



The revision of the EU Medical Devices Directives

The medical devices industry's position on four key issues: revised clinical requirements, the 'scrutiny' procedure, the restriction of 'hazardous substances,' and the re-use of single-use medical devices

1 April 2014



Contents

Foreword.....	3
The introduction of a pre-market ‘scrutiny’ procedure.....	4
Revised clinical requirements	7
The restriction of ‘hazardous substances’	10
The re-use of single-use medical devices	14
Annex: the reinforced control procedure in detail.....	18
About Eucomed	22

Foreword

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.

Industry recognizes that the regulatory system needs an overhaul due to increased expectations and technological advances, and acknowledges that positive change is necessary to improve Europe's medical device regulatory framework.

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; and
- maintains an environment that encourages and retains **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.

In this position paper, we wish to focus on four important issues for the medical devices sector that have become key concerns in the revision of the legislation: revised clinical requirements, the introduction of a pre-market scrutiny procedure, the restriction of hazardous substances, and the re-use of single-use devices.

For further information on Eucomed's position on other topics relevant to the legislation, visit www.eucomed.org/key-themes/medical-devices-directives

The introduction of a pre-market 'scrutiny' procedure

“Eucomed encourages the EU Council to replace the European Commission’s proposed scrutiny procedure with a “Reinforced Control Procedure.” This system should be built into the upgraded notified body approval system, rather than added on after it. This will avoid any sort of cherry-picking or random ‘needle-in-the-haystack’ approach to improving safety.”

The Commission’s proposal

Aimed at improving the overall quality of notified bodies and their review of certain categories of high-risk class medical devices, the European Commission proposed a ‘scrutiny’ procedure of the notified body’s preliminary assessment report for certain categories of medical devices by a Member State Authorities’ Committee, prior to the granting of the certification.

This mechanism foresees that the newly formed committee of Member State authorities, the Medical Devices Co-ordination Group (MDCG), monitors applications being handled by notified bodies and flags those for which, prior to the notified body issuing its decision, they would like to check and comment upon the notified body’s assessment and, in turn, the submission dossier of the manufacturer. The CE marking would be dependent upon both the manufacturer and the notified body addressing any issues identified by the MDCG.

The European Parliament’s position

The European Parliament augmented the procedure by clarifying the roles and responsibilities of authorities, the MDCG, and introduced the concept of additional consultation through a group of independent scientific experts – the Assessment Committee for Medical Devices (ACMD) – to support the MDCG in their decision-making.

The Parliament also installed high-level expertise and quality amongst Notified Bodies via more specific competence requirements and the concept of ‘special notified bodies (SNB)’ for certain categories of devices. Finally the Parliament added the involvement of the European Medicines Agency (EMA) into the process for initial qualification and monitoring of notified bodies.

The industry position in detail

We support the need to tackle the three key concerns, voiced by many regulators and stakeholders:

- Are all notified bodies performing at a consistently high level across Europe?
- How do we guarantee the quality and independence of the clinical experts that review the manufacturer's clinical data?
- And the need to tackle the lack of a solid and sustainable process for setting clear European standards and guidelines for medical devices.

However we believe that the procedure proposed by the Commission and Parliament will not address these concerns.

We believe that the 'Scrutiny' procedure, although labelled as an assessment of the notified body by authorities, is essentially a random duplication of the notified body product assessment. Furthermore, the assessment of the notified body's competence would have already been carried out, fully checked and peer reviewed by authorities prior to the notified body assessing any file, in the already improved designation and monitoring procedures.

As such we consider that the 'Scrutiny' proposal of the Commission and Parliament does not offer any substantive contribution to patient safety nor does it make best use of competent authority and Commission resources. The procedure essentially adds layers of random duplication at several stages of the approval process and will increase red tape and unnecessary bureaucracy.

Further, the proposal only applies to those products that are selected for scrutiny; therefore the vast majority of files by-pass the system. It is a random sampling process of certain class III medical devices, regardless of whether the technology is 'old' or 'new', rather than a fundamental strengthening of the system for all 'new' class III medical devices. We consider therefore, that the approach would create a false sense of security and can lead to unnecessary delays to important new and improved products and treatments for patients.

