

EPRS | European Parliamentary Research Service  
Transcript of an EPRS Podcast  
April 2016



PODCAST Medical devices

Voice 1: Brian

Voice 2: Sarah

JINGLE to open intro to podcast

VOICE 1

You're listening to the European Parliamentary Research Service podcast on medical and in vitro diagnostic medical devices.

VOICE 2

After a number of scandals, the European Union is about to adopt much stricter rules to ensure the safety and traceability of medical devices and in vitro diagnostic medical devices. We'll be right back with you!

END OF JINGLE

VOICE 1

Remember the breast implants scandal of 2010? When many women world-wide discovered in horror that their breast implants had been made from cheap industrial silicone which was much more likely to rupture than other implants.

VOICE 2

Scandals like this one pushed the European Union to start drafting much stricter rules to ensure the safety of medical devices and in vitro diagnostic medical devices BEFORE they are placed on the market, and tighten surveillance once they are available. But what kind of devices are we talking about?

VOICE 1

We're talking about over 500.000 devices on the market! From sticking plasters to dental filling material, heart valves, X-ray machines, pregnancy self-tests and state-of-the-art analytical laboratory equipment.

VOICE 2

EU rules on the manufacture and use of such devices were harmonised in the 1990s but they have been outpaced by technological and scientific progress, so in 2012 the European Commission proposed an update of the rules.

VOICE 1

Apart from improving safety and traceability of these products, the EU wants to create a unique device identification system that will make it easier to recall faulty products and help to fight against counterfeit devices.

VOICE 2

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MUSIC JINGLE TO CONCLUDE