeans without unnecessary delay or duplication of work.

3. Increase stakeholder involvement

EC Proposal: Chapter VIII (Art. 78)

Under the current system a Medical Devices Experts Group (MDEG) represents the primary structure for broad stakeholder dialogue. The system benefits greatly from this active collaboration where national regulators and stakeholders can discuss issues related to the implementation of the regulatory framework. The European Commission also gains valuable direct input from stakeholders on issues that may not be immediately apparent to regulatory bodies.

Legally guaranteed stakeholder involvement

The Commission has proposed that a Medical Device Co-ordination Group (MDCG) replaces the Medical Devices Expert Group (MDEG), thus giving up this primary forum for stakeholder involvement. The proposal provides for the establishment of temporary or standing sub-groups to which the MDCG *may choose but is not required* to invite outside stakeholders (patients, healthcare professionals, industry) as observers. This is not an acceptable level of stakeholder engagement and significantly reduces the current level of involvement and potentially transparency.

INDUSTRY POSITION

A standing advisory body of stakeholders must be established

Industry welcomes the creation of the MDCG but does not believe that the Commission proposal guarantees ample opportunity for stakeholder involvement.

Industry believes that the revised framework must maintain the current level of stakeholder dialogue that allow patients, healthcare professionals and industry to communicate on equal grounds with regulators and Commission on issues of mutual importance.

We therefore propose that a standing advisory body (similar to the MDEG model) be established in parallel to the MDCG to ensure that stakeholders remain as actively engaged as they are today.

4. Greater transparency & traceability

EC Proposal: Chapters II, III, VII

Patients, healthcare professionals and the public need access to information about medical devices on the European market and how they perform. The regulatory system does not currently provide this kind of information to the public.

A broad range of proposals

Stakeholders should also be able to easily and quickly report issues that may arise with the devices they encounter. In an effort to address these gaps in the system, the Commission has proposed:

- The creation of a single registration database for all medical devices on the European market with information available on the quality and safety. (Art. 27);
- Simplified web-based forms for use by patients and healthcare professionals to report incidents to national authorities (Art.61.3);
- The introduction of a Unique Device Identification (UDI) system to enhance the traceability of products on the market, reduce medical errors, fight against counterfeiting, enhance purchasing and stock management by hospitals (Art. 24);
- The introduction of an information card for implantable devices (Art. 16).

INDUSTRY POSITION

More information is needed on information disclosure and the working of the database

Industry welcomes these proposed measures as they will allow stakeholders to take better informed decisions about the medical devices available to them. However, the proposal lacks clarity on how exactly this information will be made available to various stakeholders and also lacks detail regarding the system's structure, funding and resource allocation.

We hope to have the opportunity to contribute to the development of the delegated and implementing acts, which will determine the degree of accessibility of information to various stakeholders (see also point 10 of 'additional issues').

5. Clinical evidence needs more clarity

EC Proposal: Chapter VI, Annex XIII and XIV

It is critical that requirements for clinical evidence are clear, effective and reflect the specificity and characteristics of medical devices (mechanical/physical action with no immunological, pharmacological or metabolic effect). The required data should be able to clearly demonstrate that devices perform well and are safe for patients when used by a physician as intended by their manufacturer. The current system provides legal requirements and several international standards and guidelines for clinical data which were themselves strengthened under Directive 2007/47/EC, which came into force in 2010.

Building on recent improvements

The recent improvements by Directive 2007/47/EC included the clear requirement that all devices have clinical evidence to demonstrate safety and furthermore that all implantable and class III devices must undergo clinical trials (called clinical investigations in the medical devices world) unless adequate data can be derived from investigations of the current or similar devices. The Commission has built on this Directive by adding:

- More detail for clinical requirements (Art. 50);
- A new centralised system for notifications and reporting of severe adverse events (Art.53);
- Increased protection of subjects undergoing clinical investigations (Art. 50, 52, 59);
- Extended post-market clinical follow-up by manufacturers (Annex XIII).

INDUSTRY POSITION

More clarity is needed on clinical requirements and equivalency data

Industry welcomes the proposed measures as they offer further clarification of clinical requirements and increased consistency in post-market clinical follow-up. We believe, however, that even more clarity is needed to more comprehensively define some aspects of clinical requirements including the use of equivalency data (continued on next page).

INDUSTRY POSITION (continued)

Equivalency data is that clinical data that is valid for a type or class of medical devices and therefore need not be regenerated for a specific product. For example, a manufacturer of a next generation pacemaker need not generate clinical data to prove that pacemakers can be used to treat heart arrhythmias. This is already established clinical science. They do however need to present clinical data that proves that their pacemaker works and performs with the stated and required safety and quality.

