Eucomed
Medical Technology

POSITION PAPER
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A new EU regulatory framework for medical devices

Six steps guaranteeing rapid access to safe medical technology while safeguarding innovation

SMART AND EFFICIENT LEGISLATION

"The EU regulatory framework on medical devices has brought about positive results over the last 20 years. Our system supports innovation in the field of medical technology, allows rapid access of new devices to the market; and is cost-efficient."[i]

"In revising our regulatory system, we want to keep the positive aspects whilst remedying identified weaknesses and addressing future challenges."[ii]

John Dalli, European Commissioner for Health and Consumer Policy (Autumn 2011)

A new regulatory framework for medical devices

The European regulatory system for market access of medical devices is currently under revision. It affects Directives 93/42/EEC; 90/385/EEC; and 98/79/EC.

To face the grand challenges in health such as healthy ageing, constrained health budgets, fewer carers and fewer tax-payers, Europe will need to look at shaping new models of healthcare delivery. Ensuring quality and financial sustainability should be key features of the model. In this context the European Commission and national governments will need to deliver policies which promote the necessary innovation and changes in healthcare systems. Value-based innovation[iii] in medical devices and services, which marries cost-efficiency with improved health outcomes, is an essential part of the solution to public health challenges as well as to the broader challenges to Europe's competitiveness.

Eucomed, the European medical technology industry association, recognises the need to modernise and strengthen the current medical devices legislation in Europe, in particular, by coupling more enhanced Member State engagement with better European science-based coordination and management of the regulatory system. The objective should be to achieve a smart and efficient legislative framework that is consistently implemented across the EU and guarantees patient safety, high quality and rapid access to the latest medical technologies. This legislative framework should at the same time encourage research and innovation and reduce administrative burden, in particular for SMEs, which are the backbone of the medical technology sector.

A smart and efficient legal framework for medical devices should:

1. **be robust and comprehensive, and effectively protect public health, enable efficient healthcare delivery and enhance public confidence without adding unnecessary bureaucracy;**
2. **provide effective coordination and implementation, a proper legal basis, and greater predictability;**
3. **be efficient for all affected stakeholders, and provide sustainable and adaptable solutions to address future needs and challenges at national, European, and international levels;**
4. **be consistent, transparent and driven by science-based decision making and implementation;**
5. **ensure appropriate involvement of stakeholders;**
6. **effectively foster and support innovation.**

Towards a 'smart' regulatory framework

'Smart regulation' is *"...regulation that protects the consumer, delivers effectively on public policy objectives without strangling economic operators such as SMEs..."*[iv]

Political Guidelines for the next Commission, José Manuel Barroso, President of the European Commission (September 2009)

Medical technology and services, including a large and highly skilled workforce, play a crucial role in keeping the European population healthy and productive through delivering innovation into healthcare, while also contributing to the European knowledge-based economy. The MedTech sector's ability to continue the delivery of safe and efficient life-enhancing medical care for patients and consumers is based on its strong and immense innovative capacity, which is, in turn, dependent on the existence of an appropriate and smart EU-wide legal framework, designed to boost innovation and allow for patient access to the best quality healthcare. The ability to innovate is critical for the medical technology industry in Europe to remain competitive and continue to bring valuable contributions to efficient and high-quality healthcare delivery.

The renewed framework should provide for a consistent, EU-wide regulatory approach, through improved coordination, evaluation and certification of medical devices; consistent and comprehensive implementation across all EU Member States as well as efficient vigilance and post-market surveillance systems. We need smart regulation that makes efficient and effective use of existing resources and involved structures (European Commission, national Competent Authorities, Notified Bodies and the industry) so as to retain a simple, adaptable and highly efficient system.

We outline in this position paper our proposals for shaping a renewed legislative framework for medical devices in Europe.

