Press release | 22.10.2013

Medical devices and public health

MEPs vote for stricter regulation at EU level but fall short in key areas

The European Parliament today voted on two legislative proposals, which aim to update EU rules on medical devices following various scandals (e.g. with breast implants, hip replacements). Commenting on the outcome, Green public health spokesperson **Michèle Rivasi** (France) said:

"Today's vote is a step forward but will not fully respond to the challenges with medical devices. Recent scandals with faulty breast implants, hip replacements and other devices have underlined serious flaws with EU legislation on medical devices. Today's vote takes a step to address this. The EP has today voted to ensure stricter regulation to prevent risks to public health from these sensitive products. However, we regret that it does not include provisions on full pre-market authorisation of high-risk medical devices. We also regret the failure to support provisions for a comparative assessment of innovative high-risk devices against existing treatments.

"The Greens pushed for the prohibition of toxic or dangerous substances (e.g. carcinogens) in certain devices when safer alternatives are available and welcome today's vote to endorse this. It is long overdue that we get rid of dangerous PVC softeners in devices (for example in infusion devices). Unfortunately, however, MEPs failed to support strict requirements for nanomaterials in medical devices."

Green public health spokesperson **Margrete Auken** (Denmark) added:

"We welcome the support of MEPs for Green proposals to ensure transparency on the results of clinical investigations of high-risk medical devices. This is crucial for the credibility of and public trust in such investigations. The clinical investigations will also be subject to the approval of an ethics committee. This provision, which would ensure the EU complies with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, is essential for the credibility of clinical investigations"

"MEPs also voted to support the inclusion of another crucial provision by which the use of genetic tests will be subject to mandatory counselling by a doctor and only after the person concerned has given free and informed consent. This will help ensure proper regulation of the numerous genetic tests already available in the EU."

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Responsible MEPs



Margrete Auken

Member



Michèle Rivasi

Member

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