As drafted, the current proposal could be interpreted to mean that existing and scientifically valid clinical data could be found 'non-equivalent' which could lead to a nonsensical, unethical and costly repeat of clinical investigations. Eucomed has suggestions to ensure that the definitions of 'equivalency' are scientifically sound and coherent with internationally accepted scientific and regulatory definitions.

6. Enhance market surveillance and vigilance

EC Proposal: Chapters VII and VIII

The current regulatory framework for medical devices foresees that once a medical device is placed on the market, market surveillance (preventive systems that monitor the market) and vigilance (reactive systems that are activated in case of adverse events) must be implemented by national Competent Authorities and manufacturers. These systems allow for in-market monitoring of manufacturers for compliance with the rules for rapid identification of adverse events (or trends) and appropriate response. However, there is currently a severe lack of coordinated information exchange on reported incidents across EU Member States as well as considerable variation in response time. This has resulted in duplication of efforts and potentially increased inequalities in the level of health protection across the EU.

Better coordination between national surveillance authorities

The Commission's proposal addresses these needs, calling for better co-ordination between national surveillance authorities, to ensure that only safe devices are available on the European market (Art. 78 – 80). This will be realised in part by the creation of a central European Database managed centrally by the Commission to facilitate reporting of adverse events and rapid EU-wide response (Art. 62).

INDUSTRY POSITION

More clarity of practical elements is needed to achieve greater safety

Industry supports the Commission's proposal but believes that more clarity is required to remove certain ambiguities surrounding practical elements of the proposal in the areas of scope, definitions and the reporting and analysis of incidents. Without this clarity the proposed text will not achieve the desired objective of greater safety through better co-ordination at European and national levels.

Industry believes national Competent Authorities must be empowered to increase their vigilance efforts and respond to adverse events in a timely, coordinated manner. Competent Authorities must fully embrace ownership of their role in market surveillance if Europe is to improve the level of safety for patients.

7. Clear science based classifications

EC Proposal: Annex VII

Following a globally accepted regulatory approach, medical devices are sub-divided into four risk classes based on the vulnerability of the human body taking account of the potential risks associated with the technical design of the device.

In line with regulatory approaches around the world, there is a system whereby authorities can move products either upwards or downwards in classification based on established risk through clinical practice and 'real-life' experience. Each reclassification must be scientifically valid and duly justified.

New rules that bypass the global approach

The Commission has proposed the following new rules which seem to by-pass the established European and global approach. The Commission unilaterally, without any scientific or other justification, reclassifies not only specific products but whole classes of devices which, to-date, have a low risk profile and no history of safety issues:

- Certain devices incorporating nanomaterials will be moved to class III;
- Devices for aphaeresis will be moved class III;
- Devices that are composed of substances or combination of substances intended to be ingested, applied vaginally, rectally or inhaled and are absorbed by or dispersed in the human body will be moved to class III;
- Devices in contact with the spinal column will be moved to class III.

INDUSTRY POSITION

New classifications to be deleted or scientifically justified

As the proposal is currently worded, devices with a low risk profile and no history of safety issues would automatically be placed into higher risk classes, which is inappropriate. For example, simple dental fillings could jump from low to medium risk class IIa to high risk class III just because they may contain nanoparticles even though today these products display no increased risk.

Eucomed urges that these new classifications be deleted and that any reclassifications follow the current science based reclassification procedure and safeguards that exist under today's rules. Alternately the Commission should present the data and scientific justification which would allow for a proper examination of the reason and validity for the up-classification

Additional issues

The Medical Devices Directives are broad in scope and cover several important areas. While many issues may seem strictly technical in nature, it is important to realise that their implementation could have far-reaching consequences for patients, regulators and industry alike in terms of safety, unsustainable costs and needless bureaucracy. Industry's position on each issue is outlined briefly below. For more detailed information, please see the Eucomed fact sheets on www.eucomed.org.

1. Scope

EC Proposal: Chapter I

The Commission's proposal broadens and clarifies the scope of EU legislation, extending it to include implants for aesthetic purposes (Art.1) and devices containing non-viable human tissues (Art. 1).The proposal also clarifies the issue of medical software (Art.2). Industry supports the expansion of the scope as it increases patient and consumer safety but believes some improvements are necessary, namely in the definition of the substances of human origin and the clarification that certain products that regulators consider as medical devices will continue to be considered as medical devices (e.g. medical devices containing living micro-organisms).

