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MEDICAL DEVICES REGULATION

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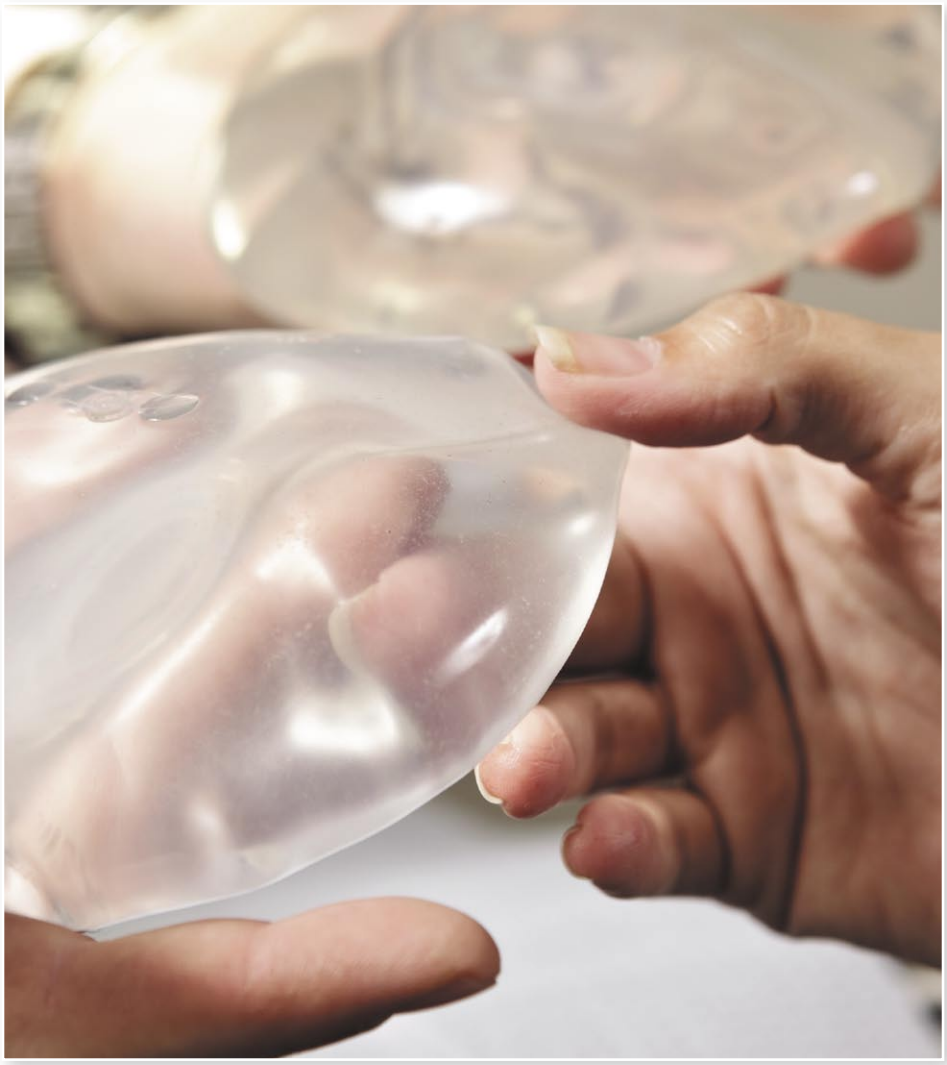
Contents

EU at crossroads on new medical devices legislation

While the EU institutions, industry, health campaigners and doctors all agree that the European approval system for medical devices – ranging from contact lenses to pacemakers – needs to be updated, the way forward on how to do it leaves politicians and stakeholders divided.



The EU was already preparing a revision of its medical devices directive when the PIP scandal involving faulty breast implants broke out in late 2011.

The French firm Poly Implant Prothèses (PIP), once the third biggest global supplier of breast implants, allegedly used cheap, industrial silicone not intended for medical use in its products for 10 years.

Many of the breast implants were prone to rupture, causing dangerous leakages of the silicone in women's bodies.

In France, of the 30,000 women who had PIP implants, almost half have had them removed and about 4,000 reported their implants rupturing.

The breast implant fraud case has affected 100,000 women in Europe and 400,000 women globally.

Over 5,000 women are now seeking compensation for harm dependent on the findings of the criminal trial of PIP's founder and four senior executives.

