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Singapore & Beyond: Asian Medtech Associations Regulatory Networking November 2017, Part 2

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By Ashley Yeo

IN THE SECOND OF TWO ASIAN Medtech Associations Regulatory Networking discussions this month, we focus on regulatory reforms in Singapore, and updates on Indonesia, the Philippines and Vietnam from recent regional regulatory meetings. This series is hosted by Medtech Insight and sponsored by the Asia Regulatory and Quality Consultancy (ARQon), the Asia Regulatory Professionals Association (ARPA), and Medtronic.

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[**Editors' note:** *In November,* Medtech Insight *sat down with Asia-based regulatory experts to discuss updates from the region in the second Medtech Associations Regulatory Networking event, sponsored by Asia Regulatory and Quality Consultancy (ARQon) and the Asia Regulatory Professional Association (ARPA). The main takeaways from the conversation on Singapore and updates from the recent APACMed regulatory track, are detailed below. The first part of this month's conversation* covered Malaysia.]

Broad-scale medtech regulatory change is under way in Singapore, as part of a program designed to speed highly-innovative products into circulation and remove certain procedural steps for lower-risk products. *(Also see "Singapore To Make Major Medtech Regulatory Changes Under Economic Growth Plan" - Medtech Insight, 2 Jun, 2017.)*

In this context, the Health Science Authority (HSA), the Singapore regulator, continues to work on simplification for class A (low risk) products. It recently decided that class A sterile products (1s) no longer need registration, which will mean additional changes to Singapore's Medical Device Regulations. Imports of class A sterile products will be submitted and processed as non-sterile class A products.

Class A measuring devices (1m) have always qualified for simplified submissions and been exempted from product registration in Singapore. The logic of now lightening the regulatory pathway for sterile class A devices is part of a policy at the HSA to allocate more time to *de novo* technologies, like cell and gene therapy, which will be a focus at the authority for the next three years. It also wants to fine-tune its approach to other fast-developing areas of regulation like telehealth and 3D printing.

The class A sterile change is seen as a very pro-industry and pro-enterprise move, but it is not a case of the HSA relinquishing regulatory oversight. The agency will still have an overview of these devices entering Singapore by means of six-monthly import license updates, a process that allows the regulator to check what companies are bringing into Singapore in terms of class 1 devices.

Industry has additionally suggested a quicker method of regulation for IVD analyzers, which are subject to frequent software updates, and to reagent-listing updates at each occasion. Analyzers should instead be listed separately, industry recommends.

Singapore Distribution Update

In October 2017, the HSA released a document intended to provide general guidance on SS 620: the 2016 Singapore Standard for Good Distribution Practice for Medical Devices (SS GDPMDS). The guidance, GN-33: Guidance on the Application of Singapore Standard, is shown here. In-

dustry has been engaged in discussions around ongoing aspects, especially secondary assembly.

Starting now, there will be a three-year transition period, enabling companies to secure certification, by certified bodies that have been accredited by the Singapore Accreditation Council (SAC). Companies have until Nov. 9, 2020 to gain certification.

AMDC And APACMed Reg Highlights

The fifth Asean Medical Device Committee (AMDC) meeting, its H2 2017 meeting, was held in Indonesia where it was announced that Indonesia will implement GDPMD (CDAKB in the local language) for distribution, similar to the systems used in Singapore and Malaysia, but there are no timelines as yet. The country will also use a bilingual registration system for submissions – Bahasa Malaysia and English will be used.

It was also announced that the Philippines will use Common Submission Dossier Templates (CSDTs) for certain products, a development that should not impact industry. Thailand has also started using CSDTs this year for high-risk products, and reportedly plans to expand them to all products within five years.

The H1 2018 AMDC meeting is set for Singapore on April 4-6, with many ASEAN regulators expected to be present. As in Indonesia, the agenda themes will include sharing experiences on best practice in radiofrequency identification (RFID).

The very next major regional regulatory event is the Asian Harmonization Working Party (AHWP) annual meeting in New Delhi, on December 4-8.

The Asia-Pacific Medtech (APACMed) regulatory track in early November followed directly after the Asia-Pacific Medtech Forum. *(Also see "Exec Chat: How Verb Surgical Will Deliver On Surgery 4.0" - Medtech Insight, 14 Nov, 2017.)* A standout presentation over the combined three-day event was reportedly Microsoft's description of hologram technology and virtual reality surgery for surgeons, the potential of big data and the controversial theme of how or when IT could replace physicians.

The regulatory debate at the meeting extended to the workload placed on regulators, with officials from Thailand, Cambodia, China's CMDA, Japan's PMDA, Vietnam's FDA, and Malaysia's MDA providing input. The AMDC chair passes next year from Malaysia to Singapore. The current Malaysian agency chair described the growing workload demands of a regulatory body, alluding to one aspirational MDA performance target of processing 70,000 medical device files per year. But full approval of all submissions in that workload would take 10 years, the MDA chair noted.

Vietnam Mulls Regulatory Deadline

For many, this illustrates the need to find appropriate ways of fast-tracking products through regulatory processes - low-risk devices especially – which Singapore is broaching. And perhaps these experiences provide a good model for other agencies – such as those in Thailand and Vietnam – that are in the throes of setting up regulatory systems. They might have even fewer resources and lesser know-how than the MDA, suggested Jack Wong, head of ARPA, the Asia Regulatory Professional Association.

Vietnam has an aggressive timeline for its new regulatory system, calling for submission of all files by the end of this year, the start date of its new system. But in recent weeks, pressure had been growing for an extension of the deadline. Of the two schools of thought on this – should applicants plan for a postponement; or simply get on with timely compliance – participants in the Medtech Associations Regulatory Networking discussion advised the latter, safer option.