2. Economic operators

EC Proposal: Chapter II

Economic operators are the various actors involved throughout the medical device supply chain, i.e. manufacturers, authorized representatives, importers and distributors. Industry welcomes in broad terms the Commission's outline of the respective roles and obligations of these operators, as well as diagnostic services and internet sales, but believes the proposal lacks adequate detail. It is absolutely essential that the overlapping obligations and responsibilities of different economic operators be clarified in the areas of device registration, vigilance reporting and market surveillance. The definition of clear roles and responsibilities for economic operators is not only critical to the functioning of the system, it is critical to the way the supply chain to hospitals and patients work. If not done correctly, it could have catastrophic effects on certain operators and SMEs within the supply chain, effectively closing their businesses overnight and risking unavailability or increased costs to hospitals and patients.

3. Reprocessing

EC Proposal: Chapter II

The Commission has proposed that reprocessors of single-use devices be assigned the same rights and responsibilities of manufacturers.

Regarding single-use devices used in invasive medical procedures, defined as “critical use” by the Scientific Committee in Emerging and Newly Identified Health Risks (SCENHIR) in April 2010, the proposal would also allow these devices to be reprocessed only after appropriate evaluation from the Commission and Member States with the latter granted the discretion to prohibit reprocessing of single-use devices on their territories.

Industry supports the Commission’s proposal that the reprocessing of single-use devices be considered as ‘manufacturing’ and thus reprocessors will be subject to the same full and strict controls as original manufacturers. Eucomed also supports the concept of establishing a safe list of single-use devices for critical use which can be safely reprocessed. However, we encourage the Commission to provide additional clarity on the process which we believe should be fully transparent, with clearly defined timelines and criteria.

4. Standards, guidelines and specifications

EC Proposal: Chapter II

Standards exist for the safety of users, patients and consumers and to provide common technical specifications for regulators and manufacturers of products to demonstrate the correct application of the legal Safety and Performance Requirements. Using standards to underpin safety is a core principle of all global regulatory systems and as such should prevail in Europe as a core vehicle to ensure the safety and compliance of medical devices. In addition to maintaining the role of standards, the Commission proposal expands the possibility to use Common Technical Specifications (CTS), a legally binding technical specification, from the In vitro diagnostic medical devices Directive to all medical devices. In addition, the formal responsibility to elaborate guidance is given to the new Member State Medical Device Co-ordination Group (MDCG).

Industry fully supports an effective implementation of the revised rules for standards, Common Technical Specifications and guidelines development. However, the current proposed measures must be strengthened to ensure that they are transparent and supported by a policy of full stakeholder involvement via a formal advisory committee made up of representatives from relevant stakeholder groups (industry, patients and physician groups). See also Chapter three on stakeholder involvement.

5. Early scientific advice

EC Proposal: Chapter VIII

Industry believes that manufacturer access to sound independent scientific advice would allow manufacturers to appropriately design its conformity strategy to fit the expectations of regulators. This facilitates the innovation cycle resulting in timely patient access to the latest technology and increases predictability and trust in clinical evidence for manufacturers, Competent Authorities and Notified Bodies. The Commission’s proposal does not contain a provision to allow for this advice. Industry suggests this mechanism be added to the responsibilities of the MDCG.

6. Governance

EC Proposal: Chapter VIII

The governance and solid implementation of the system stands on two pillars: the Member States and the European Commission. To improve the management and implementation of the system, the proposal strengthens the powers of the Member States to include a new Member State Medical Device Co-ordination Group (MDCG) and gives a clear legal basis for the Commission to take on a coordinating role to ensure harmonized implementation across the EU.

The Commission will be charged with the elaboration of several implementing and delegated acts which are needed for proper functioning of the Regulation. The Commission will also be the coordinator of several activities where Member States will be asked to act jointly, resulting in enhanced Member State engagement with better European science-based coordination and management of the regulatory system.

Industry welcomes the strengthening of the Member States' role and the enhanced role of the Commission to improve the co-ordination and management of the system. Industry opposes any proposal that seeks to discard this working, device-specific system.. Such an approach, and its inherent confusion, bureaucracy and expense would halt EU advancement in medicine and add no safety.