Six steps to a smarter legal framework for medical devices:

1. ONLY THE BEST NOTIFIED BODIES

In order for medical devices to access the market and reach patients and users, and to ensure that the product is safe and performing as designed, manufacturers must accomplish a conformity assessment and – with the exception of low risk class I devices – undergo an inspection and certification procedure carried out by Notified Bodies. Notified Bodies are independent third parties nominated and monitored by Member States' authorities. They carry out pre- and post-market conformity assessment and certification of medical devices based on the requirements of the EU Directives. The approach of Members State control and oversight of Notified Bodies has been a success not only in terms of ensuring safety, where evidence shows it to be equivalent to the US system, but also in terms of allowing for rapid access for patients and healthcare professionals to the latest innovations for healthcare. The European approach has been recognised as a leading system and is being copied internationally as it also represents an effective and efficient use of government resources and tax-payers' money.

However, time has shown that crucial areas of the Notified Body approach show signs of weakness. As structured today, the control and oversight by National Authorities of their Notified Bodies depends largely on voluntary and national approaches rather than on consistent, mandatory EU level rules and standards. This has led to questions of transparency, trust and legal certainty.

In order to continue to guarantee a consistent approach to the quality of the work carried out by Notified Bodies as well as a high level of safety across the EU, a complete series of control and monitoring measures are needed:

1. **Precise and mandatory requirements for the designation of Notified Bodies;**
2. **EU-wide mandatory accreditation standards for Notified Bodies, which include standards for competence, training, staffing, transparency and expertise of Notified Bodies;**
3. **Precise, binding, transparent measures for Competent Authorities to control and monitor the activities and performance of Notified Bodies;**
4. **Audits of Notified Bodies by joint teams composed of different national Competent Authorities and the European Commission;**
5. **EU-level oversight of the way Member States designate and monitor their Notified Bodies.**

2. ONE APPROACH TO VIGILANCE AND MARKET SURVEILLANCE

The current regulatory framework for medical devices foresees that once a medical device is placed on the market, vigilance and market surveillance systems have to be put in place by manufacturers and national Competent Authorities. They allow for rapid identification and response in case of incidents which may put at risk patients' or users' safety or the product performance.

However, there is a severe lack of coordinated exchange of information on reported incidents as well as considerable variations in terms of responses to incidents across different EU Member States. This has resulted in duplication of efforts and potentially increased inequalities in the level of health protection across the EU.

A better defined legal framework on vigilance and greater harmonisation of Member States' market surveillance activities are needed to ensure rapid and consistent EU-wide risk identification and response. This would deliver significant benefits for overall patient safety.

An effective system to ensure a rapid and consistent EU-wide risk identification and response would require:

1. **A better defined legal framework on vigilance and greater harmonisation of Member States' market surveillance activities.**

2. **A centralised reporting and surveillance system, based on an EU portal for reporting of key data and situation assessment by Member States and the European Commission. Key features of this EU portal would include:**

    - **the possibility to exchange information and facilitate timely cooperation between all the stakeholders involved (i.e. European Commission, national surveillance authorities, customs authorities and distributors);**
    - **appropriate security and data protection measures;**
    - **the use of sound, independent scientific advice from the Commission's Joint Research Centre (JRC) – see also section 6;**
    - **the ability to report relevant information, including data on the products, identified risks, risk analysis, resulting measures and relevant best practices.**

3. **Existing and past experiences, such as the EUDAMED[v] database and the ECCAIRS model[vi] should be considered as useful examples to build up a reliable reporting and surveillance system for medical devices.**

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3. STRENGTHENED HARMONISED STANDARDS

The EU Medical Device Directives set out a series of requirements - called 'Essential Requirements'- covering the safe design of medical devices, including clinical investigation, construction and performance. Manufacturers must ensure that, prior to placing a medical device in the market, they have the complete evidence on file that the product meets the relevant essential requirements which prove its safety and performance.

