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Singapore Prepares UDI System, Malaysia Seeks Regulatory Improvements And Indonesia Adjusts To Changing Environment

Asia Regulatory Roundtable hears updates on national markets and ASEANMed issues

by Ashley Yeo

Medtech industry representatives from ASEANMed member economies, notably Singapore, Malaysia and Indonesia, provided regulatory updates at the February Asia Regulatory Roundtable. These roundtables are organized by the ARQon consultancy and the Asia Regulatory Professional Association (ARPA). They are sponsored by Medtech Insight.

New medtech industry associations are proposing to join ASEANMed, the ASEAN Federation of Medical Device Industry, which lobbies for the regulatory interests of the ten-nation bloc.

The ASEANMed chair (currently held by THAIMED) will accordingly draft a revised memorandum of understanding (MoU).

This will also restate the federation's aims, which include: sharing training; improving trade awareness; and facilitating business in medical devices. The federation holds meetings on a quarterly basis.

The recent roundtable on Asian regulatory issues heard updates from industry in Singapore, Malaysia and Indonesia.

Singapore HSA And UDI Update

Singapore medtech industry representatives recently met with the Health Sciences Authority (HSA) to discuss medtech regulatory accomplishments over the past year.

The regulatory authority explained how it had continued to work on product applications, despite the additional workload under COVID-19. Industry and the regulator shared information on regulatory expedited and exemption routes for COVID-19 test kits and medtech equipment.

Industry raised the issue of the new Online Safety Compliance Application and reporting (OSCAR) system for Field Safety Corrective Actions (FSCA). Its view is that OSCAR is not as user friendly as industry would like. The industry has sent a position paper to HSA on areas that could be improved.

Alongside OSCAR, a new adverse event reporting platform is due to be launched in the third or fourth quarter of 2021.

The HSA is asking industry about where guidance on digital health training from the regulator is not clear. The authority has decided that, instead of full training on digital health regulations that apply to devices, it will focus on areas where the industry is known to have knowledge gaps or issues. The industry has asked industry to report back its experiences and needs.

The HSA, which chaired the International Medical Device Regulators Forum (IMDRF) in 2020, hosted the IMDRF-DITTA Joint Virtual Workshop on Cybersecurity on 21 September as part of its activity program. DITTA is the global industry lobby group voice for diagnostic imaging, radiation therapy, healthcare ICT, electromedical and radiopharmaceuticals.

More recently, APACMed's digital health committee in late January issued a white paper on *Digital Health Regulation in Asia-Pacific*: Overview and Best Practices. The paper was written in partnership with A*STAR's Diagnostics Development (DxD) Hub. It addresses the areas that digital health regulations in Asia-Pacific need to factor in.

The HSA has shared on its website recent guidance on change notifications arising from the EU Medical Device and IVD Regulations and related changes to registered medical devices locally.

UDI System For Singapore

The authority has also announced that a new UDI system for medical devices, based on the experiences of the US system and the EU's plans, will be applied in four phases in Singapore, beginning with high risk implantables, class D, devices.

Information on coronary stents, orthopedic joint replacements and intraocular lenses must be submitted by manufacturers to the HSA's Singapore Medical Device Register (SMDR) prior to 2022. As of 2022, these devices must bear UDI on their labels. That is phase 1 of the program.

Phases 2 to 4 will cover: all other class D devices, from 2024; all class C devices, from 2026; and all class B devices, from 2028. There is no mandatory requirement for class A devices, but UDI may be implemented on these devices on a voluntary basis by importers or manufacturers.

For the time being, manufacturers are being asked merely to do a "high-level" registration in the SMDR system, with no impact on labeling at present. It is still seen as very early days for the system. The HSA is working on a guidance document. More information will follow when available. Singapore will be the first in ASEAN economy to implement UDI for medical devices.

Other HSA Regulatory Programs And Thai Approvals Pilot

Elsewhere, the Singapore ministry of health's technology assessment and reimbursement department has requested a briefing and ideas sharing session with industry on implant-based technologies.

The authority also has a program, dating from January 2020, under which it is prepared to share evaluation reports to help the Thai FDA approve products faster, provided they have undergone full evaluation and are already approved in Singapore. The system is based on use of the ASEAN Common Submission Dossier Template (CSDT) form.

A phase 1 pilot has been completed. The phase 2 pilot, for IVDs, is now open. The Thai FDA is interested in hearing from companies that have achieved eligibility for the process.

The HSA is also looking into how long it should apply exemption orders for COVID-19 gloves, personal protective equipment and masks. It has asked industry about when it should remove the exemptions.

