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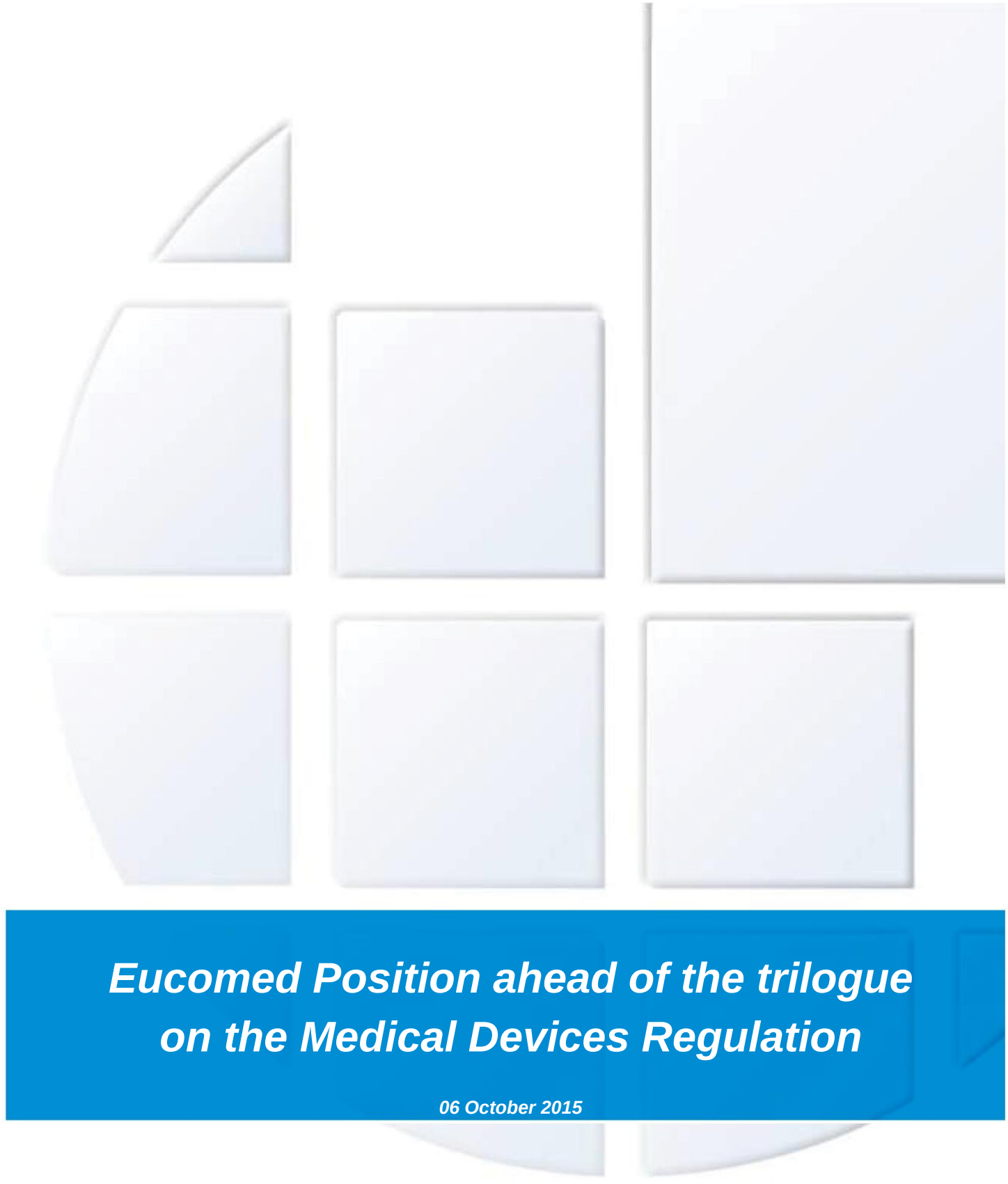

Eucomed Position ahead of the trilogue on the Medical Devices Regulation

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Contents

Executive Summary

Eucomed, the voice of the European medical devices industry, supports the European Commission's proposal of September 2012 to revise the EU regulatory system to ensure a high level of human health and safety, while adapting to the rapid technological and scientific innovative progress that is a defining characteristic of the medical technology sector.