Following a common approach in all major medical devices legislation (e.g. in US and Japan), and in order to facilitate innovation and ensure 'state-of-the-art' in terms of safety, these essential requirements are in turn underpinned by a whole series of 'Harmonised Standards' for medical devices. Mandated by the European Commission and adopted by the Member States, these 'Harmonised Standards' establish the precise technical specifications that a product must meet in order to fulfil the essential requirements. Manufacturers' compliance with both essential requirements and their correlated harmonised standards are then assessed by Notified Bodies, on a continuous basis, and by the national Competent Authorities, through their market surveillance activities.

Increasingly, due to the global nature of the medical technology sector, harmonised standards are being developed jointly by regulators, industry, academia and other stakeholders at the international level. However, the overall level of participation of Europe's national Competent Authorities at this international level has fallen behind and now seriously trails that of other regions' regulators, such as the FDA. This has resulted in international standards which do not fully reflect European regulator's needs and objectives. Consequently, Competent Authorities face problems when trying to align the text of the international standard to the corresponding European essential requirement. This may eventually result in increased confusion and legal uncertainty for both market operators and Notified Bodies and Competent Authorities and could be prevented by further engaging Competent Authorities at the drafting stage and early dialogue at international level.

EU harmonised standards, developed jointly by regulators, industry, academia and other stakeholders, should continue to prevail as a core vehicle to ensure the safety and performance of medical devices. This points to the need to re-position Europe's Competent Authorities at the forefront of international safety standards in medical technology.

Processes and procedures in the revised framework for mandating and developing medical device standards must incentivise pro-active involvement of Member States in the drafting of those international standards in order to address and advance difficulties over the implementation across the EU.

4. CONSISTENT IMPLEMENTATION OF GUIDELINES

Currently, the European Commission, in consultation with Member States and affected stakeholders, issues guidelines aimed at supporting consistent implementation and interpretation of the Medical Devices Directives which ultimately aids delivery of a uniform high level of safety and functioning of the internal market across the EU.

However, the process leading to development or revision of these guidelines lacks pace and legal certainty. In addition, when finalised and agreed, evidence shows that there are severe disparities in the way and extent to which the guidelines are implemented in the Member States. This has led to significant cross-border variations in terms of quality of conformity assessment procedures, lack of process clarity and predictability for manufacturers and national responses to vigilance. This can lead to differing levels of patient safety and access across Europe.

The inefficiencies in the development and the severe disparities in the implementation of guidelines must be addressed urgently on two fronts:

1. **Revising the current procedure for development of guidelines to:**
    a. **actively involve and commit the Members States to uniform implementation;**
    b. **use clearly defined and transparent drafting procedures including timelines;**
    c. **involve all affected stakeholders;**
    d. **seek independent scientific advice from the Joint Research Centre (JRC) when needed;**
    e. **involve the European Commission to ensure coherence with European law.**

2. **Upgrading the European Commission's current Medical Devices Expert Group (MDEG) from a voluntary committee to a formal Advisory Committee, under the future revised legal framework for medical devices. This committee could then establish and oversee a consistent guidance development process, which effectively supports Members States and industry in key areas such as good design control, risk management plans, new and emerging technologies, post-market clinical follow-up, vigilance, clinical evidence, labeling and decision-making on borderline products and classification.**

5. INCREASED TRANSPARENCY

Generally, the confidentiality requirements under the current Medical Devices Directives are seen by some stakeholders as being too restrictive (e.g. in terms of access to information about products on the market, or the functioning and decision-making of Notified Bodies). This lack of transparency has led to doubts and subsequently decreased levels of public trust in the system and confidence in the CE marking.

The review of the EU legislative framework for medical devices must result in greater overall transparency and access to information for patients, consumers, healthcare professionals and manufacturers as well as for Notified Bodies, national Competent Authorities and the European Commission through increased use of Information and Communication Technology (ICT), in particular the establishment of a single EU database, with appropriate elements available to the public.

