Medtech Insight

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Evolving Regulatory Landscape In APAC Points To Regional Medtech Growth

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The APAC territory, from Pakistan in the west to the South Pacific Islands, and stretching far into the northern and southern hemispheres, accounts for 22% of the global land surface, but roughly 60% of the world's population. In medtech terms, Japan, Singapore and Korea have led the developments in Asian regulation, while the Australasian territories have well-established codes, mirroring the EU's. Australia and Japan are part of the five-member MDSAP.

Much of the rest of the regional APAC economies are playing a form of catch-up, developing and integrating new regulations as the public demands better standards and the authorities see the wisdom of having sound regulation to rely on. That, in turn, encourages confidence, attracts business and fosters GDP growth. Notably, Hong Kong has a voluntary system of regulation still.

English is the dominant first language of most of the industry, except notably in home-use/consumer products. In some countries like Malaysia and Indonesia, halal labeling might appear on product labels. China, the waking giant, uses Chinese, and companies looking to succeed there rely on English alone at their peril. In fact China does not harmonize fully with global initiatives, like ISO and UDI concepts, preferring locally tailored solutions.

It is in the central and western regions of the Asian territory that regulatory activity is happening quickest – often from a low base – even if the plans sometimes need to be modified on the hoof.

To take Pakistan as an example, the regulator (DRAP) issued brand-new, risk-based medtech registration timelines in 2015 for all importers and manufacturers. But when it became clear that the rules were too ambitious, a new deadline of the end of 2019 was put in place. The same sort of pragmatic adjustments have been made by Vietnam and Malaysia, as the information in this e-book shows.

Meanwhile, the ASEAN medtech "harmonization" program rolls on. Successful implementation will mean the same rules being followed by all 10 member states – using a common submission dossier template (CSDT) and common rules – even though it's not full harmonization per se, on the scale of the EU system.

This e-book gives a glimpse of current regulatory activity in the larger and smaller regional markets of mainly central Asia, including Singapore, whose Health Sciences Authority (HSA) often leads in strategic decision-making locally. An APAC case study showing one medtech company's path to success completes this inside view of the world's largest medtech market-in-waiting.

In general, the wealth of regulatory activity happening in the APAC region indicates that investment in Asian health care and medical technology is set to increase markedly in the coming decade.

Ashley Yeo
Executive Editor, Medtech Insight

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China Issues Raft Of Regulatory Notices: Guidelines, Standards And More Reforms

BY ASHLEY YEO

The past two months have seen the Chinese government issue many updates for the medical technology industry, in both summaries of technical guidance and China-unique standards; and in changes to the medical device review process.

These high-level updates include the National Medical Products Administration's (NMPA, formerly the CFDA) release of four registration technical review guidelines; and 27 new industry standards for medical devices, listed in this NMPA link (all links in Chinese). Three of the guidelines are here, and the fourth is here. The NMPA has also released a notification on the 2019 revision program of medical device industry standards, including updates and new drafts.

Innovative Device Catalog Listing Provides Commercial Advantages

Under planned reforms of the review process, the Ministry of Science and Technology (MOST) has released a notification about its 2018 Innovative Medical Device Catalogue. If a company's product is listed in the catalog, it might get a faster reimbursement or a better price. It also means it should be easier to win tenders in the future. "The majority of companies included are local China companies," says Wen Peng, who is director of regulatory affairs, Asia-Pacific, at Edwards (Shanghai) Medical Products Co. Ltd., based in Beijing, part of Edwards Lifesciences Corp.

Peng explained that products are included in the catalog via an innovative fast-track process, and are then certificated for future commercial purposes. This is separate from the existing reimbursement listing process. If a company is entered in the catalog, the Chinese provinces will give the company "extra points" when it applies for reimbursement. In this way, the reimbursement process is made easier. But crucially, being in this newly published innovation catalog helps companies when they submit for tenders. These products must have a local patent, or they don't get into the innovative process, Peng notes.

Elsewhere, the NMPA has released a notice on a guideline on Submission Materials for Innovative Medical Devices Special Review. This makes changes to existing procedures, for example, after the company secures an innovative patent, it now needs to apply for medical device registration within five years. After that, the NMPA will no longer accept the "innovative medical device application." This means that when companies start to apply for patents in China, they need to be mindful of when they will start working on the innovative medical device registration.

China's CDME On Registration Process Improvements

The Center for Medical Device Evaluation (CMDE), the body responsible for conducting dossier review during the registration process, has started a discussion to develop a Group Decision Mechanism for Medical Device Registration Reviews. It is considered by the CDME that when it comes to device innovations, a reviewer should not make the final decision by her or himself; it should be a group discussion on how to approve the product.

