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MEPs vote for stricter approval system for medical devices

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The European Parliament's committee for the environment and public health (Envi) on Wednesday (25 September) voted for stricter rules on medical devices, including a new pre-market approval system, more transparency and better traceability.

Background

Medical devices are defined broadly and can include anything from sticking plasters to contact lenses, pregnancy tests, dental filling materials, X-ray machines, pacemakers, breast implants, hip replacements and HIV blood tests.

Following a huge health scandal involving faulty breast implants sold around Europe, the European Commission published proposals in late 2012 for a new regulatory regime for medical devices. The Parliament is currently debating the shape of new regulation.

The new regulations are scheduled for adoption later in 2013.

>> Read our LinksDossier: [Medical Devices: A new regulatory landscape](#)

The aim of the new medical devices rules is to improve patient safety through more transparent information and product traceability as well as removing obstacles for the industry within the EU's single market.

Dagmar Roth-Behrendt, the German socialist MEP dealing with the legislation in Parliament, said MEPs had achieved their main objective which was to better protect patients from defective products.

"We were able to enforce our goals and to be more ambitious than the Commission proposal. We really needed to put patient safety first and to bring transparency to an industry that is quite unregulated," the MEP said.

"We now hope that the improvements we have achieved will not be diluted later in the legislative process," she added.

A year ago, the European Commission released proposals for a regulation on medical devices, following a health scandal where industrial-grade breast implants were sold around Europe. The EU executive's proposals allowed for member states to better scrutinise the so-called notified bodies currently charged with ensuring that products meet certain safety criteria.

'Rushed deal'

Roth-Behrendt proposed tightening the proposal further with a centralised pre-market authorisation system for so-called 'Class III' devices such as pacemakers and hip implants, which represent the highest risk to patients.

In the end, MEPs voted for a system where special notified bodies are designated by the European Medicines Agency (EMA), based in London, in order to assess a select number of devices that pose the highest risk.

For special high-risk devices, case-by-case checks will be conducted by a new expert body, the Assessment Committee for Medical Devices.

Serge Bernasconi, the chief executive of Eucomed, the European medical technology industry association, said the deal will be a blow to patient access and medical device innovation in Europe. To Eucomed, although the Parliament's compromise proposal is presented as being "dramatically different" from the centralised pre-market authorisation system, it is in fact very similar and should be scrapped.

"The political groups in the parliament still have time to assess the impact of the system on patients, innovation and resource implications and fix this rushed deal into a right deal when the vote enters the plenary session in October," the CEO of Eucomed said in a statement.

Patients first

In separate legislation related to in vitro diagnostic medical devices (which typically include blood tests for glucose, liver enzymes and tests for drugs), the Envi committee called for the involvement of an ethics committee and introduced provisions on informed consent and genetic counselling.

The MEPs also proposed new conditions for the involvement of minors and incapacitated people in clinical studies as well as new criteria regarding access to data collected in such studies.

Katrín Fjeldsted, president of the Standing Committee of European Doctors (CPME), said she expects EU member states to uphold the "strong ethical principles" set by the Parliament when they examine the legislation in the Council of Ministers. This includes informed consent, transparency of data and protection of minors participating in clinical assessments of medical devices, CPME said.

"The Council should also uphold these provisions, ensuring the safety of patients. The same principles should apply in the clinical trials regulation, which is currently being negotiated between Parliament and Council," Fjeldsted said.

Monique Goyens, the director general of the European Consumer Organisation (BEUC), said that despite huge industry pressure, MEPs have put patient safety first.

"The Parliament has managed to enhance post-market monitoring and the new system will make it possible for consumers to report faults or mishaps. Furthermore, an appropriate increase in manufacturers' liability will compel adequate compensation for harmed patients," Goyens said.

"Consumers about to receive surgically implanted devices will receive an 'Implant Card' clearly detailing all the product's characteristics and its potential adverse effects. A basic right to such information was long overdue," she added.

However, while a compromise was reached on pre-market checks of medical devices, the result is still far adrift of the "robust system" MEPs were championing a year ago, Goyens stated.

Positions

Director of the **European Patients' Forum Nicola Bedlington** said in a statement:

"The result of this vote is an important milestone towards safer medical devices for patients in Europe. The adopted text shows a strong commitment to transparency towards the public, and ensures that patients' voice will be heard in all important parts of the process, from clinical investigations to vigilance. We call on the EU institutions to stay the course in the next phase of the legislative process."

The Association Internationale de la Mutualité (AIM), a group of autonomous health insurance and social protection bodies, said in a statement:

"Health mutuals and health insurance funds welcome the improvement of the safety and benefit of high-risk medical devices like implants or heart valves. In particular, the assessment of high-risk medical devices through special notified bodies designed by the EMA is a step in the right direction. Through this vote, MEPs have showed that the patient safety takes priority over economic interest."

Next Steps

- **22 Oct.:** Plenary vote in Parliament on new medical devices regulations.