MEDTECH INSIGHT
CITELINE COMMERCIAL

01 Oct 2012 | **News**

EU Device Reform Proposal Adds More Government Scrutiny, But No FDA-Like Review Body

by

The recommendation attracting the most concern from industry: a new Medical Device Coordination Group that would have the option to scrutinize third-party pre-market assessment reports for select devices prior to marketing.

The European Commission's proposal to reform the oversight of medical devices and diagnostics does not envision a pre-market approval agency akin to FDA as some had feared, but it would clearly increase the role of government in the process and slow launches for some products.

The Commission, which serves as the executive branch of the European Union government, issued proposed legislation Sept. 26 to make large-scale revisions to the highly decentralized regulatory system for devices and diagnostics sold in the 32-country region.

Despite steering clear of a centralized government approval process for devices, the proposal includes one provision that companies worry will bring the EU closer to such a system and unnecessarily delay product marketing. Specifically, the Commission wants a new "scrutiny mechanism," where a cross-continent Medical Device Coordination Group would have the option to review third-party pre-market assessment reports for select devices before the products go to market.

Eucomed, the European device industry trade group, had anticipated the scrutiny proposal and warned against it earlier this month. (See (Also see "*Europe Device Reg Reform Proposal: More Scrutiny Of Notified Bodies Expected*" - Medtech Insight, 24 Sep, 2012.).) Now the group will advocate for its removal as the Commission's plan is considered by the EU's two legislative bodies, the European Parliament and the European Council. Eucomed will also need to dissuade legislators who believe the EU requires an even stronger pre-market review process than

proposed by the Commission in response to recent product safety controversies in the region.

> ***Eucomed will press legislators to remove the scrutiny mechanism from the final rules, while also working to dissuade those who believe the EU needs an even stronger pre-market review process than proposed by the Commission.***

"Stronger Presence" For National Authorities

Current EU rules are controlled by the Medical Device Directives (MDD), which were adopted by member countries in the 1990s. Under the current system, non-governmental notified bodies are paid a fee by manufacturers to review documentation supporting the safety and quality of a device, with the level of review depending on the risk level of a device. For higher-risk products, notified bodies must certify the product before a company can affix a CE mark and sell it across the EU. Notified bodies also monitor and inspect manufacturers in the post-market phase.

Notified bodies apply the standards set out in the MDD, as interpreted by each member country. But policymakers say government authorities in each country are not necessarily aware of a device before it reaches the market, and there are large gaps in the countries' ability to coordinate responses to safety concerns with marketed products.

In general, standards have not been employed in a consistent way across different countries and from notified body to notified body, the Commission acknowledged in announcing the reform proposals.

At the heart of the reforms are a push for a "stronger presence" by national competent authorities in each EU country, said John Dalli, the EU commissioner for health and consumer policy, during a Sept. 26 press conference in Brussels.

"We are saying that the national competent authorities should be much more present than they were in [pre-market] authorization and [post-]market controls," Dalli said.

Selected Reform Proposals

- Scrutiny mechanism: An EU-wide expert group will have the option to review notified body conformity assessments for high-risk devices before they reach the market

- Stronger supervision of notified bodies by national authorities
- More powers and obligations for notified bodies, including the authority to perform unannounced inspections and sample testing
- New requirements for manufacturers to submit a safety and effectiveness summary to a public EU-wide database for access by patients and providers
- A mandatory unique device identification system
- A new EU-wide "portal" for manufacturers to report device adverse events and corrective actions, and a new mechanism for a "coordinating authority" to respond to safety issues occurring in more than one country
- Expanded scope of the device and diagnostic regulations to cover implants used for aesthetic purposes, disease predisposition tests and some medical software
- Tighter requirements for reprocessed single-use devices
- New standards for test services developed and performed in the same laboratory: All must comply with diagnostic device post-market vigilance standards, and those test services in the highest risk category would be subject to all pre- and post-market standards

In addition to the scrutiny mechanism, the Commission proposes stricter standards for notified bodies to become certified to assess manufacturers and stronger powers for the notified bodies themselves, such as allowing them to perform unannounced facility inspections.

Further, it introduces a new EU-wide "portal" to which manufacturers would need to submit information on device adverse events and corrective actions. The proposals establish a mechanism for a "coordinating authority" to respond if similar adverse events are reported in more than one country.

The proposals also include new requirements for manufacturers to publically disclose summaries of safety and effectiveness for high-risk devices on an emerging, standardized EU database; new rules for initiating device clinical trials in the region; and a new unique device identification mandate, paralleling UDI efforts in the U.S. (See (Also see "*Final UDI Rule Date Uncertain, But Firms Should Prep Now, FDA Says*" - Medtech Insight, 24 Sep, 2012.).)

Under the plan, the current directives would be replaced by regulations, which allow less interpretive leeway by individual countries.

Technically, the Commission issued the reforms as two separate proposed regulations, one addressing medical devices and the other addressing in vitro diagnostics. The documents are largely identical, with all of the fundamental reforms applying to both product classes.

But there are some provisions specific to each. For instance, the device regulation specifies that the scope of device oversight will extend to products manufactured utilizing non-viable human

tissues or cells and to invasive products that have an aesthetic rather than medical purpose but are similar in design to medical devices.