Malaysia Seeks Practical Regulatory Improvements

At a January meeting of the Malaysian industry and regulatory authorities, industry sought information about the possibility of submitting different device changes together, in one application. The Medical Device Authority (MDA) has agreed in principle to change the online system to allow this. Work is ongoing on this theme.

Under the new system of conformity assessment body (CAB) oversight, the government is requesting all companies with product licences due to expire in the next six months to attend briefings. The oversight was previously provided by the MDA.

The MDA is proposing to allow multiple authorized representatives for a single product. Feedback was requested from industry by the end of February on whether multiple or just single authorized representatives would be suitable for the industry.

This would effectively mean that a manufacturer or product owner would be able to appoint multiple license holders for the same product. It is thought that this would give manufacturers more flexibility. Many countries, for instance, Indonesia, allow one only, while Singapore and others allow more than one.

Changes In Indonesia

Indonesia replaced its minister of health (MoH) Terawan Agus Putranto in mid-December, in a bid to better control the coronavirus outbreak locally. Budi Gunadi Sadikin, who heads the country's task force for national economic recovery, was appointed to the role.

Coincidentally, there has been a series of directorate general retirements, including, in January, that of the executive in charge of the medical devices portfolio. A temporary executive is in charge for the present.

Industry is keen to reset its relationship with the authorities and ensure continuity in five focus areas: the EU Medical Device Regulation; diagnostics; Halal as it pertains to medical devices; awareness of innovation, including e-commerce, e-IFU and advanced technologies; and post market issues.

These themes are dominating the health care sector, along with the vaccination program and changes to the e-Catalog for medical devices, including the temporary delisting of products sourced from multinational companies.

Given the COVID situation, the Coordinating Ministry for Economic Affairs is seeking to introduce new regulations to simplify the medical device licensing process, which might change the current licensing process significantly.

For now, the MoH has simply published new technical guidance on product recalls and on process disposal, to strengthen post market surveillance. But industry fears the process is happening very fast and has the potential to create confusion; its view is that the government should develop implementing regulations to support the umbrella regulation. (Also see "*ASEAN Medtech Update: Thai Device Law Amended; Vietnam Moots Another Delay; Indonesian Reg System Updated*" - Medtech Insight, 31 May, 2018.)

Regarding Halal, the industry has had several meetings with stakeholders on government proposals to implement Halal for medical devices. The discussions are ongoing, and a draft implementing regulation for Halal has been published. There is as yet no confirmation that devices and IVDs will be excluded from the regulation.

Industry has submitted a position paper on the effects of the EU MDR and IVDR on the local industry, focusing on simplifying the regulatory pathway and the grace period for devices. In

Indonesia, the fear is that compliance with the new regulations would mean stock locally having to be replaced.

The industry has requested a meeting with the pre-market directorate on the critical role of diagnostics in COVID-19 management.

e-Catalog And Procurement Issues

The Indonesia Government Procurement Policy Institute (LKPP)'s e-Catalog remains the subject of much attention for the medical device industry. Last year, the institute decided not to renew the entries for products whose validities expired at the end of December. Only local and COVID products are currently available via the e-Catalog. New submissions for inclusion in the e-Catalog have been made, but there may be a time lag until April or May.

The LKPP has advised hospitals to purchase local products or use alternative purchasing routes to that of the e-Catalog. But it is felt that not all hospitals are comfortable with alternative purchasing processes.

Other ASEANMed Themes

Elsewhere, an ongoing theme for the ASEANMed federation is the removal of the need for local embassies to legalize documents from overseas manufacturers – free sale certificates or letters of authorization—on the import of medical devices into ASEAN countries. (Also see "*Asia Medtech Reg Discussions: COVID-19 Is A Golden Moment For Medtech And Governments To Learn How To Deal With Future Crises*" - Medtech Insight, 5 Jan, 2021.)

Vietnam and Thailand have agreed to work on ASEANMed's proposed legalization changes, and Indonesia is considering participating in the effort too. The Philippines is a signatory to the Den Haag Convention, meaning there is no legalization requirement in that country.

The International Medical Device School (IMDS) will next be held in Singapore, on 23-26 March. On 23 March, the IMDS will hold a roundtable event on local and ASEAN regulatory and market access themes, including input on the forthcoming EU MDR and IVDR and what changes they signify for local Asian device regulation.

The IMDS has also launched South Korea and China modules. Indonesia and Malaysia are next on the list to have an IMDS curriculum, starting with Malaysia, this year. The program is being shaped to extend beyond regulatory to also include themes on R&D, pitching for investment and setting up distributors.