Accordingly, the CDME and the NMPA have issued new guidance on how to set up such

groups. Speaking for industry, Peng said, "We see this as an improvement on the previous system." This is because, traditionally, a single reviewer could have decided, wrongly, to reject an application, and that decision would have stood. "Group situations are fairer." But industry is also concerned about reviews being delayed because of the new process. However, the process is already underway for some high-risk products, where a review leader is responsible for the majority of the review, and other staff are assigned to do two further checks.

Another option is simply to split the overall job among, say, clinical or biocompatibility experts, and the risk of wrong decisions is reduced in that way too. These are the two options already being used. But for the future, there is a drive to emulate the methods of the Australian TGA, which always uses several reviewers to look at component parts of an application. The new CDME process was released on the website on January 4, following drafting in 2017 and 2018.

The CDME is also soliciting comments on the Master Document Registration System of Medical Devices. For many medical devices and some consumer devices, the materials information requested by the CDME is very detailed – and most finished-product companies do not produce those particular materials themselves. They are usually sourced from external suppliers, and as the information about them is usually highly confidential, the supplier will not normally agree to disclose it to the applicants.

But in some situations, the suppliers are prepared to disclose details to the NMPA or CMDE, because there would be fewer concerns about copying and disclosure. So now, the authorities are setting up a mechanism to allow suppliers to disclose information about specific chemicals or materials for the master file, which would be sent to the reviewing center.

The information would be given a master code held by the supplier, and when companies file a product that uses the material, they would simply need to cite the vendor and the code.

Thus, if the NMPA approved a file from one company that included the material, subsequent companies' documents would not need to be reviewed. This spares disclosure of confidential information, and reduces the risks for materials vendors. That, at least, is the intention of how the procedure should work at the reviewing center. A similar process started to be developed some years ago, but there was no formal process.

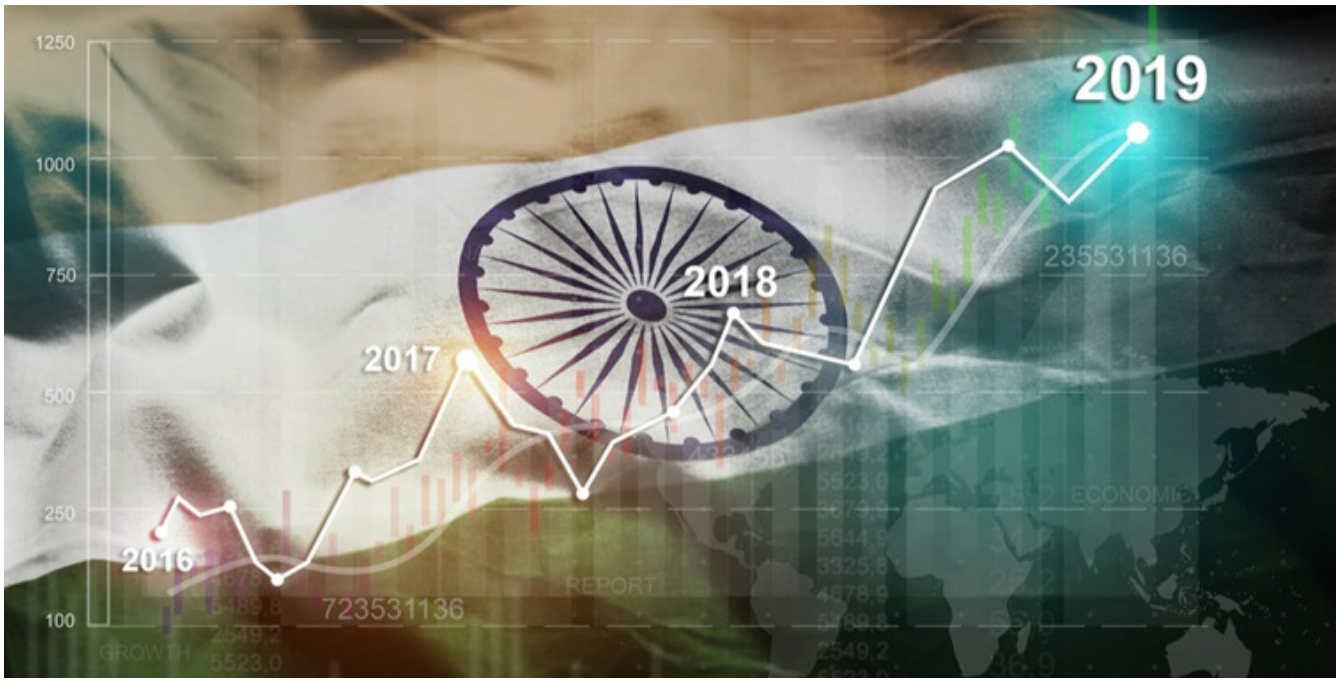
Supervision Of Devices Regulation Update Awaited In China

