Press release

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European Parliament

Medical devices: Health Committee MEPs approve stricter EU safety requirements

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. 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). Her report was approved unanimously.

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 scandal, many women simply didn't know if they had received defective implants or not. So we've also introduced a Unique Device Identification (UDI) system so we know which patient has which device; this will make it much easier to trace patients if there's a problem and patients will also be given an implant card with the UDI, which they can use to access information via a publicly accessible database", Ms Wilmott added.

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, 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", she concluded.

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.

"I am very happy that we finally got it done. People in Europe have a right that we learn the lessons of scandals such as that of the defective breast implants", said rapporteur on in vitro diagnostic medical devices Peter Liese (EPP, DE).

"Problems occurred in other areas too, e.g. on stents that are implanted into the brain or an unsafe HIV test. The new regulation is good for patients, puts an end to fraudulent and shady producers and thus also strengthens respectable producers" he added. His report was approved unanimously.

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 the life of patients 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.

Note to editors

The European Commission published the proposal in 2012, and the European Parliament agreed its position on it in 2014. However, negotiations with MEPs could start only after member states agreed their position last autumn.

Both reports will be put to a vote by the full House early in 2017.

Medical devices in the EU in figures

- there are over 500 000 medical and in vitro diagnostic devices on the market
- the sector employs over 500 000 people in about 25 000 companies, most of which are micro, small and medium sized enterprises
- they generate nearly €100 billion in annual sales in the European market
- about 6-8% of medical devices annual sales and 10% of in vitro devices annual sales is re-invested in research every year

Further information

Medical devices and in vitro diagnostic medical devices [EU Legislation in Progress] (June 2016)
Meeting documents
Recording of press conference
Latest videos and photos
Committee on the Environment, Public Health and Food Safety

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Close up of hand holding silicon breast implant - ©AP Images/European Union/EP

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