eurolab aisbl

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

Special Briefing No. 02 – June 2016

EUROLAB Special Briefing

Council and Parliament representatives confirm agreement on medical devices and in vitro diagnostic medical devices regulations

The Environment, Public Health and Food Safety (ENVI) Committee of the European Parliament and Council's Committee of Permanent Representatives (COREPER) voted to endorse the trilogue agreement. Plans for stricter monitoring and certification procedures to ensure full compliance and traceability of medical devices, such as breast or hip implants, were backed by Health Committee MEPs on Wednesday, 15th June. MEPs also approved legislation to tighten up information and ethical requirements for diagnostic medical devices used for example in pregnancy or DNA testing. Both files were informally agreed with the Dutch Presidency of the Council.

"The metal-on-metal hip scandal highlighted weaknesses in the current system. So we've introduced much stricter requirements for the bodies that authorise medical devices, and will insist that particularly high risk devices, such as implants, joint replacements or insulin pumps, will be subject to additional assessments by experts before they can be authorised.", said rapporteur on medical devices Glenis Willmott (S&D, UK).[1] Her report was approved unanimously.

Learning the lessons of the breast and hip implants scandal

The agreement provides for:

- random inspections of producers' facilities after devices have been placed on the market;
- stricter controls on notified bodies, which will have to employ medically skilled people;
- an additional safety checking procedure for high risk devices, such as implants or HIV-tests. Not only a notified body, but also a special committee of experts will check that all requirements are met;
- an "implant card" for patients, enabling patients and doctors to track which product has been implanted;
- clinical evidence of medical device safety to be provided by manufacturers (as for medicines), especially in the case of higher risk classes;
- ethical requirements for DNA testing - the legislation would also require EU member states to inform patients of the consequences of DNA tests;
- stronger post-market surveillance, more information to patients.

"Pre-market scrutiny of high-risk devices was a priority for the Parliament so I'm particularly pleased that we successfully pushed for this and that these devices will now undergo additional assessment from expert panels", added Ms Willmott.[2]

A separate law will also ensure that the new rules also apply to in vitro diagnostic medical devices, i.e. medical devices which are not in direct contact with the patient, but provide information on a person's health, such as HIV, DNA or blood test devices.

The agreed two regulations are expected to achieve a twofold aim: making sure that medical devices and in vitro

[1] ENVI Press Release: Medical devices: Health Committee MEPs approve stricter EU safety requirements, 15-06-2016 http://www.europarl.europa.eu/news/en/news-room/20160613IPR32057/Medical-devices-Health-Committee-MEPs-approve-stricter-EU-safety-requirements

[2] Ibid

diagnostic medical devices are safe while allowing patients to benefit of innovative health care solutions in a timely manner.

MedTech Europe, the alliance of the medical device association Eucomed and the in vitro diagnostics association EDMA, recognise the importance of these regulations towards the sector and the healthcare continuum at large.

"Medical technologies save lives, improve health and contribute to sustainable healthcare. And many of the proposed updates in the regulations are welcomed by our industry as they will enhance patient safety and facilitate access to new technology" says Serge Bernasconi, CEO of MedTech Europe. "I believe that the new regulations are critical in filling in the gaps of the existing laws and in bringing a more harmonised set of guidelines across the region", he added.[3]

The consolidated texts are expected to undergo legal review and language translations in the next coming months and are expected to be formally adopted at the end of 2016. The regulations would then apply to the medical devices and to the in vitro diagnostics sectors by 2020 and 2022 respectively.

The texts can be downloaded and viewed on the European Parliament website.

For more information please access the following sources:

- http://www.medtecheurope.org/node/869
- http://www.emeeting.europarl.europa.eu/committees/agenda/201606/ENVI/ENVI(2016)0615_1/sitt-2571597
- http://www.consilium.europa.eu/en/press/press-releases/2016/05/25-medical-devices/?utm_source=dsms-auto&utm_medium=email&utm_campaign=Medical+devices%3a+deal+reached+on+new+EU+rules
- http://www.europarl.europa.eu/news/en/news-room/20160613IPR32057/Medical-devices-Health-Committee-MEPs-approve-stricter-EU-safety-requirements

[3] MedTech Europe Press release: Council and Parliament representatives confirm agreement on medical device and IVD regulations, 15-06-2016, http://www.medtecheurope.org/node/869