Industry in China still awaits an update to State Council Decree No. 650 Order (Regulations for the Supervision and Administration of Medical Devices), which became effective in 2014. On May 19, 2017, Order 680 updated that legislation, and in June 2018, it was updated for a second time, with the new draft sent out for public comment. The most recent update is still under review at the State Council. Industry expects the new regulation to be released in the first half of 2019, but information is scant.

On the subject of the use in China of overseas clinical data, where accepted, these must be clinical study data, not real-world evidence (RWE). It is also understood that the product in question has to prove that the data do not show up racial differences, that is, that the overseas data can be applied for the local population in China. It can be difficult for companies to prove the "no-racial-difference" factor. The best way is to initiate a clinical trial in China locally, and compare it with the overseas data. Some products are exempted from China local clinical trials, but that status is very difficult to achieve.

FDI In India's Medical Devices Sector Plunges, Experts Blame Price Controls

BY PENELOPE MACRAE



Four years after India allowed 100% foreign direct investment (FDI) in the medical device industry through the "automatic route" requiring no government approval, inflows have crashed. The Indian association representing multinational medical technology firms blames government price controls imposed on prices of stents and knee implants that were aimed at lowering costs for patients.

"This decline was the unintended consequence of the well-meaning intention but an unnuanced implementation of price control [on medical devices] ... The anomaly needs to be corrected," Pavan Choudary, head of the Medical Technology Association of India (MTaI), told *Medtech Insight*. MTaI has consistently suggested a multi-faceted approach to reducing prices for patients. The impact of price controls on the medical device companies has been amplified by the Indian rupee's sharp depreciation against the dollar.

The medical device sector received only $66m in FDI in 2018, just slightly above levels the segment was receiving before the government liberalized investment rules in the sector. Behind "this drastic fall," in FDI was "price control," MTaI said, which represents global medical device companies such as Boston Scientific Corp. and Johnson & Johnson.

After the government allowed 100% FDI through the automatic route in early 2015, the outlook seemed rosy for foreign investment in the medical device sector. Indian Prime Minister Narendra

Modi had identified medical devices as one of the government's priorities for its "Make in India" program to spur manufacturing and create needed jobs. The government hoped making investment easier in the medical device sector would lead to a big rise in inflows.

FDI In Device Sector Seemed Set To Rise Sharply

FDI investment in medical devices jumped in 2015 from an annual average of $62.5m to $161m. In the following year, 2016, the first full year of the change in investment rules, FDI soared to $439m. "The FDI seemed set for a similar climb in future that would establish India as an attractive destination for investments in medical device manufacturing," Choudary said. Then after the price controls were imposed FDI retreated to $184m and last year to $66m.

For years, US companies have been eyeing India as they seek a foothold in a market that has massive growth potential thanks to an expanding middle class, aging population, widening insurance coverage and government universal health care initiatives. India's per-capita spend on medical devices is the lowest among BRICS countries at $3 compared with $7 in China, $21 in Brazil, and $42 in Russia, while in the US it's $340.

India imports at least 70% of its medical devices – from implantable devices to robotics – and there are fewer than 60 domestic medical device manufacturers out of around 750 with annual revenues of more than $10m. Nearly all the top 40 global medical devices firms have an Indian presence, but most have their production base outside India and import their products for the Indian market.

The investment climate soured when the Indian government, which switched from a pro-business stance to a more populist tone as it looked to ensure a second term in office and sought to uphold election promises of "more affordable health care," riled US medical device makers with price caps on cardiac stents and knee implants and accused the companies of "illegal and unethical profiteering." The government has also cut prices of a number of drugs to reduce patient costs as most medical spending in India is still out-of-pocket.

The cuts reduced prices on stents by as much as 85% and on knee implants by up to 70%. The government said price caps for other medical devices might be in store. The cap on some high-end stents lowered the price to around $450, compared with $3,000 charged earlier. The Indian government imposed caps on the stents after reports found that importers, distributors and hospitals were earning "unjustified" trade margins ranging as high as 1,000%.

