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Call for Additional Measures in EU Medical Device Legislation Proposal

The European medical technology industry, through its industry association Eucomed, has responded in detail to the European Medical Device Directive proposal. Industry welcomes many of the recommended measures but unanimously agrees that improvements in seven key focal areas are necessary to guarantee the delivery of safe, innovative medical technology that European patients, doctors and healthcare systems need. In particular it recommends a "systematic control procedure" consisting of five critical measures as an alternative to Commission's proposed scrutiny procedure. The systematic control procedure will more effectively achieve the common objective of increased patient safety. The five measures would replace the Commission's proposed scrutiny procedure, which industry finds inappropriate as it is random, ineffective and does not contribute to patient safety.

Industry recognises that the current system needs an overhaul due to increased expectations, technological advances and acknowledges that change is necessary to improve Europe's Medical Device regulatory framework. Incidents such as the PIP breast implant case should never happen again.

Important to note is that European system is known for providing its citizens with timely access to safe technology thanks to the effective decentralised device-specific approval system. Although the system needs to be improved, Europe will continue to need a predictable and effective regulatory system for patients, healthcare professionals, healthcare systems and innovation. Various reports from respected academics and researchers have shown that the European decentralised system makes medical devices available to patients 3-5 years earlier than e.g. in the United States without compromising safety. In addition, the European system forms a significant basis for other national regulatory frameworks around the globe such as Australia and Canada because of its efficiency in providing technologies to patients and doctors while guaranteeing a high level of safety.

The Commission's proposal represents a step in the right direction and many of the recommended measures are welcomed by industry as they: (1) improve patient safety, (2) do not unnecessary delay patient access to medical devices that save or improve lives and (3) do not hamper innovation. However, more improvements are necessary, especially with regards to the controls and monitoring of Notified Bodies – professional organisations that are authorized by national governments to assess the safety of medical devices before allowing them to be made available to patients (pre-market approval).

Industry believes that more stringent control measures on Notified Bodies are necessary to ensure the highest safety of medical technology for patients in Europe. The current proposed measures such as the ability for the European Commission to further specify the regular checks of manufacturers by Notified Bodies are not sufficient. Industry believes that a comprehensive systematic control procedure is necessary that includes measures to ensure that Notified Bodies are meeting the highest quality standards as well as ensuring that the clinical evidence for medical devices is being properly reviewed by independent clinical experts. This systematic control procedure would replace the proposed scrutiny procedure (article 44), which is essentially a duplication of reviews and checks and does not contribute to patient safety.

The proposed scrutiny procedure is inappropriate because it is a random sampling process of certain medical devices and the timing of the scrutiny occurs very late in the approval process - after the Notified Body has finished its assessment. The proposed measure creates a false sense of security and is essentially ineffective and inappropriate.

"The proposed scrutiny procedure is a 'needle-in-a-haystack' approach which should be replaced by a systematic procedure that prevents 'the needle' to land in the haystack in the first place. Only then will we successfully increase patient safety and prevent unnecessary delays of medical devices reaching patients. We suggest a systematic control procedure that makes sure we increase the safety of all medical devices, which is in the end the collective objective of all stakeholders. We look forward to continue our discussions with policymakers and other parties and are confident that patients in Europe will be the winner in the end" says Serge Bernasconi, Chief Executive Officer of Eucomed.

Besides the monitoring and control on Notified Bodies, industry suggests improvements on seven key focal areas and ten additional topics. The details can be found in the position paper “Towards a regulation that guarantees patient safety, ensures patient access and keeps innovation in Europe”. In summary the seven key focal areas are:

1. Only the best Notified Bodies should be allowed to approve medical devices to the market in order to ensure that the backbone of Europe’s decentralised system meets the highest safety and quality standards.
2. A systematic control procedure is necessary to improve the system and increase patient safety. The proposed ‘Commission scrutiny procedure’ (article 44) is inappropriate because it is not systematic and will not lead to increased patient safety. It should be replaced with a systematic control procedure (that goes beyond the current proposed measures). Only then will we reach the outcome that is desired by all stakeholders: maximum safety for all Europeans without unnecessary delay or duplication of work.
3. Increase stakeholder involvement to ensure that the opinions of essential healthcare actors are heard.
4. Greater transparency and traceability is critical to ensure that patients, doctors, industry and other stakeholders have access to clear information about the medical devices they use.
5. Clinical evidence needs more clarity as clear, appropriate requirements for clinical evidence are paramount to demonstrate that devices perform well and are safe for patients when used by a well-trained healthcare professional and as intended by the manufacturer.
6. Enhance vigilance and market surveillance to allow for rapid identification of adverse events and to ensure coherent and timely action by Member States.
7. Clear science based classifications are needed to avoid the currently proposed arbitrary reclassification of families of medical devices without any scientific or other justification, which will lead to global confusion. Clear and science based procedures must be followed to ensure that devices are appropriately classified.

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

- Scope
- Governance
- Economic operators
- Funding
- Reprocessing
- Transition periods
- Standards, guidelines and specifications
- Hazardous substances
- Early scientific advice
- Delegated and implementing acts

Eucomed’s position paper and detailed position per issue is available in a series of fact sheets available on www.eucomed.org/key-themes/medical-devices-directives.

Published on : Fri, 1 Feb 2013