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Press release | 26.11.2018

Greens/EFA demand debate on medical devices

Implant files

The "Implant Files", a cross-border investigation by journalists into how medical devices on the EU market, such as pacemakers, artificial hips and contraceptives, which may have caused pain, injury or even death among patients, must be debated by the European Parliament, according to the **Greens/EFA** group.

The Implant Files suggest that flaws in certification systems that have led to the approval of faulty and dysfunctional medical devices and a lax approach to regulation, have resulted in serious health issues for some recipients. In the EU, medical implants are not tested by a public body in the way that pharmaceuticals are, but by commercial companies known as "notified bodies".

The Greens/EFA group are calling for a debate in the European Parliament as soon as possible. Since 2013, the Greens/EFA group have been calling on the European Commission to have a pre-market authorisation system for certain categories of medical devices, which are implanted in the human body. The Greens/EFA group also have called for an appropriate toxicological evaluation of all medical devices, and propose the gradual elimination of substances that are carcinogenic, mutagenic or toxic to reproduction.

Bas Eickhout, Greens/EFA Member of the Environment, Public Health and Food Safety Committee, comments:

"The Impact Files are a frightening look into how faulty, dysfunctional and dangerous technologies have been approved for used in medical care without clinical trials or adequate assessments and under poor regulations. It's sickening to think that companies who are supposed to act in the interest of patients' health and wellbeing may have been harming people for the sake of profit, through dodgy practices and lax regulations.

"We need complete transparency around the safety and effectiveness of all medical devices in order to properly regulate their use and to guarantee the independence and competence of certification bodies. Large scale lobbying efforts by the medical-technology industry cannot be allowed to take precedence over people's health. That's why the Greens/EFA group are calling for debate in the European Parliament on how we can

improve on the gaps in legislation and reduce the risk of harm to patients in the future."

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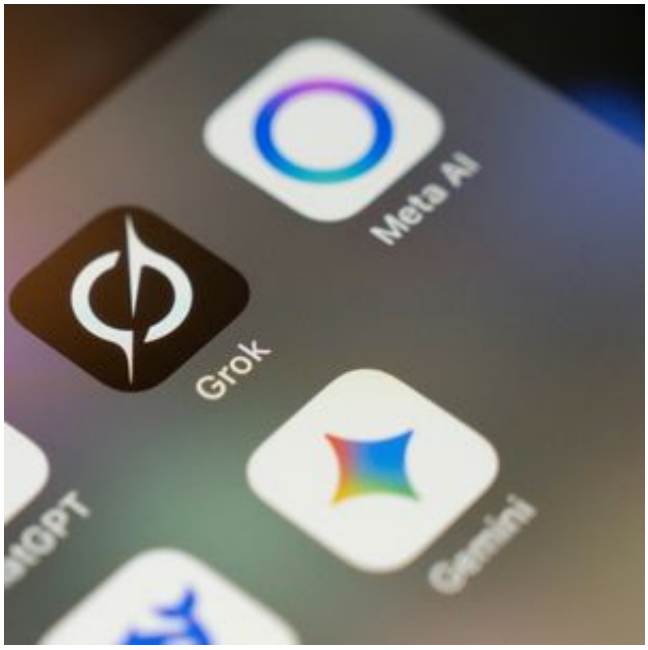

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