The caps stirred outrage from US companies, which said such one-price-fits-all controls would limit innovation and hit any potential investment plans in India. AdvaMed, the US medical device industry body that represents some of the leading US-based medical device makers, has argued strongly that the price caps would be a "discouragement for the leading and advanced medical devices companies to do business in India." The country's "singular focus on controlling ceiling prices of high-quality medical devices, without any attempt to address the larger picture and correct inefficiencies in the health care system, will not achieve its intended benefit," AdvaMed said in 2017.

AdvaMed Says Wants To Work With Indian Government To Reverse FDI Fall

Abby Pratt, vice president of global strategy at AdvaMed, told *Medtech Insight* the association had taken heed of the latest fall in FDI in the Indian medical device sector, but she did not wish to comment in detail at this juncture. "We've noted the decline and we want to work with the government to reverse this trend," she said.

An Indian medical device senior executive with a major device company, who would only speak off-the-record, said the government's price controls had made India an increasingly "unattractive case for global management to decide to invest in. It's the case of good intentions bringing unintended consequences."

Meanwhile, a top-level US medical device industry executive, who asked that their name not be used, said "investment sentiment toward India is [now] pretty low in the sector. It's been trending down for the past couple of years. Even though price controls have only affected stents and knees, it sends a signal to the broader industry … Business wants a transparent, predictable market, and from the regulatory side, they want to know, 'How am I going to get paid?' And while that's the case, people will delay investment decisions."

The US executive, who has a close knowledge of the Indian market and follows trade matters, also said the pace of development in India's medical device market is vastly different from, for example, China's. With President Donald Trump's trade war against China, US investment in that country now is also in question. India and China have similar population sizes – India has 1.3 billion people while China has 1.5 billion – But "the size of China's medical device market is $30bn and growing while the size of India's is $5–6bn and stagnating. China's making a big investment in health and infrastructure and 90% of its population has public health insurance. The situation is not perfect, but in China they're constantly building hospitals and clinics," the US executive said. China, which is a domestic consumption and manufacturing hub, allows fast-track approval of locally produced "innovative" medical devices and has reduced corporate tax for the sector to 15% from 25% as it is an "encouraged industry." China also now has near self-sufficiency in medical consumables.

Another major concern for the medical device industry is high custom-duties of 8.25% levied by India on medical devices have created a cascading incremental effect on the landed cost of medical devices. These duties are far higher than in neighboring countries, ranging from zero to 5%, MTaI notes.

Need Confidence In India To Make Case For Investing There

"In India there is a lack of [government] commitment to investing in health care, and if you take the dynamic of uncertainty around the pricing and the regulatory environment, which is still challenging and unpredictable, companies are a little bit wary of India," the US executive said.

US companies would still be there to serve Indian patients, but that might be more through exports rather than through locally made products. "When you think investment, there has to be a level of confidence to make the case to invest, and we're not seeing a lot of confidence in the market," the US executive said.

While the government has come out with an insurance scheme to provide health coverage to India's poorest 500 million people, hospitals and medical suppliers "are still trying to wrap their heads about what it means and whether it is going to be an opportunity to invest," the executive said. "With these broad Indian policy announcements, there's a lot of things to consider, the devil is in the details," said the US executive. "Also, India needs to realize there's a lot of opportunity in other parts of Asia. People recognize India's got huge potential, a huge population and is too big to ignore. Even so, there's also a pretty big risk, so they're going to wait," the executive said. Despite a rapidly growing economy, India spent just over 1% of its gross domestic product on health care for the last 20 years, one of the lowest rates globally.

India's treatment of US medical devices has been one of the key trade irritants during Trump's presidency. Ongoing trade friction between US and India erupted into the open in March when Trump announced he would strip India of a special status exempting billions of dollars worth of Indian exports from US tariffs. Trump, who's repeatedly complained about India's "protectionist policies" and tariffs on goods ranging from Harley-Davidson motorcycles to IT equipment, has not yet moved formally to remove India's preferential market access to the US market.

Indian Think-Tank Suggests Capping Trade Margins Instead Of Prices

Last August, India's federal think-tank Niti Aayog advised the government to set caps on trade margins on medical devices at 65% from the stockist, abandoning price controls, but there's been no further movement on this idea. Niti Aayog said "many expenditures are incurred by importing companies, including clinical education on deployment, and therefore trade margins should start from the first point of sale, [and] that is the stockist."

MTaI's Choudary said his group is "willing to once again play its humble role in boosting FDI, this time more enduringly … [India's government] is keenly aware of the change, which big data, [the internet of things] and [artificial intelligence] are bringing to medical device manufacturing. The cradles of these technologies as well as the coffers, which will support them, are scattered internationally," he said.