With the adoption of the European Parliament's position in April 2014 and the Council's General Approach of October 2015, Eucomed welcomes the fact that the file is moving forward and that 'Trilogue' negotiations can now begin with a view to adoption of a new Regulation early in 2016.

Eucomed notes a number of areas that still raise concern, many of which were mirrored most recently in the June 2015 Council meeting. Thus the text still warrants further work to fully meet the policy objectives and to be clear, applicable and feasible. To have a successful Regulation, Eucomed encourages policy makers in the trilogue – Commission, European Parliament and Council – to take a critical view of the three texts before them, and ask a simple question of each provision:

"Will each new measure:

1. ***See a real increase in patient safety;***
2. ***Help rather than hinder needed innovation for patients;***
3. ***Avoid unnecessary complexity for SMEs and Regulators?"***

Such an approach will help ensure that every proposed measure consistently meets the two overarching objectives of the Regulation, namely to increase patient safety and to foster innovation in medical technology in Europe, thus bolstering both people and jobs as a dynamic part of the European economy.

Eucomed believes that the following **five areas merit particular attention** and must be addressed:

1. **The 'Scrutiny' mechanism**
   Redundant with other improvements, but if there, at least make it workable and predictable

2. **Clinical evidence**
   Maintain the Commission's and a much simplified Council case-by-case approach and get the definitions of clinical data and clinical equivalence scientifically sound

3. **Re-use of single-use medical devices**
   Ensure a single high harmonised level of safety across the EU as per Commission proposal with hospitals and subcontractors appropriately covered

4. **Hazardous substances**
   Support the feasible, scientific and proportionate approach of the Commission

5. **Unnecessary added complexity and disproportionate measures**
   Strip out unfeasible, disproportionate or duplicative requirements and reverse unjustified re-classifications

1. The 'Scrutiny' mechanism

Eucomed believes that the 'Scrutiny' mechanism is redundant with other improved measures which are already in place. However, if the mechanism is maintained, it must be made, at the very least, workable and predictable

The scrutiny process was proposed by the Commission as an additional control mechanism to improve the overall quality of Notified Bodies. The mechanism is intended to be an exception rather than the rule and follow clear and transparent criteria.

Critical points

1. **The 'Scrutiny' mechanism is a duplicative assessment system with no safety gain**
2. **It delays needed innovation to patients**
3. **The 'Scrutiny' process is redundant with other improvements**, e.g. increased control on Notified Bodies by the new Committee of Member State Authorities (MDCG) and the Commission and tighter vigilance, **thus it can safely be dropped**

Our proposal

Delete the scrutiny mechanism as it duplicates other more effective measures and will not provide in itself any incremental gain in safety.

If Scrutiny mechanism maintained by trilogue

In case the trilogue negotiations decide to retain a form of scrutiny, despite the point above, then industry recommends building on the **Council's approach (Scope, focus on clinical, timing**) improved with:

a) Maximum predictability & legal certainty e.g. be exceptional based on **clear selection criteria, clear simple process flow and right of appeal**

b) **Complete logical exclusions by including harmonised standards, as per the European Parliament's proposal**

c) **A provision to review scrutiny usefulness** in 5 years (Sunset Clause)

d) **An obligation to the panel to work in parallel and not after the Notified Body** as per the Council's proposal

e) **An incentive for the early scientific advice process** (e.g.; where followed would mean exclusion from scrutiny)

f) **The addition of an implementing act for efficient governance of the expert panel**

What is the impact?

- Maximum predictability ensures that the system will actually work in practice
- Predictability also gives certainty and clarity to medical technology innovators – SMEs are the innovation engine of the medical devices sector and account for 95% of companies – and the investment community on whom they depend for funding
- The Council scope focuses scrutiny's special controls to those devices that are of most public health concern: class III implantable devices
- Other high risk classes and implants are subject to the improved controls of the new Regulation
- Given that in five years all Notified Bodies will have been re-notified to the new stricter requirements and that relevant Common Specifications and Harmonised Standards will have been identified, the need for scrutiny should be reviewed

2. Clinical evidence

Clinical evidence includes all the relevant clinical information on the safety and performance of a particular medical device (pre-clinical studies, clinical literature, clinical investigations). This information is generated, analysed and summarized in a part of the safety dossier, called the clinical evaluation report, updated throughout the lifetime of a device.

