MEPs vote for tougher controls on medical devices

Written by Kayleigh Lewis on 27 September 2013 in News

Parliament's environment, public health and food safety committee has voted to beef up existing rules on medical devices, which date back to the 1990s, to improve patient safety and decrease the likelihood of future scandals.

Dagmar Roth-Behrendt, parliament's rapporteur on the controversial medical devices regulation welcomed the overall outcome on Wednesday, saying, "We have achieved our main objective today. Patients will be better protected from defective products and a more efficient system to grant market access to new devices will be soon in place."

The new proposals aim to clarify the existing legislation, which would boost public health protection, remove obstacles faced by industry in the EU internal market, improve transparency of information to patients and strengthen traceability.
However, Roth-Behrendt expressed disappointment about the lack of ambition in the final result. She said, "My initial intention was to establish a system of pre-marketing authorisation for high-risk products such as heart valves, breast implants or pacemakers to ensure only safe products will be used in or on patients.

Overall the S&D deputy remained positive, saying, "Our new system will, however enable the best medical specialists in Europe to re-examine some devices where new technology is involved or in cases where many incidents have occurred in the past.

"Clinical investigations on patients will be more systematic and patient safety will benefit," she concluded.

The medical devices 'package' also included provisions for in vitro medical devices (IVD), such as HIV and DNA tests, authored by German deputy Peter Liese, which include stricter rules on informed consent and ethics.

He said, "It is good news that DNA tests will come with a mandatory medical consultation across the EU. Questions on pre-natal tests are not for the market place.

"Europe has a duty to make sure that advice for genetic tests is provided. Unfortunately, not all EU countries rules currently protect patients.

"It is very important that DNA tests are carried out in a protected area, by trained staff, and that appropriate consultation takes place."

He also expressed an urgency to finalise the legislation, saying, "These rules will directly affect the health of EU citizens so we need to work swiftly to progress the legislation, so citizens can benefit," adding, "We should aim to finalise the legislation ahead of the European Elections in the spring of next year."

His colleague, EPP deputy Mairead McGuinness said, "Our aim is not to make it harder for patients to access life-enhancing and essential medical devices.

"The revised legislation should enhance patient safety and equally ensure that the industry keeps coming forward with innovative medical devices that add to the quality of people's lives.

"This can be achieved by strengthening post-market surveillance and by enhancing the traceability of products", she explained.

Parliament's Greens group public health spokeswoman Michèle Rivasi also welcomed the proposals, saying, "The recent scandals with faulty breast implants, hip replacements and other devices have underlined serious flaws with EU legislation on medical devices.

"Today's vote moves us a step closer to addressing this and to ensuring these acutely sensitive products for public health are subject to stronger regulation".

However, Serge Bernasconi CEO of Eucomed, which represents the medical technology industry in Europe, was less positive, suggesting that the proposals have been rushed.

He said, "Despite the requirements currently proposed in the revised regulation, the IVD industry maintains that a staggered approach that upholds safety, while ensuring the proper management of
available resources is the most responsible approach to take.

"It is in the interest of all to find value in time in order to maintain the integrity of the new regulation," he added.

"The political groups in the parliament still have time to assess the impact of the system on patients, innovation and resource implications and fix this rushed deal into a right deal when the vote enters the plenary session in October," he added.

**About the author**

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