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FEATURE

REGULATION OF MEDICAL DEVICES

Devices and desires: industry fights toughening of medical device regulation in Europe

Proposals for regulating medical devices, which the European parliament will vote on next month, are proving controversial. **Deborah Cohen** investigates the arguments

Deborah Cohen *investigations editor BMJ,*

"Kafkaesque" and "harmful to patients" are just two of the ways that new proposals to change the way medical devices are regulated in Europe have been described by industry organisations.

The planned reforms would create an "FDA-like system [that] would kill patients and kill innovative companies," says Eucomed, the European medical technology trade association.[1]

But, as previous *BMJ* investigations have shown, the current system for allowing devices on to the market leaves patients across Europe vulnerable to poorly performing products.[2] The system has led to a raft of headlines involving failed devices—including hip prostheses, intracranial stents, vaginal meshes, breast implants, and pacemakers.

Some of the 80 notified bodies—private organisations charged with evaluating the safety and reliability of devices—have been exposed as being more interested in attracting business than guarding the safety of patients. It's those bodies that give companies a certificate to allow them to display a CE mark and sell throughout Europe.[2]

It's a system that academics have described as "fragmented, privatised, and largely opaque; safety is dealt with in an unsatisfactory way and efficacy not at all."[3]

And it would seem that many members of the European Parliament (MEPs) agree. On 25 September, a committee of MEPs on the environment, public health, and food safety committee of the European parliament agreed a series of changes that will see far more oversight and transparency than before with extra scrutiny for the highest risk devices.

Fifty two MEPs voted in favour, 12 against, with three abstentions. All of the ECR group—which includes the UK's Conservative party—voted against.

Good or bad?

But are the new proposals, which MEPs vote on later this month, a boost to patient safety or will they lead to economic demise and patient harm—the opposite of what they're intended to do? It depends who you listen to.

For some, the changes don't go far enough—they would have liked to have seen a central body assessing the safety and efficacy of high risk devices, as German socialist MEP Dagmar Roth-Beherendt, at the helm of the changes, initially proposed.

"I've been over 20 years in Brussels and I haven't seen such strong lobbying pressure before," she told *Der Spiegel*, the German weekly news magazine, this week.

The European Association for the Study of Diabetes (EASD) has also called for a central "European Device Agency."

They are also anxious that the insulin pumps and other equipment used to treat people with diabetes might not fall into the "highest risk" category and therefore won't have extra oversight. "We are talking here about devices that people depend on for their lives, such as insulin pumps and technology that monitors blood glucose," says Professor Andrew Boulton, the president of EASD.

But some—including the Directorate General for Health and Consumers (DG Sanco), the health arm of the European Commission—do not like that approach.

Eucomed and the DG Sanco work closely together. At a recent launch party to celebrate the launch of new Eucomed offices, for example, representatives from DG Sanco provided an official welcoming statement.

Neven Mimica, the European Commissioner for consumer policy, told the *BMJ*: "We are happy that we have departed from the idea of a centralised body in charge of authorisation. It is felt that the current proposals strike the right balance between innovation and safety," adding: "We want to keep the edge that industry has here in Europe."

A European Commission spokesperson said: "We do not believe that we are improperly close to industry," adding: "We regularly meet with all parties to discuss the work of the commission."

That "edge" is a key argument in the debate. Even though the proposals have been watered down, Eucomed is still opposed to the changes and says that MEPs have failed to make good political promises to support European innovation and boost

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jobs. Europe is risking its position as a global leader in the numbers of patents filed, says a 2013 Eucomed factsheet.[4]

Eucomed surveyed its members to assess the financial impact of the proposed changes and estimated that it would cost an extra €1m-€4m (£850 000 to £3.4m; $1.4m-$5.4m) to bring a high risk device to market.[4] Some of those costs come from the requirement for more clinical evidence before manufacturers can market the products in Europe. The survey findings were drawn from responses of just 19 of a potential 25 000 device makers in Europe.[1]

Eucomed hopes that politicians will prioritise profit and employment protection. As one medical technology pundit laid bare on an industry website this month: "The world's medical device makers, small and large alike, rely on Europe's efficient decentralised approval system to launch their products in a timely manner and prove to investors that their products serve patients well and are financially viable," they wrote.[5]

Not everyone is convinced. Pierre Chirac, vice-president of *Prescrire*, the French medical journal that has argued that patients need better protection, says the same points were made to stop drug regulation being tightened.

"On the economic side, the medical device companies' arguments are very similar to those heard between the 1960s to 1980s, when pharmaceutical companies were anxious about drug approval becoming stricter," he told the *BMJ*.

Slower to get devices

Another plank of Eucomed's campaign against the proposals is called, "Don't lose the 3." Far from being guinea pigs for the US market, Europeans benefit from getting "life saving" procedures at least three years before Americans, says Euromed. Manufacturers have to demonstrate the safety and effectiveness of many high risk devices before the US Food and Drug Administration grants market approval —something that doesn't routinely happen in Europe, as *BMJ* investigations have shown.

Examples cited include the transcatheter heart valve (TAVI) and renal denervation to control severe hypertension—a procedure seven million Americans are waiting for, according to Eucomed.[1]

The evidence for "Don't lose the 3" comes from a June 2012 report by the Boston Consulting Group (BCG), funded by the medical technology industry, which looked in depth at 62 high risk devices approved in both Europe and the US.[6] The group could get European data on only 172 out of 302 high risk devices approved during 2000-11.