The diagnostics rule, meanwhile, establishes EU-wide oversight for laboratory-developed tests, defined as tests that are developed and performed by the same institution as a service. It also clarifies that the regulations cover tests used to determine disease predisposition and software intended for diagnostic purposes.

Pre-Market Not The Problem, Commission Says…

The Commission first signaled plans for device reforms in 2008, when it asked for input from stakeholders. The process began shortly after the EU government had approved incremental changes to the MDD system, reflecting officials' recognition that more expansive revisions were needed. (See (Also see "*Industry Calls For More Consistent European Oversight As EU Continues Reg Reform Process*" - Medtech Insight, 5 Dec, 2011.).)

Since then, high-profile safety issues with devices have intensified public pressure for added government scrutiny, and prominent health care groups have called for a centralized pre-market review process closer to how Europe handles drugs and how FDA oversees devices and drugs in the U.S. (See (Also see "*Cardiologist Group Calls For Centralized Device Oversight In Europe*" - Medtech Insight, 23 May, 2011.).)

The breast implants that French manufacturer Poly Implant Prothèse (PIP) marketed with industrial-grade rather than medical-grade silicone have sparked particular outrage in the past year. (See (Also see "*U.K. Health Dept. Recommends Stronger Adverse Event Reporting System In Wake Of Breast Implant Scandal*" - Medtech Insight, 21 May, 2012.).) The European Parliament in June responded to that controversy by passing a resolution calling for various upgrades to the device oversight system, including a “shift” to a pre-market authorization system for high-risk devices.

The commissioners adopted many of the ideas found in the resolution, but they resisted the pre-market authorization approach, noting that the cost of building a new EU regulatory authority and the impact on innovation would not equal any benefit gained.

“Any problems in our system were not caused by the pre-market processes and procedures,” Dalli said during the press conference. For instance, he noted that the PIP breast implant matter was the result of fraud by the company, which marketed its implants using a different material than was certified by notified bodies in the pre-market phase.

“It’s not a question of authorizing something, but monitoring in the market,” Dalli said.

Increased coordination among EU countries to track and respond to safety issues is a crucial

piece of the reforms, as is the newly proposed power for notified bodies to show up unannounced for inspections of device manufacturing facilities, the commissioner said.

...But "Scrutiny Mechanism" Proposed Anyway

Nonetheless, the Commission is proposing several revisions to the pre-market phase, with the new scrutiny mechanism front and center.

Under that proposal, a notified body would be required to inform the Commission and the Medical Device Coordination Group of any conformity assessments it has conducted for high-risk, class III devices. The Coordination Group, made up of device experts from the member countries and supported by the Commission, would then have 28 days to ask the notified body to send a summary of its preliminary assessment prior to certifying the device. The Coordination Group would then have 60 days to submit comments on the assessment to the notified body. During that period, the group could request additional information within 30 days, and the 60-day clock would stop until the information was submitted.

> *Eucomed's Serge Bernasconi says he would expect a minimum 4-6 month delay for products undergoing the scrutiny process, but it could be much longer if the Coordination Group raises a question during its review.*

A notified body would not be obligated to follow recommendations from the Medical Device Coordination Group, but would be required to "give due consideration to any comments received," the reform proposal states. Further, the notified body would have to "convey to the Commission an explanation of how they have been taken into consideration, including any due justification for not following the comments received, and its final decision regarding the conformity assessment in question."

Eucomed said it welcomes most of the Commission's proposed measures, but that it has serious concerns with the scrutiny mechanism because of the delays it will cause in bringing new products to market.

"The measure would address some political calls to move the system towards a centralized pre-market authorization system as found in the United States, but will ultimately result in harming European patients and negatively impact mostly European small- and medium-sized

enterprises," the industry group said in a press statement.

In an interview, Serge Bernasconi, chief executive of both Eucomed and the European Diagnostic Manufacturers Association, said he would expect a minimum 4-6 month delay for products that undergo the scrutiny process, but it could be much longer if the Coordination Group raises a question during its review.

"If it is a simple, straightforward question that is in the file, yes, that could go relatively quickly," Bernasconi said. But, "If it is a question that is not handled in the files, then obviously it sets back the entire process until that answer is provided."

The mechanism unnecessarily makes the oversight system less predictable, he contended. "We are concerned that investors might look at this and say, 'Am I really willing to support that type of process when I don't know where it is going?' That is a huge concern. As a result, this could slow down development of innovation and access to innovation in the EU, while the system we have today is working."

But the ultimate impact of the scrutiny mechanism remains to be seen. The Medical Device Coordination Group must specify "a scientifically valid health reason" for selecting a particular file to review and the commission's proposal suggests the process should be the "exception rather than the rule."

Still, Bernasconi worries that even if it is presented as a limited policy, it could rapidly evolve. "We are very concerned that this could expand relatively quickly," he said.

He said Eucomed will try to convince Parliament and Council members to reject the scrutiny mechanism, and will also work to fend off attempts by members of those bodies to double down on the Commission's policies and insert an even more burdensome pre-market authorization process.

"There is that possibility," Bernasconi admitted. "And we are aware of it, very aware of it."

The legislative process could take up to 18 months or longer. If the two bodies can agree on final rules, they will be implemented by the Commission and the national governments. The Commission expects that the reforms will "gradually come into effect from 2015 to 2019."