Patient groups: Safety first in new medical devices regulation

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SPECIAL REPORT / Recent health scandals involving faulty breast implants and toxic replacement hips have illustrated the need to strengthen safety checks on medical devices in the EU, according to patient groups. A new EU regulation currently in the works must rectify this by putting patient safety first, they argue.

In March 2010, the French implant manufacturer Poly Implant Prothèses (PIP) was shut down after non-authorised industrial-grade silicone gel caused abnormally high rupture rates on its implants, sparking a worldwide health scare.

More than 4,000 women have reported ruptures and in France alone 15,000 have had their PIP implants replaced.

In February 2012, an investigation revealed that hundreds of thousands of patients around the world may have been exposed to toxic substances after being implanted with potentially dangerous hip devices. In May this year, French authorities revealed that surgeons had fitted 650 people with replacement hips that had not yet been certified as meeting European standards.

These examples illustrate that the current EU rules on medical devices are inadequate and that the system requires comprehensive review, said the European Consumers' Organisation, BEUC.

"Unfortunately, these scandals also led to consumer confidence in medical devices and in the supervision of competent authorities being undermined. That trust must be urgently restored," BEUC said in a statement.

Patient involvement and rights

According to BEUC, it is unacceptable that consumers are afforded a different level of protection depending on whether they have a hip replacement or diabetes. It is also difficult for consumers to understand why a device implanted in their body does not undergo the same thorough assessment as the pills they take for headache for example.

"All the more because if there is a problem with a medicine they can simply stop taking it while if there is a problem with a high-risk device, such as an implant, they must pursue invasive and risky surgery to have it removed," BEUC explained.

Dagmar Roth-Behrendt, a German socialist MEP who is in charge of steering the legislation through the European Parliament, said the current EU system of approval for devices with the highest potential risk needs a complete change.

In her report, which the European Parliament's environment and public health committee will consider in September, Roth-Behrendt has proposed a centralised pre-market authorisation system for the so-called 'Class III' devices, which represent the highest risk to patients, such as pacemakers and hip implants.

The European Patients' Forum (EPF), a civil society group, said the Parliament draft report takes some of its key concerns onboard, but that some gaps remain.

The EPF supports the Commission's initial proposal to put in place a scrutiny mechanism as it will empower the authorities to have a second look at individual assessments, ensure they are aware of new high-risk devices coming on the market, and give them an opportunity to make their views heard before the devices are placed on the market.

The patient group applauded Roth-Behrendt's report for addressing some of its key concerns, including on patient involvement.

Indeed, the Roth-Behrendt report offers to involve patients, together with other stakeholders, all along the approval process in an advisory committee which could be established under the European Medicines Agency (EMA), based in London. The committee would be able to comment, for example, on clinical evaluation and allow patient groups to report directly on incidents encountered by patients and healthcare professionals.

"We call on the European Parliament to place patient safety first when considering this issue, over economic considerations," the patient group said.

A question of life or death

Alexandra Wyke, the founder and chief executive of PatientView, a private consultancy firm working with patient organisations, told EurActiv that regulators naturally want to ensure that medical devices are as safe as possible. But neither policymakers nor doctors are always in a position to guess what patients think on safety matters.

"Dying patients are willing to take more risks than patients who are otherwise relatively healthy," Wyke said. "Patients also need to understand the risks and benefits of products that are or could be prescribed to them".

"This is why patients feel they need to be included and have a voice in the processes that assess whether a medical device should be considered safe or not. This is also their right," she said.

The European Patients Forum, for its part, argues that changing the authorisation system in the EU alone will not by itself improve the safety or quality of medical devices.

The EPF says a pre-market approval system can provide a good solution to regulate high-risk devices, but then the EMA must be granted adequate resources and expertise to carry out this task without creating undue delays for patients to have access to potentially life-saving technologies.

While BEUC's Director-General Monique Goyens supports Roth-Behrendt's call for a centralised pre-market authorisation system, the industry says such a system won't benefit patients, but rather put those who can't wait at risk.

Access to new therapies

In 2010, Dr Joshua Makower, a medical-technology entrepreneur in the United States, conducted a survey that detailed how patients in Europe are getting access to new therapies on average two years before patients in America, where the US Food and Drug Administration (FDA) follows a more burdensome regulatory system.

The survey indicates that European regulatory processes allow innovators to make new medical technologies available to patients more quickly and at a lower cost.

Lawsuits are more common in the US than in the EU, making American doctors and insurance companies more risk-averse. Reform advocates underline that 15 million lawsuits per year in the US are "frivolous".

A report by the Boston Consulting Group has also shown than medical device recalls in the US and Europe occur at the same rate while the approval process in Europe is significantly faster.

Cocir, which represents the medical technology industry in Europe, said a centralised pre-market authorisation system will result in additional complexity, delays and costs to the European medical devices sector.

“It is unclear whether a new Committee within the pressurised EMA, which has no experience in devices, would provide additional benefits to patients or healthcare providers seeking speedy access to new products and innovative technologies - or meet the ever rising demands for healthcare and improved efficiency,” Nicole Denjoy, said Cocir’s secretary-general.

Next steps:

- **18 Sept.**: The Parliament’s Environment, Public Health and Food Safety (ENVI) Committee votes to adopt its final report on the two proposed medical devices regulations (Roth-Behrendt report).
- **Nov. 2013**: Parliament will vote to accept or reject the report in a plenary session.

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External Links

European Commission

- Public health: Revision of the medical device directive

Parliament

- Environment, Public Health and Food Safety (ENVI) Committee: Draft report on medical devices
- Environment, Public Health and Food Safety (ENVI) Committee: Website

Patient and consumer groups

- The European Patients’ Forum (EPF): EPF position statement
- The European Consumer Organisation (BEUC): Medical devices
- PatientView: Website

Industry

- Cocir: Cocir urges caution on the call for an alternative marketing authorization procedure for medical devices

Studies

- Report: FDA impact on US medical technology innovation: A survey of over 200 medical technology companies

- Boston Consulting Group: EU Medical Device Approval Safety Assessment: A comparative analysis of medical device recall 2005-2009

LINK: http://www.euractiv.com/special-report-medical-devices-r/eu-crossroads-new-medical-device-news-528935?utm_source=feedly