Who Will Win The Battle For Tougher Medical Device Regulations, the European Commission or Device Manufacturers?

GlobalData

Faulty breast implants at risk of bursting, and defective metal-on-metal hip prostheses, both raising grave concerns about patient health and long-term toxicity, have plagued the reputation of the medical device industry over the past year, states a GlobalData healthcare analyst.

26th February 2013 will see the future of medical device regulations in the European Union decided, as device manufacturers and European lawmakers convene at a European Parliament committee meeting.

This meeting will be a big milestone for both sides to find a way to strengthen regulations for receiving CE Mark approval. The need to strengthen existing medical device regulations has been highlighted by major device recalls over the past year, including the recalls of breast implants developed by the French company Poly Implant Prosthese, fabricated from substandard silicone.

Priya Madhavan, MS, GlobalData's Analyst covering Cardiovascular Devices, explains the current regulatory process: “Medical device manufacturers first seek approval of their products in the European Union before making their way into the United States, because the CE Mark approval process is less stringent than the US FDA process, and manufacturers can bring their products to market approximately three years sooner than in the US. Device manufacturers are able to gain profits from selling their products in the EU and countries that recognize CE mark approval much earlier than in the US.

“However, it comes at a cost of potentially endangering the patient’s life if the device malfunctions as a result of not being subjected to a rigorous regulatory approval process.”

Market access for medical devices is regulated through the European Union medical device directives, which have been transposed into national law in each of the EU member states. The legal framework comprises three directives, the medical device directive, the active implantable device directive, and the in-vitro diagnostic medical device directive. These directives are designed to ensure that medical devices are safe, reliable and effective in patients. Compliance with the requirements of these directives is conferred by placing the CE Mark on the product, and supplying the device with a Declaration of Conformity. Regulation and reimbursement of medical devices are controlled by private firms (Notified Bodies) in each member state.

In March 2010, amendments were made to the medical device and active

implantable device directives stating that all medical devices sold in the EU needed to have a clinical evaluation report in the technical file. Although these amendments reinforce the safety and performance of innovative healthcare technologies and will increase transparency, the existing regulations still need to be enhanced.

In an attempt to strengthen and update the regulatory process to keep pace with technological and scientific progress, the European Commission adopted Proposals of a Regulation of the European Parliament and of the Council on medical devices and in-vitro diagnostic medical devices in September 2012. These proposals will replace the existing three medical device directives and will be enforced across all the countries in the EU, eliminating any variability in the interpretation or implementation of the regulations.

“The new, updated regulations aim to implement stricter requirements for clinical evidence, broaden the scope of medical devices included and regulatory reach, increase traceability, ensure thorough testing and regular checks on manufacturers, and form an expert committee called the Medical Device Coordination Group to subject high-risk devices to additional central scrutiny procedures.” Madhavan states that these regulations, expected to be adopted in 2014 and gradually come into effect from 2015 to 2019, are a step in the right direction to strengthen and centralize the regulatory process and ensure patient safety.

“A compromise must be reached to settle the increasingly vocal dispute between device manufacturers and the European Commission on this pressing issue. Device manufacturers are trying to fight major changes in the approval process proposed by the European Commission. Tougher approval regulations will delay product launches over a period of years, leading to a loss of profit and market access for device manufacturers.

“Coming out of this meeting, both sides need to reach a satisfactory solution that protects patients, but does not restrict innovation and business. These regulations will affect all medical device manufacturers in the future, and change the competitive landscape of the device industry.”

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