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EUROLAB Briefing

Stricter monitoring and certification procedures to ensure full compliance and traceability of medical devices

On Tuesday, 22 October the European Parliament voted to improve the control on medical devices via strengthened traceability rules and transparency of information for patients and medical staff, but without creating additional burdens for small manufacturers. MEPs also tightened up information and ethical requirements for diagnostic medical devices used for example in pregnancy or DNA testing. They will now start negotiating the final rules with member states.

The proposed legislation seeks to improve transparency of information for patients and medical staff and to strengthen traceability rules, without creating additional burdens for innovative small manufacturers.

Lessons learnt from the PIP breast implant scandal

Parliament's amendments would reinforce public access to clinical data for both patients and health professionals, so that they know better which product to use. In the wake of recent scandals, where the number of patients with potentially defective implants remained unknown, MEPs want patients to receive an "implant card" and to be registered, so that they can be alerted if any incidents are reported with a similar product.

Only experts can deliver the "CE" mark

The plenary vote in Strasbourg did, however, not call for greater change to the EU's current medical devices approval system which gives notified bodies in member states the overall responsibility. The outcome of the vote did not include provisions on full pre-market authorisation on high-risk devices.

A month ago, the Parliament's Environment, Public Health and Food Safety (Envi) committee called for a system with special notified bodies designated by the European Medicines Agency (EMA), in order to assess a select number of devices that pose the highest risk. For these devices, case-by-case checks will be conducted by a new expert body, the Assessment Committee for Medical Devices, the Envi committee says.

Bodies in charge of assessing medical devices often rely on subcontractors. In future, MEPs say, they should have a permanent team of in-house experts who meet up-to-date qualification requirements.

Clearer responsibilities for reprocessing "single use" devices

While some medical devices are commonly reused (e.g. stethoscopes) and others not (syringes for instance), many devices labelled as “single use” only are currently being reused on other patients after being disinfected (e.g. certain catheters or forceps). MEPs say that persons or institutions who wish to reprocess a single-use device must be held liable and ensure the traceability of the reprocessed device. A list of devices unsuitable for reprocessing should be set up via delegated acts.

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. Parliament called for an ethics committee to be set up and introduced provisions for the informed consent of patients and genetic counselling.

"Yes indeed, there are problems in the world of medical devices and this also applies to diagnostic devices. There has been an HIV test on the market for years that has been giving false negative results, with all the consequence arising from that in cases of blood transfusions or various other kinds of contact," said MEP Peter Liese (EPP, DE), who is steering the legislation through Parliament.

Next steps

The plenary voted to open negotiations with Council on both the files in the coming weeks, Possible first-reading agreements would then be put to a vote in the Public Health committee before seeking final approval by the full House.

For further information please visit:

Adopted text
http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bTA%2b20131022%2bTOC%2bDOC%2bXML%2bV0%2f%2fEN&language=EN (pages 18-174 & 175-369)

European Parliament Press Release:
http://www.europarl.europa.eu/news/en/news-room/content/20131021IPR22721/html/Medical-implants-better-controls-and-traceability-to-ensure-patients%E2%80%99-safety

BEUC Press Release:
http://docshare.beuc.org/docs/1/JIIBPKMCFPFNHFJKJCCMGJAJPDW69DBN239DW3571KM/BEUC/docs/DLS/2013-00657-01-E.pdf

EurActiv news article
http://www.euractiv.com/health/parliament-wants-tougher-medical-news-531238

Extracts from the Joint debate on Medical devices during the EP Plenary session:
http://audiovisual.europarl.europa.eu/Assetdetail.aspx?id=3d8f1c5f-0b04-4280-9cd1-a20d00ada5dd

CEOC International – EUROLAB – IFIA Position Paper on Safe Medical Devices:
http://www.ceoc.com/newsarticle.aspx?NewsId=389