The industry's proposal

Rather than adding an extra layer of bureaucracy on top of the already improved notified body system, industry considers that the best approach would be to replace the Commission's 'random' Scrutiny procedure with a 'Reinforced Control Procedure' that is applicable to all notified bodies certified by authorities to approve new high risk class III devices. This system should be built into the upgraded notified body approval system, contained in it rather than after it, thus avoiding inconsistency and any sort of cherry-picking or random 'needle-in-the-haystack' approach to improving safety.

The reinforced control procedure would be composed of three elements (full practical details are available in the annex to this document):

1. Reinforced control of Notified Bodies to ensure they are doing a good and consistent job via more frequent and rigorous checks by audit teams from Authorities (MDCG) and the

Commission of the Notified Bodies and the Conformity Assessment System for all new class III medical devices¹.

2. Systematically ensuring a high quality and independent clinical review by creating a new EU level Register of Clinical Experts², controlled by the MDCG and Commission, and vetted by authorities, who will independently evaluate the manufacturer's clinical evidence as part of the conformity assessment process.
3. Comprehensive process for the development of Common Technical Specifications and European Guidelines to ensure continued evolution, a sustained high level of safety and enhanced involvement of MDCG authorities and their experts into the Harmonised Standards and International Cooperation processes.

¹ As per European Parliament's (EP) proposal of new Article 44a para.1, focus is on new applications for class III devices including: device/drug combinations and devices manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives with exception, of renewal applications, supplement applications and applications for devices where common technical specifications (CTS) or harmonised standards cover the clinical evaluation and the post-market clinical follow-up; Broadens the scope of devices covered from the EP proposal in that all class III (the highest risk class) are covered not just class III implantable and removes the EP's proposal to include class IIb devices that administer or remove medicines as they are lesser in risk classification but do fall into the new enhanced SNBs as per the EP proposal new Article 43a

² Create a panel of clinical experts across 21 therapy groups; Therapeutic groups as per European Parliament's Proposal

Revised clinical requirements

“Eucomed encourages the EU Council to closely adhere to a device-specific approach, setting clear, attainable and scientifically valid clinical requirements for devices, and avoiding a ‘one-size-fits-all’ system. Industry believes that with fine-tuning of certain elements, the European Commission’s proposal offers a balanced and appropriate approach to clinical requirements for medical devices.”

Introduction: what is clinical evidence?

Clinical evidence is all the relevant clinical information on the safety and performance of a particular device. Clinical data can be sourced from clinical investigations, scientific literature review or clinical experience from published and/or unpublished reports. Data from similar devices can be used where equivalence is demonstrated.

This information is generated, analysed and summarized in a part of the safety dossier which is called the clinical evaluation report. This clinical evaluation report is updated throughout the lifetime of a device to include all the new information made available through real-life use of the medical device e.g. from post-market clinical follow-up, vigilance data and any new data published in scientific literature.

The Commission’s proposal

The Commission’s proposal increases the level of detail in order to improve clarity and harmonisation of clinical requirements by:

- better protecting patients involved in clinical investigations (e.g. informed consent, proof of insurance, data protection);
- introducing and aligning relevant and appropriate concepts used in the Commission’s proposal for a Regulation on clinical trials on medicinal products for human use (e.g. definition of sponsor, national level approval of clinical investigations);
- strengthening the role of the centralised database, Eudamed, for the collection of data related to the clinical investigations and introducing a new centralised system for notifications and reporting of severe adverse events as well as the possibility to centralise the application of the conduct of clinical studies in more than one EU Member State;
- extending the scope of post-market clinical follow-up by manufacturers.

The European Parliament's position

- Introduces the concept of 'efficacy' of a device (without defining the term).
- Introduces the use of Randomised Control Trials (RCTs) as the appropriate scientific clinical trial model for medical devices; any other design use must be justified.
- Increases transparency to the manufacturer's clinical evidence including the creation of lay-person summaries.

