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Agreement Announced On EU Reg Reforms, But Consensus Is Not Complete

by

The Council of the European Union heralded an agreement on new EU-wide regulations for devices and diagnostics following years of preparation and negotiation. But it appears that one of the three main segments of the government structure, the European Commission, still has misgivings about single-use device reprocessing language, and one other issue, in the negotiated texts, which could make them vulnerable.

Nearly eight years after preparatory work began, European Union legislators have finally agreed on how medical devices and *in vitro* diagnostics will be regulated for the foreseeable future. But a key power player, the European Commission, is reportedly not happy about certain details of the agreement, raising the prospect that the new regulations could still be scuttled.

The Commission, the EU Parliament and the Council of the EU have been engaged in intensive negotiations to finalize the regulations, which would set the framework for medtech design, clinical study, manufacture and postmarket vigilance in Europe for possibly the next two decades.

The Commission was the body that first proposed the device and IVD regulations in 2012 that was then sent for consideration by the Council and Parliament, and formed the basis of the trilogue negotiations. (See (Also see "*EU Device Reform Proposal Adds More Government Scrutiny, But No FDA-Like Review Body*" - Medtech Insight, 1 Oct, 2012.).) Oversight of devices and diagnostics in the EU are currently governed by a series of directives. The new regulations are intended to strengthen supervision of the products both in the premarket and postmarket phases.

Following the 10th "trilogue" meeting on May 25, the Council announced that it had reached an agreement on the texts. Under the regulations, once adopted, device firms would have three

years to comply with the new rules, but IVD companies would have a *five-year grace period* due to the significant changes it will mean for diagnostic oversight in particular. (See (Also see "*New World Of Regulation Awaits IVD Companies In Europe From Coming Reforms*" - Medtech Insight, 24 Nov, 2015.).)

The details of the agreement will not be publicly available until later this summer, but in a press release, the Council summarized some of the key points addressed, including:

- An additional check by experts that high-risk devices, such as implants, might need to undergo before they are placed on the market;
- Regulation of certain devices without a medical purpose but with similar characteristics to medical devices; for example, fillers and colored contact lenses for cosmetic purposes;
- Strengthened surveillance of notified bodies by national authorities, and authority for these bodies to carry out unannounced factory inspections;
- Explicit provisions on manufacturers' responsibilities to follow up on the quality, performance and safety of marketed devices;
- Clear responsibilities for manufacturers and other economic operators on liability, and also on registering complaints on devices;
- Improved availability of clinical data on devices, and more protections for patients participating in clinical investigations;
- The creation of a central database to cover economic operators, notified bodies, market surveillance, vigilance, clinical investigations and certificates, and to provide patients, health-care professionals and the public with comprehensive information on products available in the EU;
- Provision of key product information to patients who are implanted with a device, including any needed precautions; and
- Creation of unique identification numbers for devices.

Reprocessing Debate Contentious

The agreement also addresses the practice of reprocessing of single-use devices, and it is the language in the negotiated text on that issue, and also separate language on freedom of expression in relation to confidentiality rules, that apparently has the Commission unhappy.

Rules for single-use device reprocessing were one of the most challenges issues of the trilogue negotiations and among the last to be ironed out in the agreement announced following the May 25 meeting. But a close reading of the Council's announcement shows that it is a political agreement that was reached between the Council and Parliament, not directly including the Commission.

Sources tell Gray Sheet sister publication Clinica that the May 25 trilogue meeting took place in a very constructive atmosphere. However, during the meeting, the Commission asked the

European Parliament and Council to renounce the approach they favor for single-use device reprocessing based on establishing a “negative list,” i.e., a government list of single-use devices that are not suitable for reprocessing. The Parliament and the Council refused and went on to agree the deal together without the Commission.

The European Commission has argued that only noncritical single-use devices for non-invasive procedures should be eligible for reprocessing. It says that a better approach is a “positive list” of categories or groups of critical-use single-use devices that may be reprocessed according to the latest scientific evidence, and critical-use devices not on the list should be restricted from reprocessing. It also argues that any person that reprocesses a single-use device (SUD) becomes a manufacturer.

As for its issue around freedom of expression in relation to confidentiality rules, the Commission has complained about an imbalance between itself and national authorities.

The disagreements leave the deal technically vulnerable, since the Commission would have the opportunity to try to block the device regulation before it is formally adopted, although it is not clear it would want to sink the whole agreement due to one or two issues.

Would Commission Block Adoption?

So what will happen next? Might reprocessing of single-use devices be taken out of the package to ensure the Commission does not block the device regulation going through at the procedural level?

One expert in Brussels with insight into the discussions commented that he did not believe the Commission would be willing to take the risk of jeopardizing the adoption of the two regulations because of its problems with reprocessing and freedom of expression.

But there is one point in the process when the Commission could – if it wanted to – block the regulations; specifically, several months from now, when it comes time to vote for formal adoption of the rules. If the Commission still objects to the agreement when the Council is set to vote, it could force unanimity, rather than simply a qualified majority, to secure adoption.

Notwithstanding the Commission's concerns, the Council, which is currently presided over by the Dutch presidency, is touting the agreement as a major success.

"This agreement matters to all citizens," said Edith Schippers, the Netherlands’ health minister and president of the Council. "The deal reached will improve patients' health and it will help to enhance the quality of life of disabled persons. It will also ensure a level playing field for the 25,000 medical devices manufacturers in the EU, many of which are SMEs [small- and medium-sized enterprises] and which employ more than half a million persons."

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