Improving notified bodies

To avoid a repeat of this, the European Commission proposed to update the existing legislation on medical devices.

The term 'medical device' covers a wide range of products both used internally and externally by patients and doctors. They can include sticking plasters, contact lenses, pregnancy tests, dental filling materials, X-ray machines, pacemakers, breast implants, hip replacements and HIV blood tests.

These are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment and

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prevention of disease.

They are a ranked from Class I, a low-risk category that would include spectacles, to high-risk Class III items such as hip replacements and pacemakers, which are fitted inside the body.

Currently, it is not always possible to trace medical devices and in-vitro diagnostic devices back to their supplier. Patients, healthcare professionals and other interested parties do not have access to information on how such products have been assessed, and what clinical evidence there is to show they are safe and effective.

In its proposal, the Commission wants to improve the product evaluation process, enhance the traceability of products and place more scrutiny on notified bodies.

Notified bodies are mostly private companies that have the role of a public regulatory agency. They receive revenue based on the numbers of costumers they attract. They have to abide by national rules, but they have private incentives to achieve that work.

The Commission also wants to harmonise member state authorities' approach to regulation and improve the exchange and coordination of information, especially in the pre-market phase.

Parliament wants to introduce different system

However, the German MEP who is responsible for steering the proposed legislation through the European Parliament wants to go a step further.

In her draft report, Dagmar Roth-Behrendt, who is from the Socialists & Democrats (S&D) group, has proposed a pre-market approval procedure for high-risk Class III devices. She suggests establishing a Committee for the Authorisation of medical devices within the European Medicines Agency (EMA) to oversee the process, where patients would be represented.

The rapporteur said in a statement that the current EU system of approval for devices with the highest potential risk needs a complete change.

> "This new procedure is the best way to improve the current system and to balance swift access to innovation with patient safety"

"In my draft report, I have introduced a new and swift marketing authorisation procedure for devices with the highest potential risk, such as those implanted into the body or dispensing medicines. In my system, this authorisation is not delayed as compared to the current system: it would be given within nine months," Roth-Behrendt said.

"I believe this new procedure is the best way to improve the current system and to balance swift access to innovation with patient safety," she explained.

Industry and patient groups divided

Serge Bernasconi, chief executive of Eucomed, the European medical technology industry association, said the industry agrees with doctors and patient organisations, that changes are needed to improve the management of the current European system and keep pace with new medical technologies.

> "We need to address the weaknesses of this system to make it even safer for patients without delaying access to safe, life-saving medical devices and without stifling innovation"

However, the proposal by the Parliament rapporteur is not the right way forward, the industry representative said.

"Europe has long been known as a world leader in providing its citizens with timely access to safe technology thanks to the effective decentralised approval system. We need to address the weaknesses of this system to make it even safer for patients without delaying access to safe, life-saving medical devices and without stifling innovation," Bernasconi said.

> "The suggestion that this system will allow approval within nine months is extremely optimistic"

He added that a case of criminal fraud like the PIP breast implant should never be allowed to happen again, but a centralised pre-marketing authorisation system like the one proposed by Roth-Behrendt would not have prevented PIP.

"The suggestion that this system will allow approval within nine months is extremely optimistic. There are three points in the process which allow for potentially severe delays including a 'clock-stop' clause which can delay the approval process indefinitely. We need to keep what works and fix what needs to be improved instead of radically changing the system," the chief executive said.

While the European Consumers' Organisation (BEUC) supports Roth-Behrendt's call for a centralised pre-market authorisation system, the European Patients' Forum (EPF) is questioning whether this is needed, though applauding the Parliament rapporteur for introducing more patient involvement earlier in the process.

The Parliament's Environment, Public Health and Food Safety (ENVI) is scheduled to vote on the rapporteur's draft report in September.

MEPs divided ahead of vote on medical devices

A vote in the European Parliament's Environment, Public Health and Food Safety (ENVI) Committee over the EU's proposed new medical devices regulation, which was supposed to take place on 10 July, has been postponed until September to give lawmakers more time to work on compromise amendments.

The European Commission has tabled new rules for the approval of medical devices following a series of health scandals including a high-profile case in France involving faulty breast implants, the so-called PIP scandal.

> "We need an efficient system of market access for medical devices that satisfies the highest possible safety standards in order to serve the needs of patients"

But MEPs are divided as to how far the proposal should go in harmonising the way medical devices should be approved in future. Some committee members are worried that the new EU approval system will be too bureaucratic, while others argue stricter rules are needed to protect patients from faulty products.