The industry position: 7 steps to ensure fit-for-purpose clinical requirements for medical devices

Industry welcomes the proposal by the European Commission to improve upon current clinical evidence requirements. Certain elements, including those added by the European Parliament, still need to be fine-tuned to ensure that the requirements are appropriate to the diversity and complexity of the medical device sector and do not follow a non-implementable 'one-size-fits-all' approach. Eucomed has outlined seven steps to ensure that clinical requirements are appropriate for medical devices:

1. **Ensure no 'one-size-fits-all' approach.** The final text should reflect a case-by-case approach to clinical evaluation in order to appropriately cover the complexity and diversity of the medical device sector and its inherent pace of innovation, both break-through and iterative.
2. **Include appropriate elements from pharmaceutical legislation.** The proposals to change both the Medical Devices legislation and the EU Clinical Trials Directive in pharmaceuticals were tabled at the same time, in 2012. The Commission's proposal for medical devices offers a balanced approach by already including appropriate elements from the new pharmaceutical rules. We hope this is maintained and only relevant and appropriate changes should be considered for any transfer. If terms such as 'Clinical Equivalence, Efficacy, Effectiveness, and Performance' are added, clear and appropriate definitions are needed.
3. **Consider that effectiveness is measured across the full life-cycle.** A true picture of the safety and effectiveness of medical devices can only be captured by considering both pre-market and 'real-life' post-market clinical data.
4. **Randomised control trials (RCTs) are not always practically possible or ethical.** RCTs require the use of a placebo which in the case of medical devices is neither ethical nor practical, for example carrying out a placebo hip implant. RCTs are not the 'gold standard' in the medical devices sector and therefore, industry believes that the legislation should not automatically refer to or limit trial designs to RCTs or other designs types but should simply indicate them as examples of possible designs.
5. **Utilise the power of big data and scientific literature.** Scientifically reviewed literature and existing clinical trial data is a huge resource and should be considered favourably rather than indicating clinical trials as the 'gold standard' for clinical evidence.

6. **Consider a balanced concept of equivalence.** It is important to consider a balanced concept of 'equivalence' of devices that fosters patient and health system choice, increased quality and a competitive industry in Europe.

7. **The importance of intellectual property and know-how for medtech companies.** Intellectual property and data protection issues should be considered when addressing transparency to ensure that these measures continue to stimulate and protect medical innovation. Unlike in EU pharmaceutical law, medical devices do not have ten-year data exclusivity and market protection.

The restriction of ‘hazardous substances’

“Eucomed encourages the EU Council to support the European Commission’s proposal on the use of hazardous substances in medical devices. The proposal strengthens the current rules on hazardous substances in medical devices and guarantees a higher level of patient safety while ensuring a balanced approach. The provisions foreseen allow for the replacement of hazardous substances when alternatives with a more positive risk/benefit balance are available.”

What is a ‘hazardous substance’?

A hazardous substance is a substance that has been classified as such based on criteria outlined in already existing EU legislation (Regulation (EC) No [1272/2008](#) covering classification, labelling and packaging of substances and mixtures).

Medical devices may contain substances considered as ‘hazardous’ due to their effectiveness as a part of the device in helping patients or healthcare professionals, or, when no other alternative with the same tested safety or performance benefits is available. Examples of such substances vary, from metals (nickel, tungsten, cobalt) used in implantable devices and surgical instruments, plasticizers (DEHP) used in blood bags or lead used in electric soldering in virtually every electrical medical device.

Existing legislation regulating hazardous substances

The potential risks for patients and medical professionals resulting from the presence of hazardous substances in medical devices are currently regulated by the Medical Devices Directive, the REACH Regulation, the Classification, Labelling and Packaging (CLP) Regulation and the Restriction of Hazardous Substances (RoHS 2) Directive.

- **Sector-specific Legislation.** The current Medical Devices Directive (MDD) ensures a high level of patient safety, by calling for safety data that supports a positive risk/benefit assessment of the substance, and specific labelling and justification requirements when utilising phthalates that are CMRs. Outside the regulatory framework, there are also efforts underway across the medical device industry, to evaluate the effectiveness of the use of alternative substances.

According to the MDD, manufacturers must carry out extensive tests to prove that risks posed by the relevant substances have been eliminated or reduced as far as possible, and where some risks still exist they must be carefully weighed against the ultimate benefit for the patient.

