

Contact: Pauline Constant: +32 (0)2 789 24 01
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Parliament opens the door to safer medical devices

Laws defining medical devices will be shaken up after the European Parliament adopted the proposals in Strasbourg today. It is now over to the Council of Ministers to toughen up patient safety.

Pacemakers, pregnancy tests and hip prostheses are just a few of the medical devices that can ease consumers' lives, provided they are safe and effective. Hence the necessity for strong measures to ensure medical devices on the EU market are safe and reliable.

Patients' safety has become even more blatantly required since the PIP breast implant scandal hit the headlines in 2012. The thousands of women across Europe who had faulty silicon breasts implanted are still seeking compensation.

Although BEUC called for much more stringent measures^[1] on the authorisation of medical devices before they are marketed, the compromise reached by the European Parliament can still pave the way to increased safety.

Monique Goyens, Director General of The European Consumer Organisation (BEUC), commented:

"Today's vote finally enhances both consumers' information and involvement in the monitoring of such devices. For example, the 'implant card' will provide patients with better information on the medical device they are about to get fitted. Also, reporting defective products will be made possible for patients, enabling manufacturers to learn from their mistakes and innovate with safer products.

"However, we expected MEPs to take a bolder stance on granting consumers access to safer medical devices. Although the surveillance of devices once they are implanted will be considerably beefed up, the same cannot be said about the pre-market phase. Despite our repeated calls, there will still be no thorough evaluation of the risks and benefits of a device before it is used. Under the current system, consumers will continue to be used as guinea pigs.

"We now urge the Council to push for stricter pre-market assessment to truly protect European consumers. Moreover, The EU should say 'never again' to unfortunate episodes like the faulty breast implants fiasco and act accordingly."

Notes to editors:

[1] Read Monique Goyens' call for the adoption of the proposal (18/10/2013):

http://www.theparliament.com/latest-news/article/newsarticle/eu-parliament-has-opportunity-to-give-medical-devices-a-new-lease-of-life/#.UmTYefn_k6g .

For further information on our position:

docshare.beuc.org/Common/GetFile.asp?ID=45110&mfd=off&LogonName=Guesten

Listen to the stories of five women who had a faulty device implanted:

<http://www.youtube.com/watch?v=AUDcDep50A>

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