MEDTECH INSIGHT
CITELINE COMMERCIAL

26 Apr 2016 | **News**

Reprocessing Provisions Could Be Dropped To Ensure Timely EU Reform Resolution

by

Sources close to ongoing talks on European regulatory reforms say it's possible that policy-makers could decide to drop sections of proposed regulations addressing EU-wide policies for single-use device reprocessing to speed the overall path to resolution.

The European Commission, Parliament and Council of the European Union still plan to reach an agreement on new Medical Device and *In Vitro* Diagnostics Regulations before the Netherlands completes its six-month Council presidency at the end of June.

Reports to date have indicated agreement is imminent for one of the most contentious issues - scrutiny of high-risk devices. (See (Also see "*EU Negotiators Make Headway Toward New Device 'Scrutiny' Mechanism*" - Medtech Insight, 22 Mar, 2016.).) Questions about reprocessing of single-use devices are threatening to destabilize the path toward a final agreed text, but there is a strong resolve to not let this issue derail progress.

Sources in Brussels indicate that the commission might be considering removing the article on reprocessing of single-use devices from the text of the Medical Device Regulation if it becomes necessary to ensure that agreement can be reached on the MD and IVD regulations before the end of the Dutch presidency. But what would happen next to make progress on this controversial topic is not clear.

Despite this and other hurdles, there is a growing sense of optimism being expressed by many who are close to the talks.

Sources in Brussels told The Gray Sheet's sister publication Clinica that another two meetings involving the three EU institutions will be needed in May to seal the deal. The ninth and tenth meetings of the so-called *"trilogue"* process are anticipated to be on May 11 and May 25, sources say.

In addition to these meetings, the Dutch planned 10 to 15 technical meetings focused on the technical details of the regulations, which Clinica understands are ongoing. Separately, a stakeholder meeting is being organized in Brussels by the Dutch presidency on April 28 to give interested parties an opportunity to exchange views.

The June 17 meeting of the EU's Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) will provide an opportunity for a formal agreement to be reached if discussions have sufficiently progressed. Once agreement has been reached, the two documents can then be formally adopted.

Speaking April 21 at the London Medical Devices Seminar – convened by the UK-based law firm Bristows in collaboration with the Association of British Healthcare Industries – Mike Kreuzer, regulatory director at the Association of British Healthcare Industries, said that if agreement is reached in June, formal adoption could take place in October when the council presidency has switched to Malta for a six-month tenure. It would likely take another month for the regulations to enter into force after the legal checks and translations are completed, Kreuzer said.

If there is a three-year transition period, this would mean that the final date of application would be late 2019.

Trilogue Progress

This table summarizes reported, but unconfirmed, progress made during Commission, Council and Parliament trilogue meetings so far in 2016 (a continuation of 2015 meetings). However, details of any final agreement cannot be assured until negotiations are complete.

Meeting Date	Potential Progress	Reports Of Unresolved Issues
February 4	No reports of concrete progress at this first meeting.	Diverging opinions between parties on scrutiny for high-risk devices, liability insurance and genetic counseling.
March 16	“No outstanding questions anymore” on one of the biggest sticking points – the scrutiny of high-risk medical devices. With carcinogenic, mutagenic and reprotoxic substances and endocrine disrupting substances in devices (CMRs), it appears as if rules are being favored that would permit the presence of	Scrutiny issues still to be agreed for IVDs. Council and Parliament, but not Commission, appear in agreement on single-use device reprocessing.

	CMRs above specific thresholds – but only where justified.	
April 7	Progress achieved on liability insurance and, to some extent, on classification rules, delegated/implementing acts, transition periods and other issues.	Technical talks are needed to clarify details, in particular with regard to the IVD rules. On reprocessing, the commission made an alternative proposal which will be considered by the co-legislators. Reports suggest political stimulus is needed to finish the process.

**Follow Amanda Maxwell @clinicaamanda*

- *A version of this article appeared in Clinica.*