"In medical devices, it's time to resume our collaboration with the capital, technology and export markets of the world," Choudary said. According to MTaI, 70% of the world's total wealth and technology is in the West and Japan, while India accounts for about 5% each. "The medical device industry is high-technology and capital-dependent. Therefore, it's vital the global community is kept engaged for this wealth and technology inflow as well as to help co-create an ecosystem for manufacturing of medical devices in India," he said. The executive who did not wish to be named noted that domestic Indian companies do not have deep pockets so the industry depends largely on foreign companies.

AdvaMed had warned after the price controls were imposed there was a risk the action could curb patient access to the best available care as foreign medical device makers might not bring their newest products to India. Medical device executives and cardiologists told *Medtech Insight* a few of the latest high-end stents were not being immediately brought to India as a result of price controls.

One senior Delhi cardiologist said some Delhi hospitals were increasingly substituting cheaper Chinese and Indian-made stents to offer lower prices and still make money on procedures. Other hospitals were using foreign good-quality stents, but those hospitals were raising procedure prices, he said. Media reports have consistently indicated the lower prices on medical devices – which are only one component of overall procedure costs – are not being passed to patients across the board.

The opposition to price controls is not shared by Rajiv Nath, forum coordinator of the Association of Indian Medical Device Industry. He's welcomed the controls and wants more regulation to pressurize the medical device sector to opt for local production. "Favorable policies to boost domestic manufacturing will drive investments from Indian investors. This will lead overseas [multinational companies] to follow to protect their market share," Nath said.

Singapore Improves Time To Market For Lower-Risk Devices

BY ASHLEY YEO

Changes for low-risk class A and low-to-mid-risk class B medical device submissions were announced by Singapore's Health Sciences Authority (HSA) on May 22, and took effect June 1. The changes had been signaled earlier in the year, and were key talking points at the 6th ASEAN Medical Device Committee (AMDC) meeting, in Singapore in April. *(Also see "Next ASEAN Device Committee Meeting Looms, But National Regs Top Priorities" - Medtech Insight, Apr 4, 2018.)* The basis for the reforms is HSA's desire to respond better to different operational and emerging business models in the device industry, and to facilitate patients' access to innovation.

As of June 1, class A sterile medical devices, such as sterile examination gloves and sterile intravenous sets, will no longer need to be registered with the HSA. Safety and post-market surveillance (PMS) and monitoring needs will be met by ensuring that importers and manufacturers list with HSA all their class A medical devices on the HSA's public online class A database.

Products hitherto using the 60-day "Expedited Class B" registration route will fall directly under the new "Immediate Class B Evaluation Route." Qualifying products will have no associated safety issues globally and have either been approved by two independent regulatory agencies or have

approval from one reference agency and three years of marketing history. It is estimated that 75% of class B applications will now be granted immediate market access.

Class B and C stand-alone mobile medical applications (for example, stand-alone applications for the calculation of insulin dosage, or live monitoring of ECG for cardiac patients) will be eligible for immediate market access under the new registration route, provided that they are approved by at least one of the five reference regulatory agencies (Health Canada, Japan's MHLW, US FDA, Australian TGA and EU Notified Body) and that they have no safety issues globally.

But as premarket pathways are streamlined, checks and monitoring of product compliance will be stepped up in the post-market phase. This will ensure a balanced life cycle regulatory approach, the agency says. HSA will also horizon scan more intensively for overseas alerts and local safety signals. "This simplifies the work flow for industry and accelerates patients' access to innovative technologies," says Eugene Yoo, chairman of Singapore's Medical Technology Industry Group.

Allowing immediate entry to lower-risk devices will enable the HSA to focus attention on newer, higher-risk devices, says Chan Cheng Leng, group director of the agency's Health Products Regulation Group. Eugene Yoo, chairman of the Singapore Manufacturing Federation's Medical Technology Industry Group (MTIG) adds, "These amendments simplify the work flow for the industry and accelerate patients' access to innovative therapy and technologies."

Telehealth, Cosmetic Device Clarifications

HSA also stipulates that telehealth devices intended by the manufacturer to fulfill a medical purpose will be regulated as a medical device. But those aimed at well-being or lifestyle parameters (heart rate smart watches or smart phone monitors for fitness purposes) will not be subjected to regulatory controls. Makers of products in the latter category, however, must include wording on labels or in advertising that the product is not meant for medical purposes, that is, the detection, diagnosis, monitoring, management or treatment of a medical condition or disease.

The agency will also grant faster market access to stand-alone software/software as a medical device (SaMD) and mobile apps for products that have been cleared by a reference regulatory agency.

