MEPs have voted for more pre market authorisation, stringent safety checks and better product traceability in relation to medical devices.

In a resolution adopted on Thursday 14 June by a show of hands, MEPs agreed that the PIP breast implant case "has shown a malfunctioning at European and national levels, notably a lack of cooperation (…), and a lack of traceability of raw material used for medical devices". EU legislation in this area is to be revised this year.

The elected representatives called on the European Commission to switch to a pre-market authorisation system for certain higher risk medical devices and to improve inspection arrangements. The resolution also called for a single European database to bring together information about medical devices on the market, the registration of economic operations, vigilance and market surveillance; clinical investigations, notified bodies (which check compliance with EU rules) and EC certificates issued.

More information **here** [1].

John Brennan, Director Regulatory and Technical Affairs at EUCOMED, the industry body representing the devices industry, responded to the resolution describing the idea of a Pre-Market Authorisation process for medical technology “a step backwards”. He stated his view that the current approval approach in Europe adequately balances patient safety concerns with the need to promote innovation. He also warned against a centralised approach to authorisation, fearing this could delay patient access to new devices by two to three years. More information **here** [2].

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Links
[1] http://www.egovmonitor.com/node/51166 [2] http://www.eucomed.org/blog/120/59/blog/2012/06/19/Why-PMA-is-a-step-backwards-in-the-approval-approach-for-medical-technology/