Faced with political deadlock, the Parliament's ENVI Committee decided to postpone the vote until 18 September, leaving enough time for MEPs to work on compromise amendments.

"There is no doubt for me that we need an efficient system of market access for medical devices that satisfies the highest possible safety standards in order to serve the needs of patients," said Holger Krahmer, a German MEP from the liberal ALDE group, who is shadow rapporteur on the proposal.

"I believe that there is a lot of room for improving the current system," Krahmer told EurActiv.

While the Commission wants more scrutiny of existing national bodies in charge of authorising medical devices, the German rapporteur on the draft regulation, Dagmar Roth-Behrendt (Socialists and Democrats), proposed a much stricter centralised pre-market authorisation system.

Krahmer said full centralisation would make the approval system too burdensome and he prefers to "dramatically" improve the performance of existing notified bodies at the national level. The current process of market surveillance itself also needs to be re-jigged to guarantee better coordination, he said.

"This includes additional obligations on manufacturers like unannounced on-site inspections which are crucial to strengthen the current system. Furthermore, we need to enhance the availability and use of clinical expertise to guarantee the highest possible safety for the patients. Besides these, stricter requirements should apply to the competent authorities supervising the notified bodies," Krahmer said.

Too bureaucratic...

But he said a centralised approval system would be going a step too far. "I do

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not see any benefits for patients' safety if we just introduce a centralised pre-market authorisation at EU-level as rapporteur Dagmar Roth-Behrendt proposes," the shadow rapporteur added.

Marina Yannakoudakis agrees. The British MEP is a shadow rapporteur on the proposal for the European Conservatives and Reformists (ECR) group. Although she thinks patient safety must be top priority, she is is opposed to a new centralised approval system, which she says will "create another layer of EU bureaucracy".

> "Too much bureaucracy in the certification process may also cause delays in marketing devices, especially for SMEs"

"Our response must be proportional and limited to only ironing out the flaws and shortcomings within the current regulatory framework rather than starting again from scratch. We need to keep a member state-driven approach for notified bodies rather than handing conformity assessment, inspections and tests over to another opaque EU quango," Yannakoudakis stated. Quango is an acronym for a quasi-autonomous organisation.

The British Conservative MEP added that innovation in the medical devices sector also has to be protected.

"Too much bureaucracy in the certification process may also cause delays in marketing devices, especially for SMEs," she said, relaying concerns expressed by the medical technology industry.

... or more ambitious

Not all MEPs agree.

Michèle Rivasi, French MEP and shadow rapporteur for the Greens, said the current approval system does not guarantee safety for patients as problematic issues have occurred, even after the PIP scandal last year.

Today's market approval system for medical devices relies on national notified bodies and this is not enough, Rivasi stressed.

She remarked that national authorities are mostly funded by the manufacturers who seek approval for their devices. Therefore, the EU does not guarantee the competence of these bodies or their subcontractors, she said.

The French MEP added that Roth-Behrendt has introduced a crucial element in her report. This relates to pre-market authorisation for certain medical devices, with sufficient pre-clinical data on quality and effectiveness of the device.

This is something the Greens have long championed.

"We must never forget that for implantable devices, 'entering the market' means 'to be implanted in the patient's body.' And medical devices are not drugs. If a fault occurs you cannot simply stop the treatment. You need to re-operate the person, with all the risks that this entails," Rivasi told EurActiv.

Danish MEP Christel Schaldemose, an S&D member of the ENVI Committee, said she supports Roth-Behrendt's report as she has previously made proposals that go in the same direction.

"I'm really happy that Roth-Behrendt in her report tightens and makes the system for medical devices safer than it is today," Schaldemose said.

"The Commission's proposal is definitely a step forward, but Roth-Behrendt is even more ambitious. And this is necessary," the ENVI Committee member added. "Unfortunately, we have witnessed too many bad cases with medical devices, hurting patients. We can't accept this. We as politicians have a responsibility to protect consumers."

In-vitro devices need more transparency

Dr Peter Liese, a German MEP from the European People's Party (EPP), is rapporteur on a related regulation on in-vitro devices, which typically include blood tests for glucose, liver enzymes and tests for drugs.

In his report, Liese stresses the importance of reliable testing for proper diagnosis and treatment of health conditions. He favours continuing the current system by improving the functioning and supervision of national bodies.

