

EU lawmakers move to tighten controls after implant scare

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The European Parliament moved Tuesday to tighten controls on the safety of medical devices in the wake of a worldwide scare over faulty breast implants from France.

More than 16,000 women have had <u>breast implants</u> removed since it was found in 2011 that those from France's Poly Implant Prothese (PIP) were twice as likely to rupture as rival brands.

The European Commission set out new rules in September for authorities responsible for the inspection of 10,000 medical devices—from plasters to pacemakers.

The vote to tighten controls on breast or <u>hip implants</u> and on devices used in pregnancy or for DNA testing now requires the go-ahead from European Union member states.

"Doctors have been telling us that hundreds of hip replacements are defective and have to be taken out again, with huge expenses for the health systems and suffering for patients," said Dagmar Roth-Behrendt.

"We need a better system," added the German Socialist MEP, who is leading scrutiny of draft legislation for the 28-state bloc.

The Parliament said it was a case of "lessons learnt from the PIP breast implant scandal", which led to company founder Jean-Claude Mas being charged with manslaughter and fraud.



PIP's <u>implants</u> were banned and the company was liquidated.

MEPs want patients to receive an "implant card" and to be registered, so that they can be alerted if any incidents are reported.

Organisations in charge of assessing medical devices will have to employ a permanent team of in-house experts under the proposed changes.

The legislation on testing, is to cut down on, for example, faulty HIV assessment, said another German MEP Peter Lierse.

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