7. Funding

EC Proposal: Chapter IV &IX

As the Commission proposal points out in articles 40 and 86 on fees, Member States may charge a fee for the services they provide – this reflects the system as we know it today where industry pays fees either directly or indirectly to authorities at the national level. These fees are generally appropriate and reflect the industry's predominately SME nature (80% SMEs). Regulatory changes bring adjustments which have cost and resource implications both for SMEs and large companies. This regulatory revision is a major overhaul of the system and we expect the implications to industry to be significant. Unique Device Identification alone is estimated to cost a typical large-size company €10-15 million. In addition, manufacturers will face significant costs in order to adapt systems and procedures to the new rules and new increased levels of inspections. European manufacturers will also have to face the cost (estimated in the millions of euros) of re-registering in markets outside the EU due to the change in certificates and labelling.

To ensure that fees and levies continue to be appropriate and reflect the industry's predominantly SME nature (80% SMEs), industry calls on the European Parliament and Council to ensure that any amendments are subject to a comprehensive impact assessment. Industry also strongly suggests that prior to adoption, a final assessment be made of the full impact on manufacturers to ensure that the final costs are appropriate and reflect a sustainable funding model that demonstrates benefits to both the regulator and the regulated.

8. Transition periods

EC Proposal: Chapter X

The Commission proposes timelines for the full application of its requirements and the validity for certificates issued according to the current Directives (Art. 94). The transition from the Medical Devices Directives to the Medical Devices Regulation is likely to allow the temporary presence of products on the market conforming to either to the current Directives *or* the revised Regulation. Industry believes this transition has the potential to seriously distort the market, create significant confusion, and ultimately drive up costs for all healthcare actors.

To avoid these problems, Industry suggests that the new Regulation become fully applicable only when all the necessary delegated or implementing acts are adopted.

9. Hazardous substances

EC Proposal: Annex I, part II

In addition to the requirements already contained in the current Directive regarding substances which are carcinogenic, mutagenic or toxic to reproduction, the Commission proposal asks that special attention is given to substances having endocrine disrupting properties (Art. 7.4). Furthermore, the same Commission proposal introduces a concentration limit of 0.1% by mass of the plasticized material above which labelling is required.

Medical devices are subject to biocompatibility studies to cover toxicological aspects (EN ISO 10993 series). The use of "hazardous substances" is sometimes necessary as the material also has a proven net benefit for health. In these instances the safety data must be supported by the risk benefit assessment which includes the evaluation of alternatives. Industry supports the weighing of the use of "hazardous substances" against clinical benefit using sound scientific principles. Industry would strongly oppose any arbitrary or unscientific ban of any material that could be essential to the functioning of medical devices and a proven benefit to patients.

10. Delegated and implementing acts

The Commission has proposed more than fifty delegated and implementing acts, which will not be developed before the final approval of the Regulation. Industry believes that many of these acts afford the Commission too broad a mandate or lack sufficient detail to ensure a stable and predictable legal framework for economic operators. In addition, there is a complete lack of a mandatory consultation with stakeholders (patients, doctors, industry) in the elaboration and adoption of these acts.

Industry believes that stakeholders must be explicitly included in the elaboration and adoption of delegated and implementing acts via a formal advisory group. Furthermore, to ensure that delegated and implemented acts reflect a stable and predictable legal framework, industry has undertaken a case-by-case analysis of the acts and have suggestions on their objectives, content, scope and duration that we believe bring the necessary legal certainty and predictability.

About Eucomed

Eucomed represents the medical technology industry in Europe. Our mission is to make modern, innovative and reliable medical technology available to more people.

Eucomed members include both national and pan-European trade and product associations as well as medical technology manufacturers. We represent designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability.

The industry we represent employs more than 500,000 highly skilled workers, turns over €95 billion per year, invests some €7.5 billion in R&D and encompasses of approximately 500,000 different medical technologies from sticking plasters and wheel chairs through to pacemakers and replacement joints.