In his report, Liese calls for more transparency in the definition of medical devices. For some devices, such as genetic tests, there must be informed consent, Liese stressed, to avoid misunderstanding and serious consequences for patient's health. The conservative MEP also recommends that single-use devices, like syringes, are placed under strict rules and should not be reprocessed.

US doctors look with envy at Europe's medical devices approval scheme

The scrutiny procedure on medical devices in the US is so strict that American doctors say the system works against the interest of patients, leaving some waiting years for treatment that could save their lives. European doctors now start to worry that a similar system envisaged in the EU could have the same impact.

American doctors are frustrated that the US approval requirements for cardiovascular devices, for example, are much more stringent than in Europe, due in part to the centralised approval system.

"There is a frustration among … US care providers around delayed access to certain interventions that appear to be a winner," Dr Patrick O'Cara, a cardiologist with Brigham and Women's Hospital in Boston, told the Reuters news agency.

A common example used by US doctors are heart valves made by Edwards Lifesciences. The US company says its transcatheter aortic valve replacement (TAVR) system is particularly well suited for elderly and frail patients since it can be put in place through an artery rather than by cracking open the chest for heart surgery.

"With this disease, if you wait two or three years, 60-80% of [patients] are dead," said Dr Martin Leon, director of the Centre for Interventional Vascular Therapy at Columbia University Medical Centre in New York. "So not to have the most updated version of the device to treat more patients like this doesn't seem to be a particularly good idea."

Leon said some researchers are now calling the US "a Third World country" when it comes to availability of cutting-edge heart devices.

In Europe, EU institutions are currently looking at ways to tighten safety of medical devices after faulty breast implants placed the issue at the top of the political agenda in late 2011. The European Commission tabled a proposal which is now being examined by the European Parliament.

Some lawmakers in Parliament have said the EU system is too lax, calling for a model which resembles the US centralised approval model rather than the current decentralised one, where each country sets its own legal and safety requirements.

Dr David Holmes, a cardiologist at the Mayo Clinic and a past American College of Cardiology (ACC) president, said a middle ground was probably the best way forward. "I think we need to meet somewhere in between," Holmes said, adding that Europe might need to tighten its regulations without necessarily adding delays to its nimble approval process.

US system or not?

In the European Parliament, German MEP Dagmar Roth-Behrendt (Socialists and Democrats) is responsible for steering the new medical devices legislation through the assembly.

She has proposed a pre-market approval procedure for high-risk devices (Class III) such as pacemakers and other implants, which are inserted inside people's bodies.

Her draft report suggests establishing a Committee for the Authorisation of medical devices within the European Medicines Agency (EMA) to oversee the process, where

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> "The US system of approval also faces some problems and I have not used it as an example for the changes I propose"

patients would be represented.

Industry has warned that this approval system was as complex as the US one and might create the same kinds of delays. But Roth-Behrendt told EurActiv that she thinks this comparison is particularly misleading as she does not refer to the US system in her draft report.

"The US system of approval also faces some problems and I have not used it as an example for the changes I propose," she told EurActiv.

"The system which I have proposed, for the authorisation of the highest potential risk class of medical devices, is based on the fact that, in the recent past, too many unsafe medical devices, such as hip prosthesis or breast implants for instance, have been inserted into the body of thousands of patients. Those devices had received an approval to be placed on the EU market," Roth-Behrendt stated.

Dr Angelo Auricchio, who is member of the European Society of Cardiology and president of the European Heart Rhythm Association, said he was unsure whether the Parliament rapporteur has introduced something new.

However, he welcomed amendments to the proposal that he says has given patient groups the opportunity to be part of the preview process along with physicians and technologists, under the authority of the European Medicines Agency (EMA).

"But the fact having a pre-market approval and to have under the same large agency like the EMA… You have everything going there from devices to pharmaceutical components. This is not the right thing to do. You may not want to use the words 'it's a US-like system', but it is a US-like system," Auricchio said in an interview.

"De facto, it is like in the US. So even if you don't name it that essentially this is what it is."

US system described as 'nonsense'

America's bulky approval system is routinely used as a benchmark in Parliament debates.

At a Parliament conference on medical devices held in February, professor Werner Siebert, who is also medical director of the Vitos Orthopaedic Clinic in Kassel, said the current EU system is satisfying if everybody does the job correctly.

