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Medtech Associations Regulatory Networking, July 2017 – Singapore, the Philippines, Myanmar

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By Ashley Yeo

THE FIRST MEDTECH ASSOCIATIONS REGULATORY NETWORKING discussion, hosted by Medtech Insight and sponsored by the ARQon consultancy (Singapore) and the Asia Regulatory Professionals Association (ARPA), was held in mid-July. Updates were received from senior regulatory figures in three Asian medtech markets where regulation is evolving fast – Singapore, the Philippines and Myanmar.

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In July, *Medtech Insight*'s Ashley Yeo sat down with Asia-based regulatory experts to discuss updates from the region in the first Medtech Associations Regulatory Networking event, sponsored by ARQon Pte Ltd (Singapore) and the Asia Regulatory Professional Association (ARPA). The main takeaways from that conversation, focusing on Singapore, the Philippines and Myanmar, are detailed below.

Singapore Consultations & Priority Review Coming Out

August 1, 2017 was scheduled as a significant regulatory date in the calendar of manufacturers planning to enter the Singapore medtech market.

On that (tentative launch) date, Singapore's Health Sciences Authority (HSA) was to introduce a paid-for pre-market consultation scheme for medical device applicants and a priority-review scheme for certain types of medical devices that address specific therapeutic needs. *(Also see "Singapore To Make Major Medtech Regulatory Changes Under Economic Growth Plan" - Medtech Insight, 2 Jun, 2017.)*

The Singapore industry explained during the Medtech Associations Regulatory Networking that there will be two categories of consultation: development-process stage, where a charge of S$500 (US$368) will be made for a two-hour consultation; and pre-submission, where S$200 will be charged for a one-hour session with the regulator.

Pre-market consultations can be booked five months prior to the date of the meeting, and the relevant documentation must be submitted one month prior to the session.

The consultation involves the regulatory requirements during the development stage of the device and can include regulatory strategy, information on safety/performance studies, and other technical aspect. This is different from the consultations where companies can enquire about general regulatory requirements on the route to submission, risk classification etc. These will continue to be provided free-of charge.

The Singapore priority-review scheme was also to commence on August 1. It consists of two routes. Route 1 will apply to five types of medical devices only (ie not products that include medicinal products) in the fields of: cancer, diabetes, cardiovascular, ophthalmic and infectious diseases. To qualify, the device must *either* have a medical purpose and be entering a market where there are no existing alternative treatments or means of diagnosis; *or* it should be classified as a breakthrough technology that is superior to existing technologies. Either way, it should meet unmet clinical needs in the five health-care focus areas. Devices not meeting the criteria of Route 1 may choose to opt for Route 2 of the scheme.

In those cases, the applicant can ask the HSA for priority review, in which the product registration application is to be registered via the full evaluation route, with

an additional 15% (for Route 1) and 50% (for Route 2) charged over the existing full evaluation route fee.

It is desired to have a turnaround time (TAT) that is 25-35% quicker than the existing full evaluation route. But applicants should be well-prepared when selecting the scheme, as information requests from HSA during the screening stage which relate specifically to the Priority Review Scheme qualification criteria need to be responded to with full supporting documentation within two weeks. To fail to comply would result in an application being withdraw from the scheme and being put into the normal review pathway, where standard TAT applies. The application could even be withdrawn in the case of non-response from the applicant.

Other new features of the regulatory system, to come later in 2017 or in 2018, include improvements in speed to market for class A and B medical devices. Sterile products in class A (lowest risk) devices will no longer be required to undergo registration, as is already the case for non-sterile class A devices. But all class A devices will have to be included in a new online database.

This more self-regulatory approach will mean a lower burden and reduced compliance costs. Additionally, local manufacturers of class A devices will no longer need ISO 13485 quality system certification, as long there are equivalent quality management systems in place. Class A device manufacturers welcome these plans.

Class B provisions are also to be eased – manufacturers will henceforth qualify for immediate registration if they have *either* existing regulatory approval for the device in question from two third countries' reference agencies *or* three years marketing experience in one approved reference country. Previously, both of these criteria had to be met by applicants in the Singapore market.