A Eucomed spokesperson told the *BMJ*: "The 'Don't lose the 3' campaign is based on facts and informs Europeans what could happen to them if a centralised system as seen in the US is copied into Europe."

But critics of the report say that three years is an exaggeration and question the BCG research (and Mimica later admitted the figure was a bit extreme). They say that the latest proposals on the table are actually quite different from the FDA approach.

Not that industry agree—the *BMJ* has seen an invitation to MEPs sent by a group of industry associations this week arguing that the new proposals are like the FDA "a pathway we always tried to get around for good reasons". It goes on to say that industry has "severe concerns" and some fears it will "shut down business".

But a report by German National Associations of Statutory Health Insurance Funds, *Medical devices: myths and the truth*,[7] points out that the three year difference arises not because of the time it takes the FDA to approve a device after data are submitted but because of the requirement for trials to show it is safe and effective, which is not routine in Europe.

But this earlier access to life saving technologies does not factor in health service considerations across Europe—reimbursement or health technology appraisals that green light the use of a product. Access to market is one thing; access to a patient is another. Renal denervation, for example, has been approved in Europe since 2010 but has only been fully reimbursed in Germany and Austria as of 2013, according to healthcare analysts GlobalData.[8]

Joseph Gregory, surgical devices analyst at GlobalData, says it's the state of the clinical data that is important. "While company-sponsored studies have to date proven short-term safety and efficacy, there is still ambiguity with regards to device performance in the long term, as well as the degree of efficacy that can be achieved," he said in a press release this month, three years after the device was CE marked.[8]

"Further, looking at long-term procedure outcomes for renal denervation, there is very limited data available, as the longest follow-up to date is just three years," Gregory said.

So, although devices seem to get approval far quicker in Europe than in the US, there can still be many delays before they are used on patients.

Others also question if fast track access is always a good thing. As reported in the *BMJ*, widespread early adoption of the transcatheter heart valve before the trials had reported for the US market meant that the device has been not always used in the right subset of patients.[9]

Rita Redberg, a cardiologist and editor of *JAMA Internal Medicine*, has testified to Congress in the US about device regulation and questions some of the points made by Eucomed.

"I think we need to be more specific about 'innovation.' Most new devices are not innovative. And even if they are—unless they are life saving and there is no other treatment—I think we need clinical data to show safety and effectiveness before getting on the market and better postmarketing surveillance as well," she told the *BMJ*.

Revolving interests

It's not the first time that the BCG has produced reports for industry that support the status quo. A 2011 report analysed device recalls in both the US and Europe and found that there was little difference. "Differences between the two systems do not ultimately affect performance," it said in a press release.[10]

Quoted on the press release, was John Wilkinson, then chief executive of Eucomed. He said: "The current EU regulatory system makes innovative medical technology available to people the fastest in the world while ensuring the highest safety standards."

Fast forward to 2013, Wilkinson—in his role as head of medical devices at the UK's Medicine and Healthcare Products Regulatory Agency (MHRA)—describes the European proposals as "disproportional" and says that the MHRA is uncomfortable with the ambiguous language.[11 12] The MHRA also opposed a central device agency.

A MHRA spokesperson says: "We have been clear from the outset of negotiations that it's vital that the European system of regulation is strengthened so that people are protected against unsafe medical devices," adding: "We have also been clear that any changes to the regulatory system should be proportionate and deliver real benefits for patients."

Some see this kind of positioning as an example of the fast moving revolving door between policy makers and politicians and industry that is clouding the debate.

Former MEPs and former employees of the public health arm of the European Commission are now lobbying on behalf of industry. Dario Pirovano, an Italian national who drafted earlier devices guidance when he worked at the commission, is a regulatory adviser to Eucomed.

Former Conservative MEP, John Bowis, is now honorary president of Health First Europe, an industry-patient alliance, and wrote on the European parliament website that reducing rapid access to medical technology "ultimately harms patients rather than protects them"—perhaps overlooking some of the furore around some hip implants that appeared on the market without having to undergo clinical studies.

Bowis's view is that patients' organisations are willing to take on risk to progress new cures and treatments. "We want risk minimised and monitored; we do not want no risk," he said. On the parliament website, there is no mention of the fact that Health First Europe's entire 2013 funds were all from Eucomed.[13 14]

Celine Bourguignon is a former member of the commission, where she was a policy officer in the cosmetic and devices division. She is now lobbying MEPs on behalf of Cordis-Johnson and Johnson against proposals to make it more difficult to label a device as single use only.

However, despite the fierce battle for hearts and minds, Commissioner Mimica told the *BMJ*, he thought that no European countries were totally against the need for change. How this all plays out when MEPs gather later this month remains to be seen.

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How Europe wants to get tough on device regulation

- Special “notified bodies” will be formed to oversee the CE certification of high risk medical devices
- Notified bodies will have “in house” staff with medical, technical, and pharmacological knowledge and be able to assess or challenge evidence
- A new requirement to have a review of clinical studies by a “third party or external expert under the principles of highest scientific competence and impartiality”
- The names of those in charge of assessment and any relevant conflicts of interest will be published
- An assessment committee with groups from 21 medical and surgical specialties will scrutinise the evidence around some high risk devices. When there is concern about a particular device, it will be sent to this committee
- There will be unannounced inspections of the notified bodies
- Introduction of an open access databank called Eudamed that will log devices, including those removed from market
- Eudamed will contain certificates, details on clinical investigations, and postmarketing follow-up
- Patients harmed will be compensated for any damage and associated treatment as a result of a faulty medical device. Insured for insolvency
- Devices will come with an implant card that is to be given to patients and recorded in notes