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Europe Reaches Agreement on Medical Devices

Following the May 25th trilogue meeting Council and European Parliament reached political agreement on the medical devices and in vitro diagnostic medical devices regulation.
MedTech Europe, the alliance of Eucomed and EDMA, are pleased to hear that a political agreement has been reached on the new regulations.

The two regulations on medical devices and in vitro diagnostics include measures which will have a significant impact on patients, regulators and industry. Serge Bernasconi, CEO of MedTech Europe says “As said before, the medical industry recognises the importance of these updated regulations. The implementation will require substantial resources from all stakeholders, including industry. It is thus essential to keep the overarching goals of patient safety and innovation in mind during the translation into implementable rules”

Announcing the news in a statement, the Council said the new rules are aimed at “making sure that medical devices and in vitro diagnostic medical devices are safe while allowing patients to benefit [from] innovative healthcare solutions in a timely manner.”

The Council said the regulations, which still need to go through a formal approval process, will:

- Increase scrutiny of devices before they enter the market
- Enhance surveillance in the postmarket setting
- Improve availability of clinical data on devices by establishing a central database
- Require devices to have unique identification numbers to allow traceability through the supply chain

It has been a long process and yesterday’s agreement is a significant step towards finalising modern medical devices and in vitro diagnostic legislations that recognises the specific nature of medical technologies, contributes to increased patient safety and fosters the development of innovative healthcare solutions.

Entering the implementation phase, it is critical that the large volume of secondary legislation transfers this complex framework into feasible and implementable rules, whilst avoiding unnecessary bureaucracy for all involved parties. The industry will continue to work together with legislators and other stakeholders to achieve this objective.

At the same time, EDMA and Eucomed will actively support their members by providing the expertise and guidance to transition effectively and smoothly to the new regulations.

MedTech Europe is an alliance of European medical technology industry associations. The Alliance was founded by EDMA, representing the European in vitro diagnostic industry, and Eucomed, representing the European medical devices industry.

Its mission is to make value-based, innovative medical technology available to more people, while supporting the transformation of healthcare systems onto a sustainable path. We promote a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of its stakeholders.

Source: tctmd, EU Business
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Published on : Mon, 30 May 2016