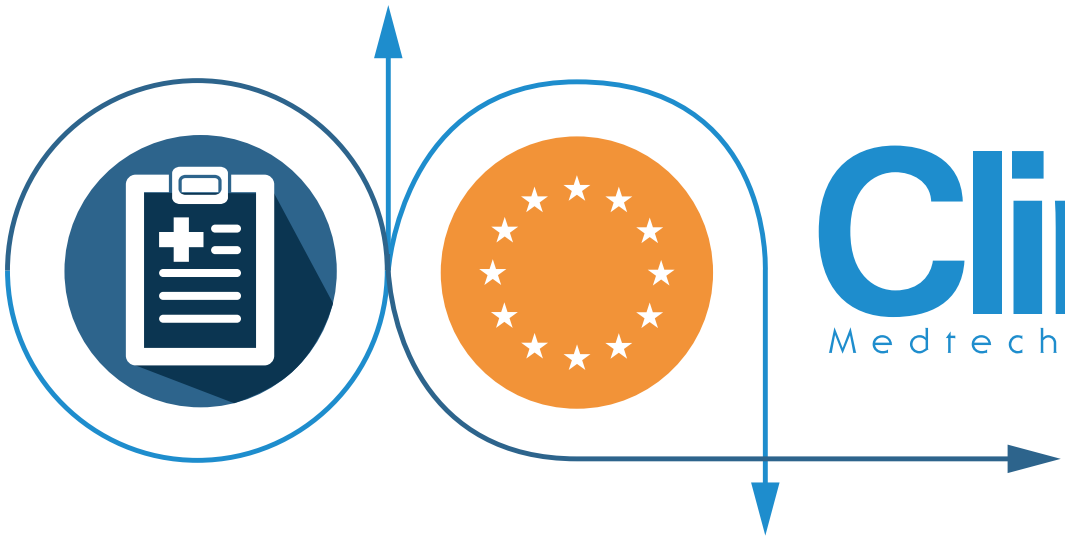

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Too Much Too Soon? Eurasian Medtech Reg Framework Speeds ahead But Russian Concerns Persist

By Ashley Yeo, 20 January 2016

THE EURASIAN ECONOMIC COMMISSION has moved fast in developing a common market framework for medical devices and medicines for its Eurasian member states – too fast, in the view of IMEDA, Russia's International Medical Device Manufacturers Association, which fears that quality may have been sacrificed in the drive to meet the 2015 year-end deadline

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The building of the Eurasian Economic Union (EAEU) trade bloc has been a work of speed since the deal was signed on May 29 2014 by the first three former CIS countries to join.

The union started officially in January 2015 with Russia, Belarus and Kazakhstan. Armenia and Kyrgyzstan have since also signed up. More are due to follow, and the Eurasian Economic Commission (EEC), under board chairman Viktor Khristenko, even harbors longer term hopes that Ukraine may still become one of the future members. Membership is also open to European and Asia-Pacific countries. In the short term, membership should rise to seven, with Azerbaijan and Turkmenistan said to be planning EAEU applications.

The aim is to establish an economic common market across industry activities, including medicine and medical products – for which the time allocated to develop the EAEU regulatory documents was extended by a year, to December 2015. However, the medtech industry, in particular, has been very concerned at the slow pace of developments for its particular sector, and the lack of communication on the details of a system that will be binding on national regulators and medical technology manufacturers.

Then, just before year-end 2015, Khristenko issued an announcement proclaiming that the EEC board had, in fact, completed its work on the 35 documents that were the prerequisite for the start of the EAEU common market for the medicines and medical products industries. The outstanding documents were approved or adopted in what Khristenko called "an extremely short time" and represented an "important step for society and business."

Specifically, the board approved seven documents and adopted several others, including (in the medtech domain): rules on conducting clinical and laboratory trials; requirements for authorized organizations conducting trials; compliance evaluation procedures; maintenance of information systems; pharmacovigilance good practice; and labelling of products.

Russian Ratification Begins

The next pivotal date in a fast-moving calendar of events was today (January 20), when the Russian State Duma (the lower house of the Federal Assembly) was scheduled to discuss ratification of the Agreement On the Uniform Principles and Rules Governing Market Circulation of Medical Devices within the Eurasian Economic Union and a similar text on medicines. This is an important step, as the common market for medtech cannot actually start working until Russia has ratified the text, which industry sources last year said would probably be in March 2016.

