Press release

PIP breast implants: "learn the lessons of this fraud"

Committees: Committee on the Environment, Public Health and Food Safety

A breast implant register, more stringent checks and product traceability, and a pre-market authorisation system are among the measures proposed by the Environment and Public Health Committee on Wednesday to prevent a recurrence of the PIP defective breast implants case. The resolution was passed unanimously.

Transposing EU legislation into national laws "has not avoided this health fraud, which has led and will lead to an international serious negative impact on public health", says the resolution.

An estimated 400,000 implants made by the French manufacturer Poly Implant Prothèse (PIP) have been sold worldwide. These implants were widely used in the UK, France, Spain and Germany. However, the number of women who have received them is unknown.

Failure of the compliance notification system

The PIP case "has shown a malfunctioning at European and national levels, notably a lack of cooperation (…), and a lack of traceability of raw material used for medical devices".

"The case of PIP implants, as well as the case of hip implants have shown a failure of the current system of certification of compliance (...), as well as of the controls of the notified bodies and their surveillance by national competent authorities", say MEPs.

Improve traceability and coordination

"It is essential to learn from this fraud and to strengthen surveillance and safety controls and placing on the market requirements" for medical devices, including breast implants, says the resolution.

EU legislation in this area is to be revised this year. Market surveillance, vigilance and the functioning of notified bodies must be improved, "so as to avoid a repetition of the PIP case", says the text.

There is also a need for "increased traceability of implanted medical devices", and for "increased coordination between Member States when it comes to reporting and warning about serious side effects or damage done" by these devices, it adds.

Furthermore, patients' associations, patient groups and health care professionals must be encouraged to report all adverse events and harmful effects of these devices without being hampered by a great deal of red tape, say MEPs.

A pre-market authorisation system

The European Commission is asked to shift to a pre-market authorisation system for certain medical devices and patients must be made aware of breast implant risks, says the text.

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MEPs call for the introduction of an implant recipient's passport, stating the implant's specific characteristics and its potential adverse effects, and a breast implant register in each Member State.

These registers should be interconnected and allow for the exchange of information when needed, for example in cases where important defects are detected in implants, they add.

Finally, a system of collective redress should be put in place to help patients to obtain compensation, says the text.

MEPs call for transparency in the functioning of notified bodies

MEPs advocate stepping up checks, inspections, market surveillance and information sharing on adverse effects so as to ensure improve medical device traceability and follow-up.

The criteria for accreditation and assessment of notified bodies and transparency with regard to their functioning and tasks should be strengthened and a European qualification management system should be established for notified bodies, they add.

A European data base

A single European data base should be established to bring together information about medical devices on the market, registration of economic operations, vigilance and market surveillance; clinical investigations, notified bodies and EC certificates issued, say MEPs.

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