However, he suggested that the EU may have too many notified bodies at national level that are empowered to approve new devices.

Siebert does not see any added value in the European Commission's proposed scrutiny procedure. But he says a pre-market approval system for the most risky categories of medical devices could be necessary.

Professor Panos Vardas, the president the European Society of Cardiology (ESC) agreed, adding that the first priority should be to ensure the safety of patients fitted with high-risk implants.

"The ESC advises that high-risk medical devices should be evaluated only by notified bodies with proven expertise in evaluating the specific type of device under consideration. Regulation should give the Commission the authority to designate notified bodies for particular applications," he said.

Auricchio said that instead of a pre-market approval, Europe should improve the synchronisation of the different national regulators.

"The problem is that we know very well that some competent authorities in Europe are extremely good and I would say even better than the American competent authorities. So it's a matter of better coordination of knowledge among the competent authorities," the doctor said.

He added that the FDA system in the US would have been unable to prevent the scandals recently seen in Europe.

"As a physician and possibly in the future as a patient, what I would like to have is certainly a safe therapy, but as soon as I'm exposed to any therapy, there's always a risk of having a problem and unfortunately that is how it is, dealing with technology," he said.

"It's actually nonsense to have a pre-market approval as the FDA has. Patients in the US often wait 4-5 years longer for great therapies that we have in Europe. We have a great advantage. These advantages have to come with the knowledge of potential risk, but what you want to do is to limit the risk and to accurately monitor the effect of the therapy," Auricchio stated.

He explained that in the US, some devices that are not characterised as high-risk (Class III) now undergo the same scrutiny process as because of safety concerns.

FDA 'losing' credibility

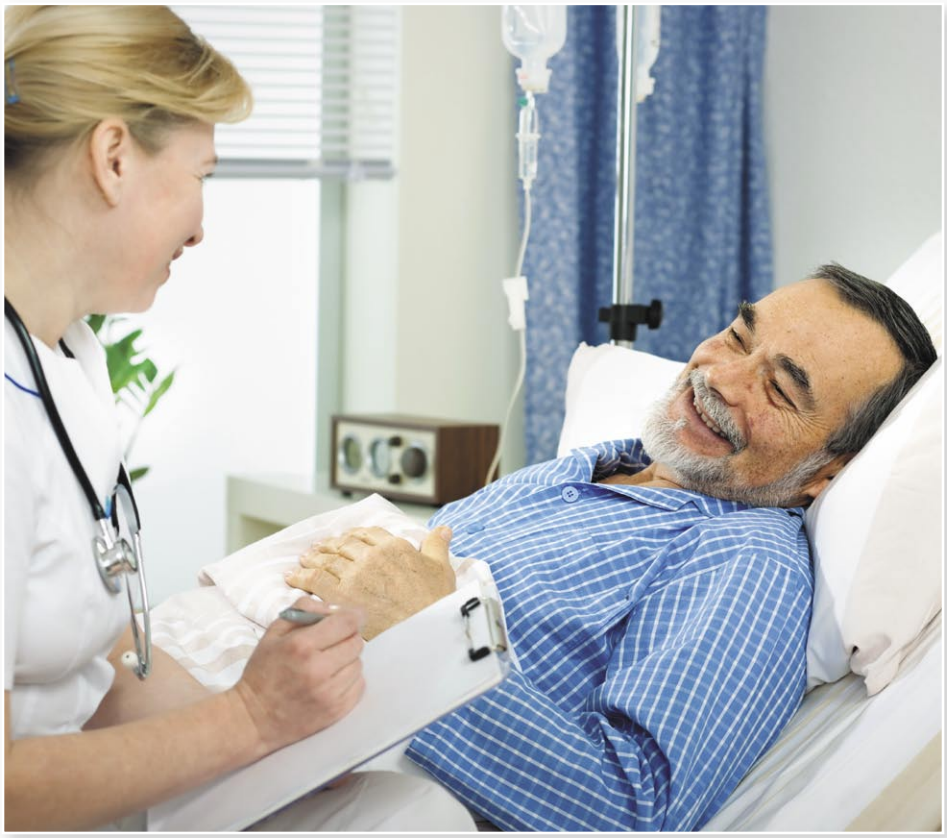
Auricchio said Europe was now also having "problems" with the FDA as the American authority wants to impose its rules on the rest of the world.