Eucomed supports the Commission and Council case-by-case approach and recommends getting the definitions of clinical data and clinical equivalence scientifically sound.

Critical points

1. The Commission and Council texts are more technology neutral and thus allow the requirements to apply across all technologies with checks being carried out by the notified body
2. The Council text introduces additional unnecessary complexity and can be simplified
3. The Council approach incentivises the creation of Common Specifications as a concrete way of setting a harmonised high level of safety and performance (as is the case today in the in-vitro diagnostic legislation where Common Technical Specifications, CTS, have been in use since 1998)
4. The Council's definition of Clinical Data is flawed. By referring to published and peer reviewed data it artificially excludes a vast amount of valid and available data e.g. registry data, which are not generally published in peer reviewed journals
5. All three texts fail to define use of the clinical equivalence principle in a scientifically sound way by artificially excluding many sources of valid and verifiable clinical data

Our proposal

a) **Build on the Commission and Council approach by keeping** a **case-by-case** review of clinical evaluation instead of an inappropriate one-size-fits-all approach (e.g. through the use of Common Specifications, CS)

b) **Revert to the Commission definition of clinical data** to include all relevant clinical data

c) **Define use of clinical equivalence principle in a scientifically sound way by including all sources of valid and verifiable clinical data**

d) Incentivise EU innovation by **ensuring clear and appropriate IP and Know-how protection:** follow the Commission/Council approach

e) Rationalise and **simplify complex processes,** especially within Council approach

f) Be 'design neutral' to **include all valid study designs**, not just RCTs

g) **Appropriate alignment** with clinical trials legislation as per Commission approach

What is the impact?

- To ensure that sufficient clinical data for all and especially high risk class products exist, the unscientific restrictions on the definition of clinical data and to the use of valid clinical data in the case of implantable and class III devices should be removed
- The narrowing of the definition of clinical data and clinical equivalence principle has negative unintended consequences:
    - The risk of requiring patients to undergo unnecessary clinical trials is unethical and in contradiction to the Declaration of Helsinki. Technologies such as sutures, screws and pins have been on the market for more than 50 years, and, subsequently, no longer require a clinical question to be answered
    - Researchers and Scientists will not do these trials as they are not 'new', or not scientifically 'interesting' or cover well understood technologies
- Exorbitant costs: even if the trials could be done they would not be financed. The number of devices covered would be in the 10s of 1000s meaning costs in the 100s of millions if not billions of Euros – when no other market, even the US market are looking for this data either pre or post market.

3. Re-use of single-use medical devices

Some medical devices are 'reusable' having been designed to be 'reprocessed' for re-use. Examples 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. Examples include syringes, catheters, blood bags, and implants. Across the EU, governments are divided. A few Member States permit the 'reprocessing' of single-use devices in their health systems as they see a public health need, yet others ban the practice on grounds of public health protection.

Eucomed supports a single high harmonised level of safety across the EU as per the Commission proposal, with hospitals and subcontractors appropriately covered.

Critical points

1. The Commission proposal treats the manufacturer and "reprocessor" as one and the same to ensure a harmonised high level of safety across Europe

2. The Council follows the Commission lines and adds recognition that the default across Europe should be a ban

3. The Council approach differs significantly from the Commission in that it further allows Member States who do want to reprocess to set up national rules. This approach allows Member States to decide not to apply certain rules and to create different non-harmonised rules for hospitals and sub-contracted commercial reprocessors working on behalf of hospitals

4. Furthermore, across all three texts, the Commission, Parliament and Council, there is a general approach of exempting hospitals from following all harmonised rules when reprocessing single-use devices e.g. harmonised safety and vigilance measures

Our Proposal

a) **Eucomed calls for a single harmonised high level of safety across the EU by reverting** to the **Commission Proposal,** with **hospitals and subcontractors appropriately covered**

b) Include the European Parliament's **Report** and the possibility for setting out **detailed quality standards**

c) Or, alternately use **Council's proposal without paragraph 1b** and include EP's report and standards as in 2 above

What is the impact?

