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The European Federation of National Associations of Measurement, Testing and Analytical Laboratories

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EUROLAB Special Briefing

The European Parliament voted on its first reading of the draft legislation on medical devices

Stricter monitoring and certification procedures to ensure full compliance and traceability of medical devices such as breast or hip implants were agreed by the European Parliament on Wednesday. Members of the European Parliament (MEPs) also tightened up information and ethical requirements for diagnostic medical devices used for example in pregnancy or DNA testing.

Lessons learnt from the breast and hip implants scandal

European Parliament's amendments would strengthen the procedure for placing new medical devices on the market so as to ensure that unsafe products or devices that have undergone insufficient controlled trials on patients can no longer be used on or in them.

In future, MEPs say, notified bodies should have a permanent team of in-house experts who meet up-to-date qualification requirements. A new group of bodies should assess devices considered "high risk", for instance, devices that can be implanted in the human body.

In the wake of recent scandals, patients wearing implants would also receive an "implant card" and be registered, so that they can be alerted if any incidents are reported with a similar product.

Safety rules for in-vitro diagnostic medical devices

In separate legislation, MEPs reinforced patient safety for medical diagnostic devices used, for example, to perform pregnancy tests, diabetes self-tests, and HIV and DNA tests. European Parliament called for an ethics committee to be set up and introduced provisions to require the informed consent of patients to testing protocols and genetic counselling.

Next steps

The European Parliament voted on its first reading of the draft legislation, in order to consolidate the work done so far and hand it over to the next Parliament. This ensures that the MEPs newly elected in May can build on work done during the current term.

For further information:

Source: European Parliament Press release: http://www.europarl.europa.eu/news/en/news-room/content/20140331IPR41182/html/Medical-devices-better-controls-and-traceability-to-ensure-patients%E2%80%99-safety or contact the **EUROLAB General Secretariat**: info@eurolab.org