"They understand that because they have been heavily criticised by American doctors for increasing regulation without a significant benefit for the US system or for US doctors. They are losing now their credibility and now they are trying to blame someone else on the other side and they try to influence our good politicians," Auricchio said.

But Europe should be happy with its system, with some exceptions, the doctor stressed.

"I do accept that there have been issues in the past and there continue to be issues, but these issues can be solved. Europe has to have a much different way of regulating things compared to what the US has," Auricchio said.

Patient groups: Safety first in new medical devices regulation



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.

> "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"

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,

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and give them an opportunity to make their views heard before the devices are placed on the market.

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

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

> "Patients also need to understand the risks and benefits of products that are or could be prescribed to them"

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,

Medical tech sector worried about innovation, SMEs

The European medical technology industry worries that a centralised pre-market authorisation system in Europe will destroy innovation, research and development within the sector. It warns especially that small and medium-sized enterprises (SMEs) could disappear with the proposed new system.

The industry said SMEs will not benefit from the proposed system, warning that they are the ones doing most of the groundwork when it comes to inventing new cutting-edge technologies which can save the life of patients.

> "The proposed EU approval system would delay patient access to life-saving medical devices by 3 to 5 years without adding additional safety"

The European Commission has tabled new rules for the approval of medical devices following a health scandal in France involving faulty breast implants.

Dagmar Roth-Behrendt, a German socialist MEP who is in charge of steering the legislation through the European Parliament, has proposed a centralised pre-market authorisation system for so-called 'Class III' devices, which represent the highest risk to patients, such as pacemakers and hip implants.

But Serge Bernasconi, chief executive of Eucomed, the European medical technology industry association, told EurActiv that independent research has shown that the proposed EU approval system would delay patient access to life-saving medical devices by 3 to 5 years without adding additional safety.

He cited one example of a technology called "renal denervation" which is applied for the treatment of severe, uncontrolled hypertension for patients whose condition can't be treated solely by pharmaceuticals. This technology is already saving the lives of patients in Europe while an estimated 7 million Americans with the condition are still waiting for this treatment to be approved.

Other examples cited by Bernasconi include two cardiovascular treatments (Cardiac Resynchronisation Therapy and Transaortic Valve Implantation), which have already provided patients across Europe with an additional 50,000 life years in the period between EU regulatory approval and US approval.

"These are just a few of the many examples where Europeans had access to these devices first and that lives were prolonged because of them. If you are a patient with no other choice – having access to these devices is really a matter of life or death," the executive said.

The suggestion that a centralised pre-market authorisation system will allow for approval within nine months is extremely optimistic, Bernasconi added, referring to the draft report by Roth-Behrendt MEP in the European Parliament's environment and health committee.

"There are points in the process which allow for potentially severe delays. Eucomed acknowledges that change is needed to improve the system, but this proposal shares many of the same well-known problems that cause delays in patient access and stifle innovation in the US under the FDA system," the industry representative stated.

Consumers, patients call for safety first

Monique Goyens, director-general of the European Consumers' Organisation

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(BEUC), has repeated along with patient groups that safety must be the top priority in an updated EU medical devices directive.

It underlined that 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.

Goyens supports calls for a centralised pre-market authorisation system and said the industry was not focusing on the right issues.

"We believe that the issue of a pre-market authorisation giving unnecessary delays is the wrong question. There is anyway a long delay from when a device gets a classification and until the patient has access to it," she said.

Killing smaller companies?

> "Too much bureaucracy in the certification process will cause delays in marketing new devices"

This view is not unanimously shared however.

Marina Yannakoudakis is a British MEP from the Parliament's European Conservatives and Reformists (ECR) group, who is a shadow rapporteur on the medical devices regulations.

She told EurActiv she is worried that too much bureaucracy in the certification process will cause delays in marketing new devices, citing the example of a small US company called CardioFocus.

CardioFocus manufactures products to treat atrial fibrillation, a very common hearth rhythm defect. Its product are implanted inside the heart and for this reason, they are classified as Class III device, meaning that risks associated with them is highest, receiving a great deal of approval scrutiny.

Stephen W. Sagon, who runs CardioFocus, said his company has tried to get its products on both the US and EU markets and experienced how the two different approval systems work.

CardioFocus brought the device to Europe in early 2009 and achieved a CE mark within a relatively short period of time. In the US a feasibility trial began in late 2009, and CardioFocus finally received permission to begin a clinical trial at the beginning of 2012.