IMEDA, the Moscow-based International Medical Device Manufacturers Association, whose membership of 40 com-

panies comprises the global industry's multinational leaders, is not yet ready to add to the chorus of cheers.

Speaking to *Clinica* during the European MedTech Forum, in Brussels in early December, IMEDA executive director Sergey Kolosov and legal director Mikhail Potapov said that while matters – at that stage – sounded positive in theory, there were two major problems: the long-time absence of published official documents (on registration and evaluations etc), still not available less than one month out from scheduled adoption; and the actual content of the documents. But of one thing they could be sure: the documents would be adopted by the deadline.

"The time frame for the preparation of the documents is the main problem, but another is that quality of the documents cannot be guaranteed," Kolosov said during a break in the MedTech Forum program. He also pointed out that the EEC head (a former Armenia prime minster and ambassador to the US) is a new appointee and will probably need time to feel comfortable in the chairman's seat.

Technical Issues Surface

In addition, the general idea of harmonized registration procedures has not gone down well with Belarus and Kazakhstan. The idea is that companies can apply to any country in the union with a registration application. But there is another school of opinion that says there should also be an evaluation in each of the other countries where the product is to be sold.

Others still believe that if one state does not agree with the evaluation that another has given on a product, there should be some sort of dispute procedure to be able to engage the reference country. This could lead to products being refused to be admitted to certain markets, and this runs contrary to the central idea. "It looks good on paper, but go a bit deeper, and you'll see that the states are all trying to secure their interests and that there could be some technical problems," said Kolosov.

IMEDA is also pressing for a transition period when the new scheme comes in to ensure that manufacturers do not lose their legal rights and the registered status of products that were cleared under the national systems. Companies also need time to prepare for using the new Eurasian market system, he said.

Industry Seeks Transition Period

"Medtech is different from pharma, where there is a keenness to have everything implemented immediately," Kolosov said. That would in theory have meant the new system taking full effect as of January 1 2016. Potapov added: "We would like to see both systems working in parallel – the local and the EAEU systems – for at least two years." The rationale for this is that the industry has been unsure of the ability of EEC to adopt good quality documents that explain and regulate the system.

"Now we can see that we were right, and we recommend keeping the local system during a transition period," said Potapov. 2021 had been originally been floated as the date (ie for registration certificates issued before 2016 to be valid until 2021), but then IMEDA gleaned that there could be some problems adopting this. And while the Russian health ministry, Roszdravnadzor (the federal service on surveillance in healthcare) and the regulators of the other countries have been in talks on this matter, nothing has yet been decided and thus there is still no news on local transition periods.

So there is likely to be problems with the agreement on the circulation of medical devices. "The main idea was that if you want to register a new device, you would now do it under the new system – but that it is not yet possible," said Potapov. When the new Russian national regulatory system, under Decree 1416, started up in 2013, only 73 medical devices were registered that year in accordance with newly adopted rules. In 2014, there were more new devices registered (over 700), but that was still far short of the several thousand registrations granted per year during the previous system.

The point is that, without a transition period, IMEDA sees a similarly big shortfall in products registered. "Manufacturers should have the right to choose. In fact, we asked for a transition period of just two years – not until 2021. It is important that the circulation of medical devices remains smooth," said Potapov.

IMEDA staff were trying to keep their members up to date as best they could, all the time being uncertain if the final adopted documents would be the same as the original drafts that had gone out for public consultation.

Russia Seeks Best Practice Examples, Networking

Like the European Union, the EAEU is run by a body above national state level. Mindful that the 28 EU countries have already gone through this same process of unification, Kolosov believes that the EAEU could draw best practice methods from the EU experience, as a means of educating Eurasian regulators. At the same time, IMEDA is keen to attend and speak at international meetings, like the European MedTech Forum, to get over the messages about the progress – and pitfalls – with the nascent EAEU harmonized system.

"The last thing we want is for members to be unable to sell their products. The whole idea of the unification is "register once, circulate freely" within the five countries," said Kolosov. That is in an ideal world. But regulators and manufacturers are bound to encounter problems of some sort, he believes, adding: "Practical implementation of the EAEU is going to be the big issue of 2016."