European Parliament

Press release

Medical devices: more safety, more traceability

Plenary sessions [05-04-2017 - 12:47]

Stricter rules to ensure that medical devices such as breast or hip implants are traceable and comply with EU patient safety requirements were backed by MEPs on Wednesday. MEPs also approved laws to tighten up information and ethical requirements for diagnostic medical devices, e.g. for pregnancy or DNA testing.

Both proposals had been informally agreed with 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, be subject to additional expert assessments before they can be authorised.", said medical devices rapporteur Glenis Willmott (S&D, UK).

Stronger post-market surveillance, more information to patients

"We've also agreed a much stronger system of post-market surveillance so that any unexpected problems are identified and dealt with as soon as possible". "With the PIP breast implants scandal, many women simply didn't know if they had received defective implants or not. So we've also introduced a Unique Device Identification system to help trace patients, who will also be given an implant card, which they can use to access information via a publicly accessible database", Ms Willmott added.

Learning the lessons of the breast and hip implants scandals

The rules provide 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, and
- clinical evidence of medical device safety to be provided by manufacturers (as for medicines), especially in the case of higher risk classes.

"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", Ms Willmott concluded.

A separate law will also ensure that the new rules also apply to in-vitro diagnostic medical devices, i.e. those that are not in direct contact with the patient, but provide health information, such as HIV, DNA or blood testing devices.

"We learned the lessons of scandals such as that of defective breast implants", said rapporteur on in-vitro diagnostic medical devices Peter Liese (EPP, DE).

"Problems have occurred in other areas too, e.g. with stents that are implanted into the brain or unreliable HIV tests. The new regulation is good for patients, puts an end to

fraudulent and shady producers and thus also strengthens respectable producers", he added.

Ethical requirements for DNA testing

The legislation would also require EU member states to inform patients of the consequences of DNA tests.

"DNA tests can have severe consequences for patients' lives and they should not be carried out without proper information and counselling. Member states pointed out that this is first of all their responsibility and that they will therefore accept EU rules only to a certain extent. It is important that member states fulfil this obligation. We will be very vigilant on this question", said Mr Liese.

Further information

- Steps of the procedure: http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2012/0266(COD)&l=en
- Glenis Willmott (S&D, UK): http://www.europarl.europa.eu/meps/en/35743.html
- Adopted text (2012/0266(COD); 2012/0267(COD)) will soon be available here (05.04.2017) : http://www.europarl.europa.eu/plenary/en/texts-adopted.html
- Video recording of debate (click on 05.04.2017) : http://www.europarl.europa.eu/ep-live/en/plenary/search-by-date
- Video of the press conference (if applicable) : http://www.europarl.europa.eu/ep-live/en/other-events/schedule
- EbS+ (05.04.2017) : http://ec.europa.eu/avservices/ebs/schedule.cfm?sitelang=en&page=3&institution=0&date=04/05/2017
- Audiovisual material for professionals: http://www.audiovisual.europarl.europa.eu/medical-devices
- EP research: Medical devices and in vitro diagnostic medical devices: http://www.europarl.europa.eu/thinktank/en/document.html?reference=EPRS_ATA(2017)599366

Political groups

- Press release by the EPP group: http://bit.ly/2oCdVAJ
- Press release by the S&D group: http://bit.ly/2o8yGTV
- News pages of the ECR group: http://bit.ly/1Y0YFrj
- News pages of the ALDE group: http://bit.ly/2ikk6qK
- News pages of the GUE/NGL group: http://bit.ly/1UrAlM9
- News pages of the Greens/EFA group: http://bit.ly/2m6JiBA
- News pages of the EFDD group: http://bit.ly/1TUnDFU
- News pages of the ENF group: http://bit.ly/2cxzxcR

Contacts

Baptiste CHATAIN
Press Officer
Telephone number: (+32) 2 28 40992 (BXL)
Telephone number: (+33) 3 881 74151 (STR)
Mobile number: (+32) 498 98 13 37
Email: baptiste.chatain@europarl.europa.eu
Email: envi-press@europarl.europa.eu
Twitter: EP_Environment