High-risk devices used for the modification of a person's appearance or anatomy are subject to regulatory controls. Implants, injectable dermal or mucous membrane fillers, and invasive devices for fat removal or fat degradation are examples of such products, the full range of which is shown on a new HSA positive-identification list.

The regulatory also specifies that manufacturers of devices that require the user to have particular skills and knowledge for their safe use will have to provide relevant training.

More Change Ahead

More regulatory reforms are in the works in Singapore, including an effort to streamline submission requirements for post-approval changes to registered medical devices and to prescribe quality management system requirements for the licensing of manufacturers, importers and wholesalers. Agency officials signaled these plans at the 6th AMDC meeting, in April. Also at that meeting, officials previewed upcoming medical device guidance (released later in 2018), including a focus on:

- Essential principles for safety and performance;
- Labeling;
- Product registration; and
- Change notification.

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

BY ASHLEY YEO

The recent Asian Harmonization Working Party (AHWP) technical committee (TC) leaders conference was hosted in April by the current chair, Saudi Arabia, in Riyadh. The next annual AHWP meeting is scheduled for the Sultanate of Oman, on November 11–14, an event that offers a good platform for networking with regional regulatory professionals, as well 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. Also a new WG10 has been founded.

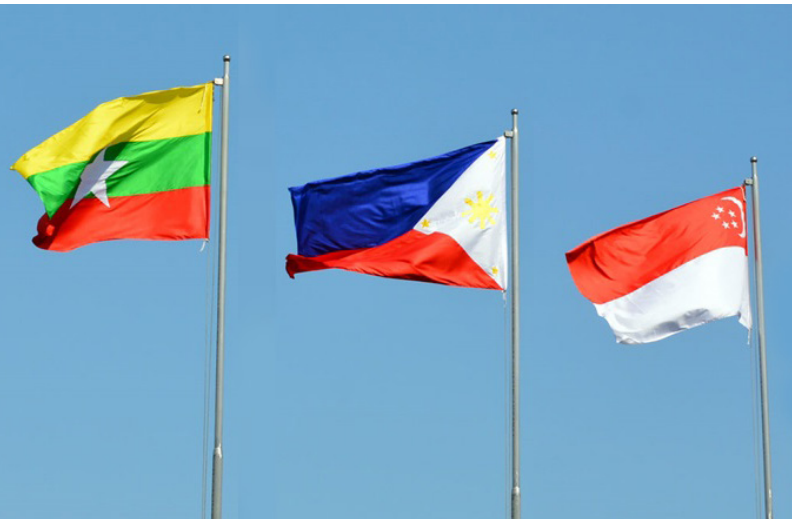
Korea

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 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 March 18 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 May 30 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, Feb 12, 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, Jun 12, 2019.)*

Exec Chat: How B Braun Is Staying Ahead Of The APAC Game

Parents have always been warned against playing favorites with their children. This lesson, it seems, could also be applied to nurturing your business across the many and varied markets in Asia-Pacific. "I don't believe in setting priority markets," Anna Maria Braun, president of B Braun Medical's APAC operations, told *Medtech Insight* unequivocally, when asked to point out specific country markets that stood out more than others for growth opportunities. "Whether it's China or Sri Lanka, all markets are crucial for us. We have very good development in the somewhat smaller markets and we value them as much as we value the big markets like China, Australia, Japan, India. This is also part of our success – we don't prioritize markets. We have a very strong base in ASEAN [Association of Southeast Asian Nations] and within that group, you have many small countries that show excellent growth and there are opportunities there. Our strength is to encourage any market – we don't say we will focus on the top 3 or 4 only, while the rest can develop how they see fit."

ANNA MARIA BRAUN, President, APAC, B Braun Medical

Evidence that this strategy works is reflected in the firm's financial reports. The German multinational, whose portfolio encompasses more than 5,000 products across 18 therapy fields, reported total sales of €6.47bn in 2016, up 5% from the previous year. A big driver of this growth was sales from Asia-Pacific, which grew 11% constant currency (8% reported) year-over-year to €1.16bn. This makes the region the third largest contributor to group revenue after Europe (including Germany) and the US.

In an interview with *Medtech Insight* at the recent Asia-Pacific Medtech Forum in Singapore, Braun said she did not see this upward trajectory flattening out any time soon. "[B Braun's APAC growth] is definitely not stabilizing. The region, for us and also for many other companies, have been a key growth driver for the group and this is how we see the future. We don't see stabilization, but [instead] for APAC to continue delivering double-digit growth."

