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ASIAN MEDTECH UPDATE: Thai Device Law Latest; National Issues Aired; ASEANMed Seeks Medtech Industry Role At AMDC

By Ashley Yeo

THIS MONTH'S ASIAN MEDTECH ASSOCIATIONS' REGULATORY networking discussions cover the current progress of the Thai medical device regulation, which must be in place before the national elections; Vietnam's efforts to introduce practical, workable device regulations; ASEANMed's aims to represent the regional industry at AMDC; and other ASEAN national updates. This series is hosted by *Medtech Insight* and sponsored by the Asia Regulatory Quality Consultancy (ARQon) and the Asia Regulatory Professionals Association (ARPA).

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Thai medical device industry association ThaiMed has been asked by Thai FDA to give feedback on the draft amendments to the Medical Device Act (BE 2551) within two months. *(Also see "ASEAN Medtech Update: Thai Device Law Amended; Vietnam Moots Another Delay; Indonesian Reg System Updated" - Medtech Insight, 31 May, 2018.)* Addressing the July Asian Medtech Associations' Regulatory Networking session, ThaiMed said it was being asked to comment on the application of the proposed medical device regulation for IVDs and non-IVDs, and labeling issues. The draft is not yet available in English.

The association also pointed out that Thai FDA will be using an e-submissions process in future, meaning companies perhaps no longer needing any direct contact with FDA staff. But training in how to use the process will be required before devices can be listed as approved in Thailand. Thai FDA does not have the budget for such training, so ThaiMed and the regulator are working jointly to instruct manufactures on the new submission method. Three-hour classes of 60 students per session are ongoing.

ThaiMed's main preoccupation is developing its position and comments on the new draft. ThaiMed is seeking clarity in three main areas: a proper definition of the term "product owner;" and extension of validity from the proposed two years to three years (given the work involved in filing applications and renewals); and on a clause that appears to request that manufacturers avoid having products stocked up in hospitals. The current draft "won't allow us to keep products in the hospital," said ThaiMed.

Having an English language translation has become a pressing issue. The original plan was to wait until the draft had gone through all committee and public hearing stages before being translated from Thai, given the costs involved and notion that there was not a real need. But interest in the content of the amended regulation outside Thailand has been high enough to warrant a change of heart, so changes may be afoot. The new regulation will have four risk classes, like the ASEAN Mdical Device Directive (AMDD).

The aim is to have all changes agreed and incorporated in a final proposal by November, so the legislation can be in place before the February 2019 Thai elections. If not, the fear is that the whole process might have to be restarted. "We hope that we will pass everything before November," ThaiMed said, adding that it would like to see the new law "in place before the elections."

Elsewhere, draft requirements for good distribution practice (GDP) have been released in Thailand, and public consultations are either underway or planned. GDP is not

a mandatory requirement in Thailand, and can be outsourced to third-party certifiers. Although GDP is voluntary, ThaiMed has been asked to give feedback on this theme too, also within two months. ThaiMed says it will work with FDA in a bid to complete this task by October/November.

ASEANMed Update – Philippines

ThaiMed currently has chairmanship of ASEANMed association, which was formed six years ago and has members from eight ASEAN member states (excluding Laos or Brunei, which do not have medical device associations at present). It is the aim of ASEANMed to engage with the ASEAN Medical Device Committee (AMDC) to represent industry at the next AMDC meeting in late 2018, and is still discussing how best to do so. ASEAN industry feedback will be called for in August/September to gauge progress with AMDD ratification status around the member states.

The ASEAN planning committee is another useful information forum. This is a US-led initiative that hosts ASEAN medtech networking calls to provide information and possible outreach on local regulatory issues.

The recent session discussed the Philippines' classification of consumer products such as diapers and sanitary pads as medical devices. National industry association PAMDRAP will take up this anomaly with the Philippines FDA. The Philippines has a big workload at present, given the ongoing updating of Administrative Order 2018-002, and new fee schedules, including for "licenses to operate," as well as for product registration. *(Also see "Asia Reg Roundup: Philippines Sets Short Reg System Deadline, Vietnam Defers, Malaysia Extends" - Medtech Insight, 16 Feb, 2018.)*

Malaysia

In Malaysia, the final deadline for compliance under Act 737 on 2012 was June 30, which came and went without major issue. No product applications were withdrawn, and even after July 1, the regulator was asking for more information from applicants and allowing 90 days for responses.

A draft halal standard, issued on June 15, drew responses from three medtech associations, AMMI (the Association of Malaysian Medical Industries), APACMed (the Asia Pacific Medical Technology Association, Singapore), and US industry trade group AdvaMed. They requested a revision on the new standard, developed by JAKIM (the Department of Islamic Development Malaysia) and Standards Malaysia, claiming variously that it would negatively impact supply chain innovation.

The halal standard affects all products, but industry say it should focus on biological products only. A halal decree (Decree 33 [2014]) is said to be imminent in Indonesia. This would also introduce standards that would affect medical devices. It is due to be enacted in October 2019, but there is uncertainty over whether the decree has been suspended. Experiences in Indonesia could be a useful pointer for Malaysia as it proceeds with its halal standard.

The Malaysian Medical Device Authority (MDA) has announced that labeling compliance will be fully implemented with a three-year transition to help industry. *(Also see "Companies Given More Time to Meet Malaysian Labeling Rules" - Medtech Insight, 7 Aug, 2018.)*

Vietnam

Similarly, experiences in Vietnam, which has had to rein back somewhat on its scheduled introduction of Decree 36, could provide lessons to learn for Thailand, according to views expressed at the current Asian Medtech Associations' Regulatory networking discussions.

The local industry group has formerly requested an extension to Jan. 1, 2020 of the medical device registration requirements under Decree 36. *(Also see "Industry Responds To Vietnam's Draft Decree 36, And Justifies 2020 Deadline Extension" - Medtech Insight, 31 Jul, 2018.)* A letter sent to the Department of Medical Equipment and Construction (DMEC) in mid-June also seeks clarifications on labeling and traceability.

The main thrust of their argument is that adequate time must be allowed for transitions and adjustments by all stakeholders. The example of Malaysia, which ordered several postponements for Act 737, serves as an example of the need to proceed at the appropriate pace. Industry is also keen to know if new fees will be established under the current daft decree on amendments to Decree 36. Revisions to the Decree are likely to be published in the near future, industry believes.

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