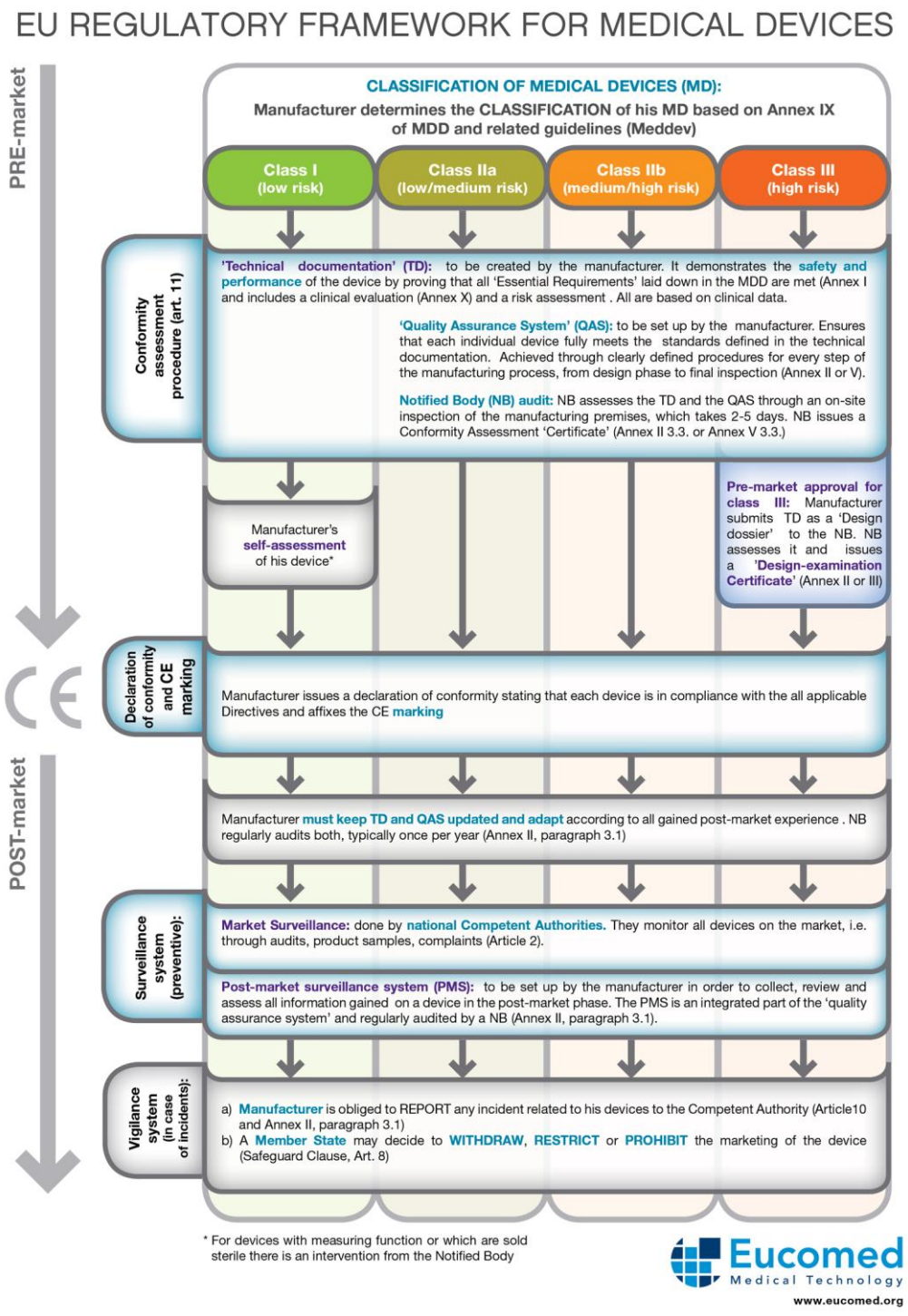
Eucomed promotes a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of society.

Eucomed is a member of MedTech Europe, an alliance of European medical technology industry associations