She acknowledged, though, that there are differences in growth rates from country to country; markets like Japan and Taiwan are more mature and will grow at a slower pace than Indonesia, for example. But there are still

insights to be gained from more mature markets; the opportunities there lie in taking a "system partnership" approach, Braun said.

In the Q&A below, Braun explains this approach in more detail, and also discusses the critical role of innovation in keeping the company ahead of the competition, where the opportunities for innovation lie in commoditized products, the regions' regulatory and market access challenges, and dealing with local low-cost competitors.

Medtech Insight: What exactly do these system partnerships entail?

Anna Maria Braun: it's one of key strategic initiatives to engage with the customer and take a more holistic approach to finding out what they need. Not just sell a single product or service but really look into their entire system and discuss with them the whole patient pathway – from the patient entering the hospital, being diagnosed, treated and then being discharged – and we analyze with the customer where are the gaps, how we can support and make this process better while improving outcomes.

There are cases where we do look at single therapies and discuss with them how we can address their specific needs and achieve benefits in certain therapies. Or additional adjacent processes, for example, sterilization or patient discharge management, how we can support that and help our customers gain efficiencies. For that you need the customers on the other side who are aware where their cost challenges or their problems lie and you need to build their trust to address these problems. That's the way we want to approach the customers in future across the APAC countries.

The theme of this year's Asia-Pacific Medtech Forum is innovation and the critical role it plays in sustaining companies' growth in the region. What initiatives does B Braun have in place to ensure there is a constant flow of innovation into its extensive portfolio?

Braun: Innovation is one of our core values. Without innovation, our company wouldn't have lasted as long as it has. You pointed out how huge our product portfolio is, and it takes a lot of effort to maintain that, the incremental innovation. Apart from working with our teams within the group, we also put more emphasis on looking at what's happening around us externally but there is no one-fix solution to handle it. So we've created an innovation hub to centralize all our links to external innovation. We have different models where we either invest on our own in start-ups at different phases – seeding or later stage – or we invest in funds specific to the medtech industry that look at technologies or start-ups. We've partnered with Trendlines, an Israeli incubator. We have one fund in Israel but also one now in Singapore where we are partners and it gives us a window to see what is happening in the markets and we decide what we want to engage in. So while we are pushing our own internal innovation, we also have different means of seeing what's happening outside.

A significant proportion of your products are the more commoditized products. Where do you see the innovation coming from with those devices?

Braun: Those products still have opportunity for innovation. For example, having certain sensors in them to provide more information so you can make these commoditized products smart. Then there is the manufacturing process, which is crucial. Every aspect we work on is to help realize this so-called Industry 4.0 – that's the term we often use in Germany. Because these products are commoditized, the level of automation in their manufacturing is already very high but it's about taking the next step up to the "connected factory." So when a customer complaint comes in, it analyzes what is the root cause – is it the product, or the handling or another challenge – a feedback

loop can be created directly to the production floor and give us a lot of knowledge and opportunity for improvements without losing too much time. The same with the supply chain – how do we revolutionize the supply chain so that as soon as the nurse or doctor uses a product, this is triggered back and goes right into the production planning for the facilities. These elements of innovation are very interesting to look at for commoditized products.

The commoditized products that you are offering tend to be vulnerable to competition from local low-cost manufacturers. How big a threat do you view these potential rivals to be?

Braun: I don't see competition as threat. In Germany, we have a saying, "Competition enhances the business." Of course, local players that develop good products will challenge us and that is good. The danger is to become too complacent, but in the end, especially for commodities, it is a question of scale; to be able to produce a significant volume of IV catheters, for example, and to have the benefits from production costs, you really need to have scale [that B Braun has] and not be present in just one market. So, I don't see local competitors as a threat. I know you have to watch them and be challenged by them. That will keep us on our toes and that will be beneficial for everyone because we need to develop better products.

Regulation and market access are two big challenges that are often brought up by medtech companies operating in APAC. From your perspective as leader of an APAC business, just what is the magnitude of these challenges?

