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EU Parliament Panel OKs Pre-Market Review Process Derided By Industry

by

The compromise pre-market provisions merge components of a pre-market “scrutiny” procedure proposed last year by the European Commission and proposals from legislators seeking even stricter pre-market oversight. The CEO of the industry trade group Eucomed calls it a “PMA in disguise carried out on a case-by-case basis” and says it will harm innovation and patient access to new technologies if adopted.

The European Parliament’s Public Health Committee approved a new pre-market review process for high-risk devices amid 30 accepted compromise amendments to medical device and diagnostic reform legislation Sept. 25.

The compromise authorization provisions merge components of a pre-market “scrutiny” procedure proposed last year by the European Commission and proposals from legislators seeking even stricter pre-market oversight. (See (Also see "*Pre-Market Question Attracts Debate At EU Parliament Session On Device Reforms*" - Medtech Insight, 11 Mar, 2013.).) The reform package, which was approved by a vote of 52 to 12, with three abstentions, is now scheduled to go before the full Parliament for consideration in October.

Committee supporters say the compromise provisions will lead to safer devices. The reform effort was prompted in part by outrage over defective breast implants and safety issues with metal-on-metal hips.

"We have achieved our main objective: Patients will be better protected 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,” said Dagmar Roth-Behrendt, a member of Parliament from Germany who has led the committee’s actions on the device legislation.

The compromise measures would create new "special notified bodies" and a centralized committee that could perform pre-market reviews on select high-risk devices.

Meanwhile, the device industry is indignant that the proposal will harm innovation, suggesting that the costs associated with the new process will be higher than the European device industry's total R&D budget.

"If the proposal is carried in the next plenary vote in the European Parliament it will throw a blanket over European medtech [small-and-medium-sized enterprises], innovation and inbound investment," the trade group Eucomed said in a Sept. 25 statement.

"Special" Notified Bodies, And A New Committee

Currently, nongovernmental notified bodies, which are hired by device makers to review their products and/or facilities, provide the only stamp of approval necessary to launch a device in the European Union. Last year, the European Commission proposed a new nonbinding scrutiny mechanism in which a centralized Medical Device Coordination Group would have the ability to review pre-market conformity assessments performed by notified bodies for select high-risk devices. (See (Also see "*EU Device Reform Proposal Adds More Government Scrutiny, But No FDA-Like Review Body*" - Medtech Insight, 1 Oct, 2012.).)

But Roth-Behrendt and supporters in Parliament saw the need for stricter oversight, and in April, Roth-Behrendt, the designated Public Health Committee rapporteur for the bill, issued a proposal for a more PMA-like process for high-risk devices. Under her plan, either a centralized European Union agency or country-specific authority would need to review and approve a device submission before the product could be launched. (See (Also see "*Pre-Market Authorization And Other Sweeping Proposals Unveiled In EU Parliament*" - Medtech Insight, 22 Apr, 2013.).)

The compromise approved last week appears to try to split the difference, although some details about the finalized amendments remain unclear. First, it would establish a new designation called "special" notified bodies that must handle all conformity assessments for higher-risk devices. The European Medicines Agency, which performs drug reviews in Europe, would be responsible for designating notified bodies as "special" based on their meeting a minimum threshold of expertise in clinical and product-related areas, among other requirements.

EMA would be tasked with managing the network of special notified bodies and encouraging "the

development of conformity assessment benchmarks and to help develop and spread best practice within and outside the network." Specifically, special notified bodies would have to abide by stricter conflict of interest rules, maintain certain types of expertise and experience, and together seek to "find common answers to similar challenges concerning the conduct of conformity assessment procedures in innovative technologies." The approved language also envisions training for personnel and periodic re-assessments of their qualifications.

Any company seeking to market a device in the following category would be required to seek review from a special notified body: implantable devices; class III devices; class IIb devices "intended to administer and/or remove a medicinal product;" and devices manufactured using "tissues or cells of human or animal origin, or their derivatives, which are nonviable or are rendered nonviable."

The second phase of the compromise provisions is the involvement of a new "Assessment Committee for Medical Devices."

The ACMD would be composed of several subgroups specializing in different clinical specialties, for example, cardiology and anesthesiology. Each subgroup is composed of one expert per European member country, and the subgroups would be coordinated by the chairs of each subgroup, plus a representative from the European Medicines Agency and three representatives from patients' organizations.

Under the plan approved by the Public Health Committee, special notified bodies must alert the ACMD of any conformity assessments they are conducting for qualifying high-risk devices. The ACMD could then elect, if it finds necessary, to request the preliminary conformity assessment from the notified body and additional information, and review the device data before it can be marketed.

