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Malaysia Moves: Asian Medtech Associations Regulatory Networking November 2017, Part I

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By Ashley Yeo

THE SECOND ASIAN MEDTECH ASSOCIATIONS REGULATORY Networking discussion focused on a range of regional issues, including the latest on-the-ground news and views. Hosted by Medtech Insight, and sponsored by the Asia Regulatory and Quality Consultancy (ARQon), the Asia Regulatory Professionals Association (ARPA) and Medtronic, this session is reported in two parts, with this first part focusing on Malaysia.

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[**Editor's 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 Malaysia are detailed below. A second part will cover the conversation on Singapore and updates from the recent APACMed regulatory track.*]

The pressure is on medtech manufacturers in Malaysia to comply with new medical device legislation by the end of the year, but the government has not ruled out an extension. deadline

Malaysia's Medical Device Act 2012 (Act 737) is due to be in place fully as of Dec. 31, 2017. On July 25 of this year, Malaysia's Medical Device Authority (MDA) published a new regulation that set out the necessity of swift and timely compliance with the deadlines of Act 737, which became effective on June 30, 2013.

The new notification, "Full enforcement of registration requirements of medical devices under section 5 of Act 737," stipulated that as of Jan. 1, 2018:

- Manufacturers can only import medical devices that have MDA certification, and
- Acknowledgement letters issued by the MDA in the wake of Act 737's effective date, enabling device companies to maintain commercial activities in the interim, will be invalid for companies that have not acquired MDA certification by Dec. 31, bearing in mind the Oct. 31 document submission deadline.

Concerns have been expressed at the fast-approaching deadline. The recent Medtech Associations Regulatory Networking session raised the issue of any updates with regard to the full enforcement deadlines, and if an extension was under consideration at the MDA.

To date, the answer is that the authority is, in fact, working on the possibility of a timeline extension and is seeking justification for this. Industry has provided a white paper to the MDA asking for the agency to consider a one-year extension. The MDA itself is doing a survey on the readiness of companies to comply with Act 737 as of January 2018. *(Also see " Malaysian device system targets total life cycle regulation " - Medtech Insight, 7 Jul, 2014.)*

For its part, the local association is working with other medical device and trade associations to seek a moratorium of the enforcement date, and their findings were due to be sent to the MDA by the end of November.

Update On Labeling Of Devices

At a recent meeting with the MDA on the authority's draft labeling guidelines, industry representatives learned that the registration number, as shown in the

Malaysia register of medical devices, will still need to be shown on labeling before the device can be placed on the market.

Written confirmation of this is still pending, but industry has been told that Aug. 7, 2018, is the enforcement date, and any products manufactured after this date will require the registration number appended to the label. This information was contained in an MDA circular issued in August 2016, giving a two-year transition period for compliance. *(Also see "Medtech Gets Two Years To Meet Labeling Rules In Malaysia" - Medtech Insight, 9 Aug, 2016.)*

In addition, the Bahasa Malaysia language will be required on all parts of the packaging, and not just on the instructions for use (IFU), as earlier understood by industry. But this is required only for home-use and OTC devices – not those intended for professional-only use. *(Also see "Asia Reg Roundup: Vietnam Decree, Malaysia Labels And More" - Medtech Insight, 16 Sep, 2016.)*

Further, class A (low-risk) medical devices are no longer required to have an IFU – but this must be justified in the product registration dossier.

The MDA has also issued a consultation on regulations for devices imported for exhibition purposes and demonstration devices. The consultation ran until mid-November; industry representatives are not aware of any special concerns.

Malaysia Leads On Halal Standards For Devices – Indonesia, Brunei Not Far Behind

Finally, standards on voluntary halal certification of medical devices in Malaysia are currently being drafted, and are to be the focus of a second public forum soon. The target date for go-ahead is late 2017 – which may be too ambitious, insiders acknowledge. Nevertheless, the new requirement could be a reference and set precedent for other countries in South East Asia: If halal, which addresses adherence to Islamic law, is made a specific requirement in Malaysia, it could have an impact across the region.

Multinationals and well as local companies are monitoring the situation very closely. Indonesia has a draft bill on placing halal logos on all health-care products. Industry lobbying has succeeded in putting a hold on this for devices and lifesaving drugs for the time being; the priority locally is around food and consumer products. But once Malaysia's standard is released, it may lead to renewed activity in Indonesia, a prospect that industry has some concerns about.

Brunei is reportedly also looking at placing halal logos on medical devices – and that is even before it has a national device regulatory code in place. Malaysia may unleash a domino effect, industry representatives participating in the Medtech Associations Regulatory Networking discussion observed.