Press release | 25.09.2013

Public health

Medical devices would face stricter EU regulation under EP vote

The European Parliament's public health committee 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:

"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.

"MEPs have today voted to ensure better evaluation of high-risk devices before they are put on the market. Importantly, the committee accepted our proposal that innovative high-risk devices should always be assessed against the existing reference treatment. Both of these provisions are crucial for ensuring that such devices are safe for public health and actually represent added therapeutic value. The Greens also pushed for the prohibition of toxic or dangerous substances (e.g. carcinogens) in certain devices when safer alternatives are available. We welcome the support of the committee for this common sense proposal."

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.

"MEPs also voted to support the inclusion of another crucial provision by which clinical trials would 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 also essential for the credibility of clinical trials."

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Responsible MEPs



Margrete Auken

Member



Michèle Rivasi

Member

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