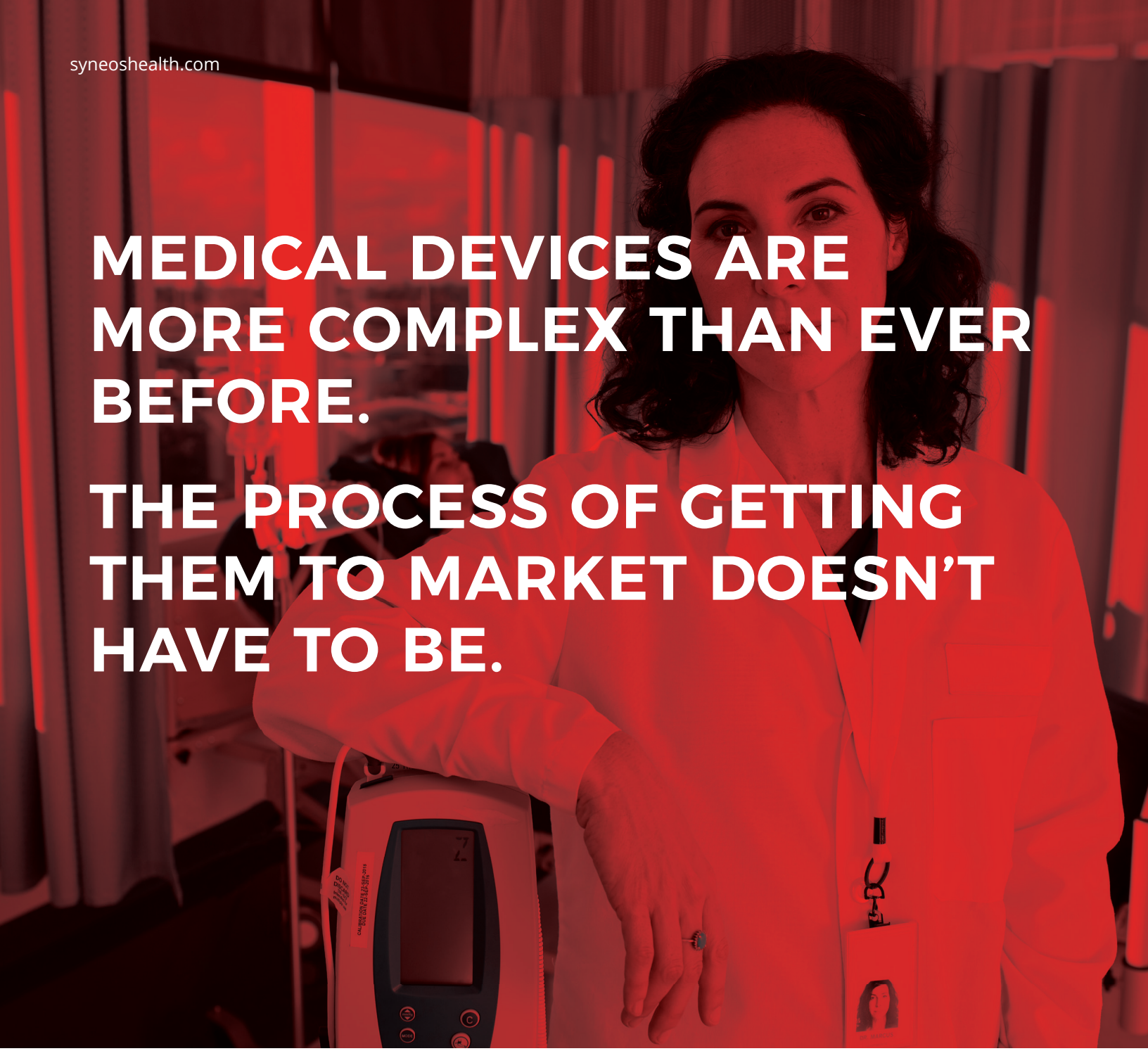
Braun: They are very big challenges and it's about the increased complexity. It creates a lot of tensions and our job is to figure out how to live with or resolve these tensions. But the complexity comes in when the country comes with their own individual approach. We can't start producing a different product for every country or have a specific study done in the country for all the portfolio products. There needs to be some harmonization, in APAC

> **"Whether it's China or Sri Lanka, all markets are crucial for us." – B Braun's Anna Maria Braun**

and in the world. But that's the task for [a regional medtech trade association] like APACMed to engage with the governments and work on a sensible solution. We have to live with this and resolve them eventually. So it's about constantly engaging with all the stakeholders and increasing transparency on how to solve these issues.

B Braun is on the board of APACMed and was pivotal in establishing the association three years ago with other key global medtech players. What were the catalysts for setting up an organization like APACMed at this particular juncture in time?

Braun: All the founding members of APACMed felt the need to have a platform in the region where we can address the challenges in APAC. It is a very diverse market and more than half of the global population resides in this part of the world – APAC is the world on a smaller scale because any problem you have in the global health care arena you can find in APAC. We didn't want an association that only represents European or US companies, but one that represents medical device companies that operate in APAC. This is what we want to move forward with and find new ways of cooperation. The needs are so big, not one single company or one single government can address all these challenges, which is why we wanted to establish APACMed and drive new solutions and new cooperation models to address these needs.



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