"Call that a 2-3 year lag before we could secure FDA permission to initiate our trial," Sagon said in an interview.

"Ultimately, the difference in the size of the clinical experience that was required for approval was an order of magnitude larger in the US than it was in Europe," he said, adding that CardioFocus is still engaged in a clinical trial in the US.

"We have treated more than 1,000 patients in Europe since we began. Probably closer to 1,200-1,300. The product is working quite well. It's only because it works so well that we continue to enjoy some real commercial success," Sagon said.

As SMEs usually perform better when it comes to innovation within healthcare, according to Sagon, a stricter EU system with larger requirements of capital available to continue the efforts would result in the smaller companies scanning the globe for places with less commitment of resources.

Potential backlash

Daniel Bertholet, who is on the Medtech Task force of the European Venture Capital Association (EVCA), told EurActiv that he had sent letters to MEPs and Commissioners to express his concern about possible changes in the medical device regulation.

He warned there could be a potential backlash on innovation, for SMEs in Europe, on jobs and patients as well.

Bertholet said Europe is one of the world-leading centres for medical technologies with a great medical community, very innovative, ready to try new technologies. The medical doctors are innovative in Europe and there is a strong engineering tradition as well. The industry employs more than 500,000 people, turns over €95 billion per year and encompasses some 500,000 different medical technologies.

"What we have seen in the last five years is that the FDA [US Food and Drug Administration] has raised its regulatory requirements so much that most US companies have come to Europe to perform their clinical development and launch their product in Europe first because they cannot access the US market before about four years. This can also happen in Europe if the regulation goes through as it has

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been proposed by the ENVI Committee," Bertholet said.

> "Now the system is at risk and this is too bad for Europe"

"The European system benefits patients and innovation in Europe. It's currently taking jobs from the US. It also means the most recent and innovative procedures are currently not available to US patients and medical doctors. Now the system is at risk and this is too bad for Europe," he said.

'Risk of overshooting'

> "If we have a centralised regulatory system in Europe, we will lose innovation"

A centralised pre-market authorisation system in Europe would have a "dramatic" impact, according to Bertholet. He said companies will go bankrupt because if it takes five years to get market approval, it will be difficult to get financing as no one would want to lend to a company for five years without revenues.

"If we have a centralised regulatory system in Europe, we will lose innovation. We will have research and development in Europe, but the clinical development will be done somewhere else and the market launch will be done in some other places for example in emerging markets," the investor said in an interview.

"A reform is necessary, don't misunderstand me, but the Parliament is at risk of overshooting because of the PIP scandal which is really a fraud problem. There are other issues at stake, not only patient safety. There's also job creation and to keep innovation in Europe," Bertholet added.

> "If the new regulation is approved as such, many European companies would probably have to relocate to Asia"

He said that due to the FDA's stricter approach in the US, less money is now invested in medical devices. A lot of investors have exited the sector, as they see it as a 'high-risk sector', and this could also happen in the EU.

"If the new regulation is approved as such, many European companies would probably have to relocate to Asia. They would have to turn global very quickly. Jobs would be created elsewhere and patients would be treated later in Europe than other patients around the world," Bertholet said.

Balance and trade-offs

Asked how many heart patients have died in the US, waiting for CardioFocus's product to come on the market, Sagon said:

"It's certainly impossible to know. What we see today is that devices that are approved for our clinical application are reporting less successful results than we are. I don't think as a result, I could have counted the number of patients who have been neglected, but I could probably say that more patients would have been better treated had they had access to this technology at an earlier date."

The CEO of CardioFocus said the healthcare systems make the determination to do no harm, a pledge very similar to the physician's oath.

"By doing no harm, does that mean you are doing the best possible job you can? Because trying to do the best job possible job can always involve the risk that you might fall short. These are inherent trade-offs," he said.

"I think at the end of the day, it's about balancing the assurance of quality, most importantly, the quality of the people that you engage to do the work," Sagon stated.

The CardioFocus executive said the European system has created an opportunity to engage the highest quality people to do the most efficient work. It has helped European physicians be at the forefront of their field, helped European patients received the best therapy and European universities and medical centres now offer the best therapies. It has also provided a boost for the industry and to economies.

"It's not that the more time you spend in the approval cycle, the better things are going to be. Rather, it may simply mean the more expertise you bring to the entire process, the better things are likely to turn out," Sagon said.

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