- **Horizontal Legislation.** The EU legislation on chemicals is '[REACH](#)³' which addresses the manufacture and use of substances and mixtures, including their use in medical devices, with the aim of improving the protection of human health and the environment. The REACH Regulation also looks to progressively substitute very dangerous chemicals with suitable alternatives, once they have been identified. Other legislation such as [RoHS 2](#)⁴ restricts the use of hazardous substances in electrical and electronic equipment.

As of 22 July 2014, electrical and electronic medical devices will also need to be free of the presence of six hazardous substances in the scope of the RoHS Directive.

The Commission's proposal

The European Commission recognises the strength of the existing rules in sectoral and horizontal legislation and has maintained the current risk-benefit regime to control the risks posed by hazardous substances in medical devices. The Commission aims to ensure that devices are designed and manufactured in a way that reduces "as far as possible and appropriate" the risks posed by hazardous substances which may 'leach' or leak from the device, requiring "special attention" to chemicals which are 'carcinogenic, mutagenic or toxic' (CMR) and to substances having 'endocrine disrupting' properties.

In addition, the Commission proposal requires that all products containing more than 0.1% by mass of the plasticised material, be clearly labelled as a device containing 'phthalates'. If the devices containing 'hazardous substances' are to be used on children, pregnant or nursing women, the manufacturer must provide specific justification for the use of these substances including information on residual risks and, if applicable, appropriate precautionary measures.

Thus, the Commission proposal recognizes that in certain cases, the use of hazardous substances remains essential in some medical technologies (e.g. blood bags) but that whenever such substances are not essential, a manufacturer's risk assessment will indicate when alternative substances can be used.

The European Parliament's position

In October, the European Parliament voted for amendments to the European Commission text that are of particular concern as these measures would apply a general 'one-size-fits-all' ban on all substances which are CMR or Endocrine Disruptors (EDs) and would immediately restrict access to a vast number of critical devices for patients.

The Parliament proposed a new regime for the management of hazardous substances that introduces new criterion, the concentration of 0.1% by weight in homogenous materials, to ban the substances mentioned above.

³ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

⁴ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment Text with EEA relevance

There are five key areas where the Parliament's proposal fails to effectively address the issue of enhanced patient safety in medical devices that contain hazardous substances:

- **Disregard of potential benefits.** The proposal does not consider whether using these chemicals in medical devices may pose any actual risks for patients or medical professionals in the course of the use of the device; instead, it is based on the intrinsic hazardous properties of chemicals themselves – not their risk or potential exposure to patients. It also disregards the potential benefits that devices containing these substances provide to patients.
- **Scope.** The proposed ban would cover an extremely wide range of substances, used in thousands of devices from intravenous bags, tubing and catheters (tubes) to blood bags and surgical instruments, without any consideration as to whether the use of such hazardous substances in medical devices may in actual fact pose any risk or harm for patients or medical professionals. By including substances having endocrine disrupting properties, this further widens the scope of chemicals impacted and will be hugely difficult to implement in practice.
- **Timelines.** The ban proposed by the European Parliament would fully apply three years after entry into force of the Regulation. Such a short deadline is not realistic, considering the administrative and technical burden that would be required for industry to thoroughly evaluate suitable alternatives (if available) as it requires the redesigning and re-approval of the devices concerned. Three years is also a limited time to prepare and apply for any needed derogation.
- **Delegated acts.** The granting of a derogation period of four years via a delegated act is extremely burdensome, especially for SMEs who make up to 95% of the industry, requiring a continuous provision of data. Moreover, the procedure to request exemption still needs to be defined (e.g., is it a company-specific derogation, or does it apply to any product/substance combination?) and is expected to overburden the European Commission with thousands of applications. As a consequence, due to resources and the time needed for approving and publishing all of the exemption requests, the period proposed seems unworkable and is likely to be substantially longer than three years. This could lead to a very critical situation where patients will no longer have access to essential medical devices that are freely available today.
- **Fragmentation of EU legislation.** The European Parliament's amendments do not take into account measures put in place under established EU legal frameworks such as REACH and RoHS that already regulate this sector and that have been designed specifically to evaluate and restrict, where necessary, the use of hazardous substances and to move to alternative chemicals when suitable alternatives have been identified.

