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Asia Reg News: AHWP Catch-Up, Korea, Malaysia, Indonesia and Vietnam Updates

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By Ashley Yeo

PART 1 OF THIS MONTH'S ASIAN Medtech Associations Regulatory Networking discussions features Asean medtech market developments and Asian Harmonization Working Party news. Part 2 was a guest presentation on the current Brexit and EU IVDR outlook. This feature is hosted by Medtech Insight, the Asia Regulatory and Quality Consultancy (ARQon) and the Asia Regulatory Professionals Association (ARPA).

The recent Asian Harmonization Working Party (AHWP) technical committee (TC) leaders conference was hosted in April by the current chair, Saudi Arabia, in Riyadh. It is likely that China will be the next chair. But, in the meantime, the next annual AHWP meeting is scheduled for the Sultanate of Oman, on 11-14 November, an event that offers a good platform for networking with regional regulatory professionals, as well and as providing knowledge updates.

At the meeting of the TC, addressed by Sasikala Devi Thangavelu of the Malaysian Medical Device Authority (MDA), there was much discussion about Working Group 1 (WG1) starting work on guidance for artificial intelligence (AI). Meanwhile, WG3 will be working on cybersecurity for high-tech devices. And WG2, focused on change management guidance, will discuss a final draft jointly with WG1 and WG3. A new WG10 has been newly founded.

Korea

A presentation at the TC leaders' conference by Korea's Ministry of Food and Drug Safety (MFDS) signaled several medtech regulatory changes ahead. Two new

laws are currently being reviewed by the Korean National Assembly, with legislation expected this month for both: the In Vitro Diagnostic Act, to support the development and market authorization of IVDs; and the Medical Device Industry Promotion and Innovative Medical Device Support Act, to develop the premarket pathway for innovative devices.

Elsewhere, the unique device identifier (UDI) system implementation in Korea continues. Recent work includes revisions of the implementation dates for the system, and a notification on obtaining UDI and placing of bar codes, both in December 2018. In addition, a notification on the required information and scope and on how to submit data, was released in in March this year. The dates for UDI placement have now been announced as follows: class 4 devices (high risk), July 2019; class 3 (serious risk), July 2020; class 2 (potential risk), July 2021; and class 1 (low risk), July 2022.

The Medical Device Information Integrating System (MDIIS) is due to be in place in October. This is an electronic data processing system that is designed to effectively record and manage information on medical devices, from approval to manufacturing, importing, distribution and use. It also aims to enhance the supply chain with prompt identification of defective medical devices and market withdrawals.

Recent new guidance in Korea includes: a Guideline on Standards for Obtaining UDI and Placing UDI Bar

Codes, including details on the composition and obtaining UDI for medical devices; a Guideline for Placing UDI Bar Codes (directions for types of bar codes, how to print and associated equipment needed - a printer and a reader); a Guideline on Non-biodegradable Polymeric Mesh (directions for preparing submission materials for non-biodegradable polymeric mesh) – all December 2018; and a Guideline on Bio-informatics Approaches for Next-Generation Sequencing – NGS (directions for analyzing genetic data and how to validate the performance as per the testing fields), January 2019.

Malaysia

Malaysia recently published new guidance, which was finalized after the Medical Device Authority (MDA) met with industry, following the latter's concerns over new guidance. The inaugural medical device collaboration meeting was held on 18 March to select topics for the group to work on. These will include combination products and change notification.

The group has been collecting feedback and will present additional items to the authorities in due course. The MDA also is still working on labeling requirements. These items are all described as works in progress for the end of 2020. The authority has also been asked to work on renewal requirements. Halal labeling has been proposed for Malaysia, but there are no recent updates on this.

Indonesia

However, Indonesia has moved ahead with Halal labeling plans. ARQon reported on 30 May that the JPH (Halal Product Guarantee) law went into effect at the beginning of May. All items included under the definition of "product" in the JPH law must be halal-certified. This includes goods containing animal elements, which must be halal-certified. Medical devices in classes A, B and C will have transition periods of seven, 10, and 15 years, respectively, while the class D transition period will be determined through the regulation.

The technical rules for halal implementation will be regulated by the Ministry of Religion (Peraturan Menteri Agama/PMA). There will be three regulations for JPH derivatives, namely: PMA Phasing Halal Certification, PMA Implementation of Halal Certification, and a Ministry of Finance Regulation (Peraturan Menteri Kewangan/PMK) on tariffs and fees.

Vietnam

Vietnam's new Medical Device Decree 169 contains many improvements compared with Decree 36, but there will, nevertheless, be challenges for industry when it is introduced. *(Also see "ASEAN Updates For Malaysia, Vietnam: Asian Medtech Associations Regulatory Networking " - Medtech Insight, 12 Feb, 2019.)* Industry is also worried about the decree's timelines – with only six to seven months until it is in force, and uncertainty over the ability of the authorities to review everything in time. A major challenge for industry is classifications. There are new rules but no clear guidance, so industry cannot begin or plan for the work, but new guidance should come soon, industry hopes.

Part 1 of this month's Asian Medtech Associations Regulatory Networking discussions was published yesterday. *(Also see "IVDR And Brexit Outlook For IVD Firms: EU Themes To The Fore At Asian Medtech Associations Reg Networking " - Medtech Insight, 12 Jun, 2019.)*

*May Ng of the Asia Regulatory and Quality Consultancy (ARQon) and Jack Wong (ARPA) will present at KNect 365 Life Sciences MedTech Summit, at Crowne Plaza – Le Palace in Brussels, Belgium, on 17-21 June 2019.

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