

Implant files: Thousands of victims due to dodgy certification rules



(Press Release, Brussels, 28 November 2018) The current system of approval of medical devices is carried out by private agencies, dominated by business interests. EPSU calls for an urgent overhaul of these procedures.

In the last few days the so-called implant files, unveiled by [the ICIJ group of international investigative journalists](#), have revealed that patients around the globe have been unwitting test subjects for new medical devices and technology. Thousands of people have been injured, maimed and even killed by poorly-tested implants. Estimates for 2017 put the numbers at 14,000 in Germany and about 18,000 in France (approximately 158,000 cases in the last 10 years). In the UK, regulators received 62,000 “adverse incident” reports linked to medical devices between 2015 and 2018, amounting to an average of 15,000 cases annually.

What should be an exception has become the rule: ninety percent of the implants are used in patients without having been previously tested in clinical trials. Legally, this is possible, but it should only happen in exceptional cases. In reality the rules are circumvented to launch new products quickly and cheaply across all European

countries.

In 2015, a scandal stemming from the use of cheap silicone implants made by a French company helped trigger negotiations between the European Parliament and the European Council on the revision of EU regulations on medical devices. These were finally agreed in May 2017 and will take effect as of 2020. They comprise an additional control procedure before medical devices can be used with patients, define how the clinical evaluation of a product should be carried out and require product identification numbers to be introduced.

The implant files show that there are flaws in the current regulation because of the lack of a public health angle. The new regulation foresees detailed documentation procedures, but it fails to tighten up regulation before approving medical devices for use. It does not require authorisation of medical devices and technology by a public independent agency, as is the case with drugs.

The risks to patient safety and the proper use of resources in health systems have become more than obvious and authorities have failed to tackle this due to insufficient legislation and lack of political will. At the root of the problem is the fact that commercial testing companies or certification agencies make their income from the very tests paid for by the manufacturers of medical devices and technologies. The current system means that the certification body could approve products in order to make money for private interests so creating serious risks for society.

EPSU takes the revelations and the lessons learned from the implant files seriously and calls for urgent changes to be made to the governance of the approval system for medical devices and technology:

- The safety and health of patients should be given a very high priority similar to the approach in health care systems.
- The regulation of health care-related issues can not be outsourced to certification agencies operating with a commercial interest, but should be carried out by public agencies operating in the general interest and also capable of enforcing it.
- EPSU identifies similar risks with attempts to push for a stronger recourse to EU-level standardisation tools and mechanisms. If private certification procedures are used instead of approval of services or providers by state-run

and state-controlled agencies operating in the general interest – including health care, social services and education and professional training – scandals like the implant files will only recur.

- There needs to be transparent information on key aspects for the proper and effective operation of health care systems. We as citizens, patients and taxpayers cannot accept the non-disclosure of relevant information on the basis of business secrets or interests when it touches on important elements of patient safety.
- The precautionary principle should apply as in other fields of product and service approval.

End

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