Furthermore, the European Parliament's amendments could create confusion as a substance could be authorised under REACH but banned under the future Medical Devices Regulation. It is essential to ensure legal certainty and consistency between REACH and the Medical Devices Regulation requirements and timeframes.

The proposal also fails to reflect the direction of European Commission policy on 'substances of very high concern' (SVHC): the Commission's roadmap on SVHC aims to encourage an integrated approach for the management of risks posed by hazardous substances by collating

a list of such substances and assessing how risks should be managed in order to prevent duplication of regulations.

The industry position in detail

Eucomed encourages the EU Council to support the European Commission’s proposal on the use of hazardous substances in medical devices. The proposal strengthens the current rules on hazardous substances in medical devices and guarantees a higher level of patient safety while ensuring a balanced approach. The provisions foreseen allow for the replacement of hazardous substances when alternatives with a more positive risk/benefit balance are available. The medical devices industry is committed to introducing a phasing out of hazardous substances in medical devices and the Commission proposal outlines the appropriate conditions for carrying this out.

Moreover, as there are currently no clear criteria to define endocrine disruptors, nor a legal framework for their risk management, we believe that the Commission’s proposal can be further strengthened by referring to an already existing list of risk-assessed substances, such as those identified under Annex XIV of the REACH Regulation.

Eucomed believes that the European Parliament’s amendment is excessive, unworkable and potentially dangerous for patients. This ‘one-size-fits-all’ approach may suddenly deprive European patients of access to both ‘every day’ and innovative medical devices where the risks of exposure are far less than the risks of foregoing critical procedures related to the device. Indeed, the European Parliament’s amendments will result in a heavy and bureaucratic system that will require a considerable amount of resources and administrative measures from Member States to enforce and monitor.

Abbreviations	
CMR	Carcinogenic, mutagenic and reprotoxic
DEHP	Di(2-ethylhexyl)phthalate
PVC	Poly(vinyl chloride)
REACH	Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals
RoHS 2	Restriction of Hazardous Substances Directive
EDC	Endocrine disrupting chemicals

The re-use of single-use medical devices

“Eucomed encourages the EU Council to support the European Commission’s proposal on the re-use of single-use devices, which will ensure a balanced approach that puts patient safety first and can be practically implemented.”

What is the re-use of single-use medical devices?

Some devices are designed to be ‘reprocessed’ for re-use. Examples of reusable medical devices that can be reprocessed for re-use include surgical instruments such as reusable stapling devices and biopsy forceps. *Single-use* devices, on the other hand, are designed to be used once and disposed of. Syringes, catheters, blood bags, and implants are typical examples of devices that are designed to be used only once.

Many single-use devices have been developed to respond to public health concerns or healthcare professionals’ needs. Such devices are not designed to be reused, often cannot physically be disassembled to allow adequate cleaning, nor can they withstand the necessary aggressive sterilisation processes in the way that a reusable device can.

Increasingly, in order to face mounting pressures to implement cost control, some single-use medical devices are being reprocessed for re-use (either at hospitals or via third party reprocessing providers) despite the fact that they were intended for a single use.

Currently, some Member States prohibit the practice of reprocessing and reusing of single-use devices whereas other countries have guidelines in place to govern these practices.

The reprocessing of *reusable* medical devices is a common practice in many clinical settings such as hospitals or doctor surgeries and consists generally of cleaning, disinfection and sterilization, according to the manufacturer specifications. Reusable medical devices can also be reprocessed by external reprocessors which are experts in ensuring that the devices can be reprocessed in accordance with the manufacturer’s specifications, and returned to the clinical practice for use.

Reprocessing methods for reusable devices vary significantly depending on the medical device and the treatment needed to be applied to the particular device to render it fit for reuse. A high level of control is needed to ensure optimal hygiene and sterility standards are met. In case of an insufficient level of quality in reprocessing, biological contaminants can remain on the device, therefore increasing the risk of patients being exposed to contaminated products, with potentially serious health consequences.

The European Commission's proposal

The European Commission aims to ensure that the reprocessing of single-use medical devices is regulated in a harmonised way at European level, optimising patient safety, while allowing Member States the freedom to adopt a stricter regulation and prohibit this practice on their territory, as is already the case in some Member States today. Standards, responsibilities, and liabilities for those involved in reprocessing of single-use devices are clearly defined in the Commission's proposal.