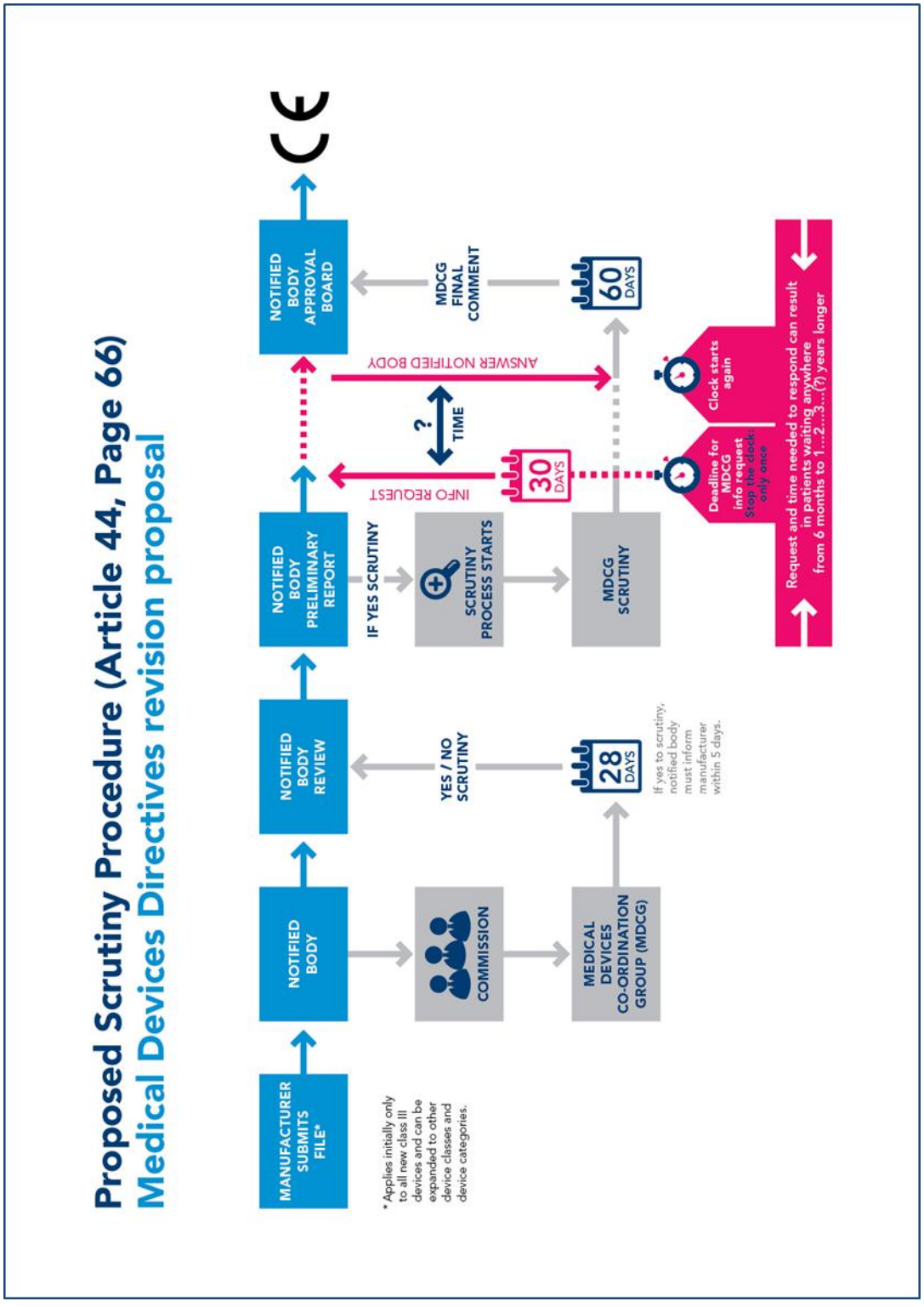
For more information visit www.eucomed.org

Appendix 1

Here below is a schematic overview of the **current** EU regulatory framework for medical devices. For more information please visit: www.eucomed.org/key-themes/medical-devices-directives/the-eu-system-for-medical-devices



Appendix 2


Proposed Scrutiny Procedure (Article 44, Page 66)
Medical Devices Directives revision proposal
MANUFACTURER SUBMITS FILE*
NOTIFIED BODY
COMMISSION
MEDICAL DEVICES CO-ORDINATION GROUP (MDCG)
28 DAYS
If yes to scrutiny, notified body must inform manufacturer within 5 days.
YES / NO SCRUTINY
NOTIFIED BODY REVIEW
NOTIFIED BODY PRELIMINARY REPORT
IF YES SCRUTINY
SCRUTINY PROCESS STARTS
MDCG SCRUTINY
INFO REQUEST
30 DAYS
? TIME
ANSWER NOTIFIED BODY
Deadline for MDCG info request Stop the clock: only once
Clock starts again
Request and time needed to respond can result in patients waiting anywhere from 6 months to 1...2...3...(?) years longer
60 DAYS
MDCG FINAL COMMENT
NOTIFIED BODY APPROVAL BOARD
CE
* Applies initially only to all new class III devices and can be expanded to other device classes and device categories.

Endnotes:

[i] FDA Impact on U.S. Medical Technology Innovation, Josh Makower, MD & Consulting Professor of Medicine, Stanford university; November 2010

EU Medical Device Approval Safety Assessment, A comparative analysis of medical device recalls 2005-2009 , Boston Consulting Group, January 2011

Regulation and Access to Innovative Medical Technologies, A comparison of the FDA and EU Approval Processes and their Impact on Patients and Industry, Boston Consulting Group, June 2012

[ii] See above

[iii] See above

[iv] See above