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Safer medical devices: MEPs strike deal with Council

Plans for stricter monitoring and certification procedures to ensure that medical devices such as breast or hip implants comply fully with safety and traceability requirements were informally agreed by MEPs and the Dutch Presidency of the Council on Wednesday. MEPs also secured tighter information and ethical requirements for diagnostic medical devices, e.g. those used for pregnancy or DNA testing.

"I'm delighted that we finally have an agreement on this key legislation, which will allow us to put in place high standards for the manufacture, authorisation and placing on the market of medical devices." said Public Health Committee Chair Giovanni La Via (EPP, IT.

Stronger notified bodies and post-market surveillance

"Patients want to be confident that the devices used to treat them, or even implanted in them, are safe and effective and we have agreed a number of measures to give them this confidence", said rapporteur on medical devices Glenis Willmott (S&D, UK).

"These include stricter requirements for notified bodies, aesthetic devices covered for the first time and a Unique Device Identification system so that we know which device has been implanted in which patient. 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", she added.

"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.

Learning the lessons of the PIP breast implant scandal

"I am very happy that we finally got it done. People in Europe have a right to expect us to learn the lessons of scandals such as that of 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 unsafe HIV-tests. The new regulation is good for patients, puts an end to fraudulent and shady producers and thereby strengthens also respectable producers" he added.

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Ethical requirements for DNA testing

EU member states will be obliged to inform patients about the consequences of DNA tests, which has long been a controversial issue. "DNA tests can have severe consequences for the lives 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 meet their obligations. We will be very vigilant on this question", said Mr Liese.

Background

The agreement provides for:

- random inspections on the producers after devices have been brought out on the market,
- stricter checks on notified bodies, which will have to employ medically skilled people,
- an additional safety check 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 trace which product has been implanted, and
- a requirement for medical device manufacturers to provide clinical evidence of the safety of their products, especially in the case of higher risk classes.

The European Commission published the proposal in 2012, and the European Parliament already agreed on its position two years ago. However, it was not until last autumn that member states agreed a position, thus enabling negotiations with MEPs to start.

Next steps

Both reports will be put to a vote in the Public Health Committee in June.

Further information

Committee on the Environment, Public Health and Food Safety

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