The Commission proposal provides clear and distinct requirements for both reusable and single-use devices. Anyone wishing to reprocess a single-use device becomes the manufacturer and must meet all obligations incumbent on manufacturers including labelling and vigilance requirements. The proposal also provides for a positive list of single-use devices for critical use (those used for surgically invasive medical procedures) that can be safely reprocessed.

The European Parliament's proposal

The European Parliament voted amendments to the European Commission text that:

- considers all devices to be reprocessable by default
- requires manufacturers to prove the 'impossibility' of reuse,
- exempts reprocessors from the full obligations of a manufacturer, in particular, the obligation to undergo conformity assessment
- requires the Commission to retain a list of medical devices that are unsuitable for reprocessing (negative list)
- obliges manufacturers of devices, currently labelled as 'single-use' and not included on the Commission's list of 'single-use' devices, to re-label their devices
- introduces an implementing act to develop quality and safety standards for reprocessing of single-use devices
- calls for a report into the functioning of the system for reprocessing of single-use devices after four years

The industry position in detail

Industry supports the Commission's proposal. In particular, the approach 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. To ensure an equal level of safety for patients, we believe that the health institutions should not be exempted but subject to the same provisions as all reprocessors. Eucomed also supports the concept of establishing a list of single-use devices for critical use which can in fact 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 scientifically sound criteria. In addition, further clarity is needed on the roles and responsibilities of reprocessing service providers to healthcare institutions to ensure that they are meeting the full reprocessing rules under the regulation,

as the Commission's general provision contained within Article 4.4 exempts healthcare institutions from certain provisions of CE marking.

As to the European Parliament's position, the medical device industry believes that Parliament's amendments create a potential threat to patient safety, contains several ambiguities which will be hugely cumbersome to implement, resulting in endless bureaucracy and costs. Eucomed's chief concerns on the Parliament's position are outlined below:

- **A potential threat to patient safety.** Despite the huge variation of medical devices, the Parliament position renders all products reusable by default unless the original manufacturer can prove that their device cannot be reprocessed. This 'one-size-fits-all' approach is counter-intuitive and unrealistic in terms of patient safety and general clinical practice. For example the reuse or suggestion that you can reuse single-use items clearly designed for single-use, such as sterile syringes, blood bags and condoms, could pose a serious threat to patient safety.

Moreover, the proposal by the European Parliament fails to ensure that reprocessors meet the same safety and regulatory obligations fulfilled by the original manufacturers. Technical and safety standards of reprocessed devices are not subject to any external checks putting patients and users at risk.

- **An impossible 'one-size-fits-all' approach.** A general rule that all devices are reprocessable is being proposed by the European Parliament. But due to the huge variation in medical devices, the infectious substances that they are exposed to, the materials used in medical devices, the specific product design as well as the therapy and the healthcare setting in which they are used, this 'one-size-fits-all' approach would be an impossible challenge to implement.
- **A complex and unclear process capable of causing major delays.** All devices will be treated as reusable, except if a device is included in a list to be created by the European Commission. The handling of a list of non-reprocessable devices will be in practice impossible to create and maintain by the Commission as it needs to be product-specific and would imply the oversight of around 500,000 products. The rationale for the inclusion of a device in the list is also currently vague; it is not clear how a manufacturer could realistically prove that a device can never be re-used.

A decision on whether a device is single-use or not can be challenged, leading to an endless cycle of discussion and an unpredictable situation. Such a process may also cause confusion amongst healthcare professionals on whether they can re-use a device or not and delay innovative medical devices reaching patients while awaiting an unethical and unnecessary decision on its 'reprocessability'.

- **The creation of 'Europe-only' rules and extra costs for SMEs.** All medical devices, currently labelled as 'single-use' and not included on the Commission's list of 'single-use' devices, will be required to be re-labelled, according to the Parliament. The proposal would imply that products specified as 'single-use' in other jurisdictions such as the United States, Canada and Japan, would be re-labelled as 'reusable' in Europe. This proposal isolates Europe both from a patient safety and trade perspective, impacting an industry mainly dominated by small and medium-sized companies (SMEs, around 95%) of which many are based in Europe. It will add enormous bureaucracy and costs for companies attempting to compete in global markets.