New Committee Is "Almost Kafkaesque" – Industry

Device firms delivered harsh criticism on the compromise, even as details on the somewhat convoluted Committee voting process were being pieced together.

Eucomed said the compromise was a "rushed deal" that "seeks to satisfy the time pressure that Parliament feels ahead of the European elections," which are scheduled for May 2014, "but not the needs of Europe's patients and doctors."

In particular, the trade group calls the ACMD committee "almost Kafkaesque in its construction with over 600 medical experts chosen from across Europe deciding across 21 subcommittees." Eucomed contends, "No assessment has been made of any kind as to what real safety gains there would be, what delays it would cause for lifesaving devices reaching patients and what the exact cost of the added bureaucracy to European governments and industry will be." The group

estimates that the new requirements would cost between 10 and 25 billion Euros.

The association further questions why the European Medicines Agency – "an agency with limited medical device expertise" – would be qualified to do the job of overseeing the special notified bodies.

"Let it be clear that this is a PMA in disguise carried out on a case-by-case basis and will deal a blow to patient access and medical device innovation in Europe," Eucomed CEO Serge Bernasconi said.

Device Reprocessing, Inspections Also Addressed

Pre-market review is only one of many issues addressed in the device reform legislation and in the compromise amendments. Other topics that are addressed include reprocessing of single-use devices; notified body inspections of manufacturing facilities; and general post-market surveillance and mitigation.

The provisions approved by committee, as with prior proposals, put the onus on original manufacturers to prove that their device is single-use and should not be reprocessed. And even if a manufacturer gains a "single-use" designation, that can be removed if a reprocessor can prove that the device can be reprocessed safely.

The European Commission would also have the authority to curate the list of single-use devices via a regulatory maneuver called "delegated acts."

Eucomed opposes these provisions, citing growing consensus in Europe about safety concerns with reprocessing single-use devices, "including a full ban in France," the group writes.

The compromise amendments also impose new responsibilities on notified bodies – special or otherwise – in the area of inspections. Under the amendments, notified bodies would be required to "conduct unannounced inspections at least once a year of all premises at which the medical devices coming within their remit are manufactured."

Additionally, the European Commission would regulate the level of fees notified bodies are allowed to collect, in order to ensure a "level-playing field across Member States." Further, the amendments state, "These fees shall be proportionate and consistent with national standards of living. The level of fees shall be made public."

Notified bodies' reports on inspections, along with post-market clinical data and unique device identifiers, would be gathered in a database monitored by the Medical Device Coordination Group. That data, along with periodic safety-and-benefit reports, forms the basis of the post-market surveillance strategy, which includes the possibility of revocation of a class III device's

conformity.

The periodic reports on safety-and-effectiveness, the amendments state, shall be submitted once a year for the first two years after initial marketing. The reports shall include summaries of data "benefits and risks of the medical devices, including results of all studies with a consideration of their potential impact on the certification" as well as data "relating to the volume of sales of the medical devices including an estimate of the population exposed to the medical device." (The data would be available to providers, as well as the public upon request.) If, in the MDCG's opinion, the balance of benefits and risks have changed, the group can refer the device back to the notified body, which would change the certification as appropriate.

The amendments also require manufacturers to take out liability insurance before putting a product on the market, to compensate patients in the event of a faulty device. Compliance would be enforced by Member States' competent authorities.

Industry stakeholders say they support some reforms the regulatory process, in particular unannounced inspections and strengthened oversight on notified bodies, which, they say, directly address the safety problems that have surfaced in Europe. But they fear the additional steps and requirements will only serve to degrade the industry and patient access to important treatments and diagnostics.

During a panel discuss at AdvaMed's annual MedTech Conference Sept. 23, in advance of the Committee vote, CEOs expressed those concerns.

"The risk is that we might end up with higher [bar] pre-market and higher post-market," André-Marie Ballester, CEO of Sorin Group, said.

Ballester said that the current CE mark process "had predictability," something he feared would be lacking with the type of reforms suggested by the Parliament.

"What we have seen in United States across the past seven or eight years is continuous decline in funding of small companies," Ballester said. "Europe has been the rising star. I'm afraid this change could slow down this progress Europe has made."

At this juncture, nothing is set in stone. The proposal must be voted in plenary session by the whole Parliament, which is scheduled for sometime during an Oct. 21-24 session. After that, the European Council, which is made up of the heads of European member countries, must consider the reforms before final legislation is sent to the executive European Commission.

Complicating matters is the May 2014 continental elections, which may upend whatever package emerges.

“We now hope that the improvements we have achieved will not be diluted later in the legislative process,” Roth-Behrendt said.