- Whenever governments decide that devices labelled as single-use, and subsequently implanted or in contact with blood or other body fluids of a first person, can then be reprocessed and re-used on another human being, then they must ensure that both the first, second and even successive patients receive the same high level of safety
- De facto, the Council's approach creates 3 different levels of safety standards for the patients for the same device in a country, depending on whether the product is original, commercially reprocessed or reprocessed by a hospital (for which again these rules can differ from country to country)
- Moreover, these different levels of safety are not made apparent or transparent to the patient
- Hospitals need to be included. Hospitals are the primary re-user and hence biggest potential reprocessor of single use devices. Controls across Europe on hospitals that reprocess single-use devices should be clear on how reprocessing performed by them will be carried out to the same high harmonised EU safety rules

4. Hazardous substances

A hazardous substance is a substance that has been classified as such based on criteria outlined in existing EU legislation (Regulation (EC) No 1272/2008). 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 and 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.

Eucomed supports the feasible, scientific and proportionate approach proposed by the Commission.

Critical points

1. The Commission has proposed that where risk of exposure is present, control of that risk must be demonstrated and specific information must be provided to users (in the form of labelling) in the case of phthalates

2. The European Parliament introduces a de facto ban on the use of substances classified as Carcinogenic, Mutagenic or toxic to Reproduction and substances that are Endocrine disrupters; there is a provision to allow 4-year renewable derogations for continued use

3. The Council has expanded the labelling requirements from applying to phthalates (which are already subject to labelling requirements), to covering the full list of hazardous substances classified as Carcinogenic, Mutagenic or toxic to Reproduction (CMR 1A or 1B) – potentially thousands of substances – based on their intrinsic properties, irrespective of any risk for patients or users of medical devices

4. These approaches disregard the Commission's risk based approach, as it considers only hazard and not the risk of exposure to that hazard. The fact that a device contains a substance which is classified as hazardous certainly does not mean that the device becomes dangerous

5. The Council approach reduces the effectiveness of the labels, as they no longer communicate anything about the existing or even potential risks of a device. It would result in an unnecessarily bureaucratic burden to industry

6. Moreover, the classification of substances is constantly changing; hence labels would need to be regularly modified. This would represent a major expense for this requirement alone for the medical technology industry

Our Proposal

Maintain the Commission Proposal which allows for a practical benefit/risk management system for the use of hazardous substances.

What is the impact?

- Before placing a product on the market, manufacturers must demonstrate that their clinical data supports a positive benefit/risk assessment for the use of the hazardous substance, and when such substances are present must meet specific labelling and justification requirements. Outside this regulatory framework, there are also efforts underway across the medical device industry, to evaluate the effectiveness of the use of alternative substances
- The Council approach respects this principle but goes too far - what if there is no exposure, or exposure below allowed limits, then there is no danger and it is misleading to label as such
- The number of substances that pose no risk but yet would need to be on the label could be several thousand – leading to meaningless information being given to patients and users and crowding out the 'real' information on risks
- The European Parliament approach brings with it an unnecessarily bureaucratic derogation and renewal process, for example even where, as is often the case in such a diverse industry, there is no new scientific information to report. As many thousands of devices will have no new information in any given year, and that there are nearly 25,000 SMEs making these devices, this sets a disproportionate and unnecessary bureaucratic burden and high costs to SMEs for no safety gain

5. Unnecessary added complexity and disproportionate measures

A great deal of additional changes have been made to the text since the Commission proposal, in particular the Council has added a significant amount of new text and new requirements including administrative requirements.

As the text was already large and highly technical from the Commission, these additional changes should be gone through by the Council Secretariat, the European Parliament with the help of the Commission to strip out any unnecessary, unfeasible or duplicative requirements.

Eucomed believes that unfeasible, disproportionate or duplicative requirements should be removed and unjustified re-classifications reversed.

Critical points

1. The Commission and Council text come with several disproportionate changes in the classification system without any justification

2. The text being considered disregards the current system of broad interested party discussion and consultation through the Commission's Medical Devices Experts Group (MDEG), a much needed platform for regulators, stakeholders and the Commission to discuss issues related to the implementation of the regulatory framework

3. The 'derogation' in Council's Article 42.3 de facto equates the assessment process for class IIb implantable devices to that of class III devices

4. Well-established and recognized technologies, already on the market and in safe clinical use for over 5, 10 and even longer years, are treated as if they are 'new' in terms of assessment and renewal requirements for CE marking

5. The text and provisions foreseen have significantly evolved since the Commission's original proposal in 2012, with many changes brought during the three years that the text was discussed in Council ranging from the functionality of the Eudamed database to additional requirements for clinical evaluation and investigations