The costs and additional administrative burden for this proposed procedure are anticipated to be excessive. In particular, asking a manufacturer, and in particular an SME, to demonstrate that their device cannot ever be reprocessed somewhere, somehow by someone will present manufacturer's with a practicably impossible task both scientifically and economically to complete. Furthermore, if some entity does determine how to reprocess a manufacturer's single-use device, the original manufacturer is then under the obligation to stop marketing their device until they have carried out a series of tests. Thereafter they must also provide evidence on how many times and under which conditions the currently single-use and later reusable device can be reprocessed, as well as the associated patient safety implications.

- **A lack of clarity on the roles of manufacturers and reprocessors.** The responsibilities of the manufacturer and reprocessor are not clear in the current Parliament position. The reprocessor has to comply with all requirements except the 'conformity assessment'⁵ requirements (even for high-risk 'class III' devices). There is no procedure to assess whether the reprocessing process guarantees the required level of cleanliness and sterility or whether the reprocessed device can deliver the same performances as the original device. This is unacceptable: quality must be consistent for both new and reprocessed devices.

Clarity is also required as to who will be liable after reprocessing, i.e. references to the original manufacturer on the reprocessed device could cause issues related to liability.

- **Standardisation is not feasible.** The European Parliament proposes that the Commission create international standards on 'good reprocessing practice'. But due to the huge range and complexity of medical devices and users, this appears to be unrealistic: thousands of standards would need to be created to cover all devices in all healthcare settings, in order to ensure high levels of safety. A generic guide to good reprocessing procedures would be insufficient to guarantee the validation of the procedure required for each product.

⁵ Conformity assessment means the activity/steps necessary to show that your device meets the relevant safety and performance requirements.

Annex: the reinforced control procedure in detail

Overall Approach: **Oversight by MDCG and Commission of the Notified Bodies and the Conformity Assessment System for all new class III medical devices⁶ and introduction of an EU level Register of Clinical Experts**

Three elements:

1. **Reinforced control of Notified Bodies** to ensure they are doing a good and consistent job
2. Systematically ensuring a **high quality and independent clinical review** by creating a new EU level Register of Clinical Experts, controlled by MDCG and Commission, and vetted by Authorities available to notified bodies
3. Proper process for **development of Common Technical Specifications and European Guidelines** to ensure continued evolution and a sustained high level of safety and enhanced involvement of MDCG and experts into the **Harmonised Standards and International Cooperation** processes

	Position: Reinforced Control Procedure	How to do this
1	Reinforced control of Notified Bodies to ensure they are doing a good and consistent job	Combination of Regulation (EU) No 920/2013 and European Parliament’s ‘Special Notified Body’ Approach – But ‘Specialised Notified Bodies’ not ‘Special’
	a) More rigorous criteria for class III Notified Body designation and monitoring	i. Use MDCG (upgraded NBOG) plus Commission for designation and monitoring of notified bodies as per Regulation (EU) No 920/2013

⁶ As per EP proposal new Article 44a para.1, focus is on new applications for class III devices includes: device/drug combinations and devices manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives with exception, of renewal applications, supplement applications and applications for devices where CTS or Harmonised Standards cover the clinical evaluation and the post-market clinical follow-up;

Broadens the scope of devices covered from the EP proposal in that all class III (the highest risk class) are covered not just class III implantable and removes the EPs proposal to include class IIb devices that administer or remove medicines as they are lesser in risk classification but do fall into the new enhanced SNBs as per the EP proposal new Article 43a

