



PIP scandal: "stricter rules" needed on breast implants

Breast implants came under scrutiny Tuesday in the Environment Committee when MEPs discussed whether silicon implants should be subject to stricter controls and better traceability following the scandal caused by faulty silicon implants.

The EP has been pushing for better rules for the last 20 years, adopting a resolution in 2001 and a report in 2003. "There should be a common approach across the EU to deal with this scandal," according to British Socialist Catherine Stihler who drafted the 2003 report. Up to 500,000 women, mostly outside the EU, are believed to have been affected by the use of low-grade silicone in breast implants produced by French manufacturer PIP.

"At the moment, the legislation that covers implants in the EU is the one on medical devices," which is currently being updated, Stihler explained. During the meeting 24 January, the Commission said it was conducting a "stress test" on a proposed update to EU legislation on medical devices, due to be published in March.

"I am pleased the European Commission is dealing with this seriously and quickly," said British Socialist Linda McAvan, the author of an "oral question" on the issue. Since many women are unsure whether their breast implants are defective, unique identification of products could ensure effective tracking in future, she added.

McAvan also highlighted the need for better cooperation within the EU and internationally, noting that problems identified by the US Food and Drug Administration (FDA) several years ago had come to light only very recently.

An opportunity

For Stihler, the PIP issue "is an opportunity...so that there can be stricter rules (but) more can be done, there should be a register so that people can check what implants have been used so that if affected by the PIP scandal, they can take action."

"There should be an insurance scheme for private health providers and those that produce the implants to avoid what is happening now," she said. "There's an issue about liability, the company who produced the faulty implants doesn't want to cover the costs of the replacements. We need an insurance scheme in the future for private health providers."

She asked the Danish presidency of the Council to put the topic in the agenda of the next council meeting on health, as "there should overall be a common approach across the EU to deal with this scandal."

"An implant is not for life, it should normally be replaced," Stihler said, noting that many women are unaware of this when they decide to undergo surgery. "Good providers have to give people the right information," she added.