Our Proposal

a) **Reverse 'unjustified' and unassessed reclassifications**

b) **Keep European Parliament's Stakeholder Committee** (MDAC)

c) **Keep Commission's proportionate conformity assessment processes** e.g. for class IIb implantable devices

d) **Simplify and eliminate unnecessary complexity across many processes** e.g. how current clinical data fits into the new Regulation, certificate renewal processes, implant card, Single EU database, Vigilance, ensure Unique Device Identification (UDI) synchronised with global approach, Labelling and Registration; rules for economic operators; tasks of the new Authorities group

e) Increased complexity over the Commission proposal merits a **new impact assessment before adoption** especially focussed on feasibility, transition timing and the prioritisation of the many delegated and implementing acts (>50) needed prior to implementation

What is the impact?

- **Reclassifications**: As the proposal is currently worded, a number of categories of devices have been up-classified into higher risk classes. The rules of the current classification system and in the future Regulation allow changes to classification via comitology with a threshold that requires all reclassifications to be duly justified. No such justification has been presented for the changes proposed by the Commission. The Council adds further changes in classification also without due justification

- Thus many device categories with a low risk profile and with no history of safety issues, regardless of their long established and safe use in clinical practice, would automatically, and without any transparent or reasoned justification, be placed into higher risk classes. 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

- This would be against 'better regulation', risks excessive burden to many SMEs and would put Europe further out of line with the globally accepted classification system. All re-classifications should be reversed unless duly justified

- **Stakeholder Committee:** The current level of dialogue that allows stakeholders (e.g. patients, healthcare professionals and industry) to communicate with Regulators and the Commission on issues of mutual importance must be maintained to foster exchange of information and transparency

- **Proportionate Conformity Assessment Processes:** Council's derogation in the class IIb implantable assessment approach de facto treats class IIb implantable devices as if they are class III.

This is despite the fact that the class III assessment system is reserved and specifically designed to fit only those devices that are classified as 'critical' in terms of public health risk, counted in their hundreds. It is not designed to cater for the many thousands of class IIb devices. Class IIb devices are also classified according to their public health risk and have their own specific assessment system which includes design checks appropriate to the public health risk and the many thousands of device types.

It also ignores the built-in adjustment system in the current and new rules that allows Authorities to move products from one class to another in reaction to changing information on public health concerns.

There is also a cost difference. Class III assessments can cost five to ten times as much as a class IIb device and depending on the interpretation of categories or groups of device types; could cost even more.

Council's derogation overly complicates the process for products that are safely on the market and will ultimately clog up the system with thousands of disproportionate assessments, result in a potentially insurmountable cost burden to many SMEs and risk loss of safe and clinically established devices to the health system.

- **Simplify and eliminate unnecessary complexity:** Many examples of unnecessary complexity exist, especially in the Council text, and deserve to be simplified as part of the trilogue process.

  For example, well-established and recognized technologies, already on the market and in safe clinical use for over 5, 10 and even longer years, are treated as if they are 'new' in terms of assessment and renewal requirements for CE marking

- This approach triggers serious consequences, most notably at the time of the 'new' assessment or renewal under the new Regulation. This is because the Commission's restriction of the clinical equivalence principle and the change in clinical investigation requirements for class IIb implantable and class III devices and, in addition, Council's redefinition of what constitutes 'clinical data' creates a discontinuity in the continuous activity of data collection. This discontinuity would bind patients, doctors, manufacturers, notified bodies and health authorities to seeking unfeasible or unethical clinical investigations while all the time ignoring far more relevant real-life clinical use data

- This risks patients, physicians losing safe technologies used for years in clinical practice by missing out on recognising valid real-life clinical data

- To ensure continuity and avoid sudden loss of well-established and recognized technologies to the healthcare system, either the clinical requirements should be scientifically defined or at least an efficient measure or protocol should be inserted that recognises valid and useful real-life data in the assessment and renewal processes of the new Regulation

- **Impact Assessment:** for the new Regulation to be fully implementable, a thorough assessment of the impact of the additional requirements should be conducted, including the feasibility of the over 50 delegated and implementing acts, foreseen in the Regulation, being enacted in time.

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 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.

For more information visit www.eucomed.org