This database should ensure appropriate means of personal data protection and include relevant information on:

- **Devices on the market (including unique device identification, UDI)**
- **Registration of economic operators**
- **Vigilance**
- **Market surveillance**
- **Clinical investigation**
- **Notified bodies and enforcement**
- **CE certificates**

6. AN INTEGRATED APPROACH: BETTER COORDINATION AND MANAGEMENT

Today the EU oversight of medical devices is highly decentralised with significant reliance on Member State appointed notified bodies and frequent inspection of manufacturers. This European approach makes it possible to manage what is a highly innovative and diverse industry in terms of products, technologies and services. The decentralised approach is best placed to provide the capacity to efficiently deal with the many applications related to over 500,000 products on the market from over 22,000 medical technology businesses, 80% of which are SMEs. At the same time, this approach avoids bottlenecks and allows for appropriate costs and timescales as well as supporting a high degree of innovation, all of which ultimately benefits patients, healthcare professionals and carers. The decentralised approach, which is the essence of the current system, should remain a basic principle of the future legislative framework for medical devices in order to preserve safety, flexibility and pace.

However, the current system, although generally solid, suffers from disparate national approaches. It needs improved coordination at EU level to ensure uniform application by Member States, especially in the areas of Notified Bodies and vigilance. Furthermore, the current system lacks sound independent policy and scientific advice on medical technology to allow it to make the best policy proposals. These three needed elements, coordination, science and policy advice, can be satisfied via resources from within the Commission by DG SANCO supported by the Commission's Joint Research Centre (JRC).

To strengthen the three crucial components - coordination, science and policy advice - in the regulatory framework for medical devices, the system will require resources from within the Commission by DG SANCO, supported by the Commission's Joint Research Centre (JRC). The JRC can actively play a crucial role in key areas such as:

1. **auditing Notified Bodies to ensure a comparable, high level of quality across the EU;**
2. **coordinating vigilance incident reporting systems[vii];**
3. **more extensive horizon scanning and foresight intelligence on potential health concerns;**
4. **providing expert policy advice in medical technologies to support evidence-based decision making and legislation (expert networks);**
5. **providing scientific advice on medical technologies to Member States, the European Commission and innovators.**

Independent and experienced in the broad range of technologies that reflect the medical device industry, the JRC is the natural partner for DG SANCO and Member States to shape and drive a smart EU legislative framework for medical technologies, which will bring forward safety and innovation in order to face current and future broader healthcare challenges successfully.

CONCLUSION

By improving the current EU regulatory framework for medical devices through the solutions outlined in this paper, Europe would benefit from a smart legal framework that:

1. **is robust and comprehensive and will effectively protect public health, enable efficient healthcare delivery and enhance public confidence without adding unnecessary bureaucracy;**
2. **provides effective coordination and implementation, a proper legal basis, and greater predictability;**
3. **is efficient for all affected stakeholders, and provides sustainable and adaptable solutions to address future needs and challenges at national, European, and international levels;**
4. **is consistent, transparent and driven by science-based decision making and implementation;**
5. **ensures appropriate involvement of stakeholders;**
6. **effectively fosters and supports innovation.**

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.

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[i] Commissioner John Dalli speech on "Responsible innovation for citizens and patients" for the European Institute in Washington, 21 September 2011
[ii] Commissioner John Dalli speech at the Eucomed MedTech Forum: Driving Innovation in European Healthcare, 12 October 2011

[iii] Contract for a Healthy Future – The role of Europe's medical technology industry in steering healthcare systems onto a sustainable path. October 2011. www.reforminghealthcare.eu

[iv] Political guidelines for the next Commission, José Manuel Barroso. 3 September 2009
[v] EUDAMED, http://ec.europa.eu/consumers/sectors/medical-devices/market-surveillance-vigilance/eudamed/
[vi] ECCAIRS, http://ec.europa.eu/dgs/jrc/index.cfm?id=2820&dt_code=HLN&obj_id=673
[vii] JRC is already responsible for similar tasks in the area of transport safety and hosts the European Co-ordination Centre for Aviation Incident Reporting Systems