	Position: Reinforced Control Procedure	How to do this
	b) Encourage further specialization of class III Notified Bodies c) Undertake more regular audits of class III Notified Bodies	ii. Add EP's concept of 'Special Notified Bodies' (SNB) But not 'Special' rather 'Specialised Notified Bodies' through their competence = more rigorous 'competence-specific' criteria and more frequent checking by MDCG and Commission for NBs that assess class III devices; iii. Add to this specific tasks for MDCG to audit the competence of internal clinical and technical experts, including the SNB's system for assessing internal clinical competence, and the SNB's system for selecting external registered clinical experts iv. Full transparency: Commission and MDCG informed by SNB of all new class III device applications v. MDCG and Commission can audit the SNB at any time
2	Systematically ensuring a high quality and independent clinical review by creating a new EU level Register of Clinical Experts, controlled by MDCG and Commission, and vetted by Authorities available to notified bodies	New EU panel of clinical experts, placed on a register by authorities, and available to NBs who scrutinise clinical evidence in class III device submissions
	a) MDCG to vet and maintain a list of registered clinical experts	i. Create a panel of clinical experts across 21 therapy groups (groups as per EP Proposal) ii. Experts are proposed to the panel by Member States; Commission sets criteria for nominations iii. MDCG and Commission vet and approve nominations iv. Commission manages and publicly publishes the list of registered clinical experts and conflict of interest statements v. MDCG ensures that experts are replaced when some expert resigns; Commission to define a qualification process for this in collaboration with MDCG and Special NB (SNB) vi. Number of specialists per specialty is as needs dictate
	b) Where the file needs external clinical expertise Notified Bodies to engage only clinical experts from the register	i. For all new applications for class III devices SNB notifies MDCG and Commission of the device application ii. SNB applies system for assessing internal clinical

	Position: Reinforced Control Procedure	How to do this
		<p>competence and, if external expertise is needed beyond their own internal clinical experts, so selects an expert from the list based on 1) relevant therapy field, 2) expertise, 3) availability), 4) Any Competition or IP conflicts</p> <p>iii. SNB informs Commission and MDCG and company of all experts to be involved in the review</p> <p>iv. Where chosen, the external expert now co-reviews the clinical elements of the file with the SNBs clinical and technical experts</p> <p>v. If and when the approval (or refusal) decision is made the SNB informs the Commission and MDCG of the decision and enters the details into Eudamed</p>
	<p>c) Early pre-submission advisory meetings are recommended (promotes increased safety, improved quality of submissions, efficiency for system and especially helpful for start-ups and SMEs)</p>	<p>i. Company with new class III devices (as defined in the scope above) can present their regulatory and clinical strategy to SNB, early in the design process, and can confirm agreement to work with this SNB for this product (early discussions on manufacturer's risk management plan)</p> <p>ii. This allows SNB to select a vetted expert early and an advisory meeting can be held between company, SNB and the expert on the manufacturer's development plan including draft clinical plans and any interim results and reports prior to submission.</p>
3	<p>Proper process for development of Common Technical Specifications and European Guidelines to ensure continued evolution and a sustained high level of safety and enhanced involvement of MDCG and experts into the Harmonised Standards and International Cooperation processes</p>	<p>Give MDCG real management powers over the safety standards within the system and in particular playing an active role in the development of safety and performance specifications and guidelines</p>
	<p>Defined process for National Authorities and the Commission, together with stakeholders, to actively manage and update safety standards</p>	<p>i. Based on information from managing the system – New device applications, Vigilance, Post-market Surveillance, SNB and SNB monitoring, MDCG working groups, MDAG input, international regulatory cooperation, harmonised standards and emerging Public Health Concerns – a fundamental and specified task of the MDCG and the Commission should be to create or update as needed any required Common Technical Specifications and European</p>

	Position: Reinforced Control Procedure	How to do this
		<p>Guidelines to ensure continued evolution and a sustained high level of safety.</p> <ul style="list-style-type: none"> ii. In the case of work at the Harmonised standards, International Standards or international regulatory cooperation levels, the MDCG should be free to nominate one of its experts or an expert from the list of registered clinical expert to act as a rapporteur to ensure MDCGs issues are addressed and to regularly inform the MDCG, Commission and MDAG; This activity should be coordinated and funded by the Commission. The Commission may also nominate one of its staff to follow work at the Harmonised standards, International Standards or international regulatory cooperation levels, iii. This should follow a defined process and work programme and be carried out in cooperation with the MDAG. This work should be transparent to the public via the Commission's web-site.

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 575,000 highly skilled workers. The market size is estimated at roughly € 100 billion while around 8% of sales revenue is ploughed back into research and development. The industry encompasses approximately 500,000 different medical technologies from sticking plasters and wheelchairs 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.

For more information visit www.eucomed.org