Philippines Medtechs See Positive Changes In IVD Reg System

Some minor organizational changes have been made at the Philippines FDA's medical device group, with a new group being set up to focus on regulations, the Philippine industry reports. Previously, it was the role of the FDA's product registration group to develop medical device regulations. The new group will have a remit of crafting medical device and equipment regulations.

The FDA's CDRRHR (Center for Device Regulation Radiation Health & Research) is working on the latest draft of new IVD regulations. This will define the registration process for *in vitro* medical devices and establish a risk-based IVD system with four risk classes: A, B, C and D. The industry has played its part, participating in an IVD regulation "writeshop/workshop" in mid-July, where it made constructive comments on various proposals. The expectation is that its inputs will be considered. "We feel they will be open to accepting the industry's feedback," said a representative of the Philippine industry.

There will be also performance evaluation requirements that will be assessed by independent government laboratories before some IVDs are allowed to be sold in the market. At the same workshop, the labs agreed (in principle) to harmonize their document requirements for conducting performance evaluations. Performance evaluations apply to some IVDs only, and the industry is hoping that they won't be required for lower-risk class IVDs.

It is expected that the FDA will issue the latest version of the draft IVD regulations and hold public hearings/consultations in the next two-three months. Barring any unexpected issues during the consultation process, implementation of the regulations could happen in a 6-12 month-period from the time of issuance, so it will possibly be implemented in Q2-Q3 of 2018.

This system is for IVDs only. Industry is still awaiting approval of the proposed regulations covering medical devices, which it hopes will be approved within the next quarter.

Myanmar Medical Device Law Is Good News For Foreign Manufacturers

The much-anticipated Myanmar medical device law (including IVDs) has not yet been issued, but the ministry of health has finalized the draft and sent it to the country's Parliament for approval. The Myanmar medtech industry believes that it will be passed perhaps within the next 2-3 months, and by the end of the year at the latest.

The Myanmar FDA has ensured that the draft regulation is in harmony with Asean Medical Device Directive (AMDD). The new rules make several improvements over the current system. The Myanmar industry notes that only "good quality, reliable devices" can be registered and imported. There will be a new system of only one distributor per product. Previously, there were cases of some suppliers selling the same products through two or three Myanmar importers. Under the new law, there will be only one license holder – although importers can use many sources.

Under Ministry of Commerce Notification No 36/2017 (issued on June 12, 2017), foreign manufacturers of hospital equipment are now permitted to trade directly in Myanmar. This is expected to promote foreign and domestic investment in the Myanmar economy and open it up to private investment. Previously, overseas companies had to work with local parties, but now foreign companies can complete the whole process and set up as an officially registered company in Myanmar.

The documents on import requirements for different classes of medical devices are available at www.fdamyanmar.gov.mm.

This comes against the backdrop of a changing atmosphere and business climate in Myanmar, a country of 54 million people, as it transitions from a centrally planned to a market economy. "The government is officially welcoming all foreign investors," said a representative of the Myanmar industry.

Medtech Regulation Is Coming All Across Asia

In the past, it has not been easy for foreign medtech companies to be product license holders in Myanmar, so this is potentially good news. If companies are intending to build their business in Myanmar, they should take advantage of this new opportunity as soon as possible, the Asia Regulatory Professionals Association (ARPA) advises.

In fact, medtech regulation is coming to many parts of Asia, ARPA, observed: Myanmar (now); Vietnam (by end of this year); India (next year); and Hong Kong (two years' time), where class A voluntary registration currently takes 9-12 months, but will be slower and will come with fees when regulation comes.

"Engage with local regulators now and help shape the future regulatory environment," ARPA recommended.

ARQon agreed that medtech manufacturers – local or overseas – should take the chance to do early impact studies and product submissions to benefit from faster approvals and reduced fees.

Published online August 7, 2017

[**Editors' note:** *The next AMDC (Asean Medical Device Committee) meeting will be held in Indonesia in October. The next Medtech Associations Regulatory Networking discussion, sponsored by ARQon Pte Ltd (Singapore) and the Asia Regulatory Professional Association (ARPA), will be held in September – Medtech Insight plans to host them regularly throughout the year, focusing on markets around the globe.*]