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Asia Medtech Reg Discussions: COVID-19 Is A Golden Moment For Medtech And Governments To Learn How To Deal With Future Crises

by Ashley Yeo

The fast-tracking of COVID-19 relevant health care products should be a blueprint for a systemic approach to matching innovation with clinical needs, say Asian medtech regulatory experts.

The experiences of COVID-19 within the medtech industry have varied from company to company and from country to country. Asia was hardest hit by rising infections in the early months of 2020, but recovered more quickly than other regions and countries following swift action.

In fall 2020, *Medtech Insight* moderated a panel of regional regulatory experts to gauge their thoughts and expectations of national control efforts, and what stakeholders – industry and governments included – must learn to ensure future health care crises are handled more efficiently.

"*How has COVID-19 changed the medtech industry in Singapore and ASEAN*" was the theme for the panel discussion jointly held by Asia Regulatory Professional Association (ARPA) and the Singapore Manufacturing Federation Medical Technology Interest Group (SMF MTIG). Company representatives, industry and professional associations and the regulatory consultancy, ARQon, were also on the panel.

Among those participating were Jack Wong, founder of ARPA, and Ng Xi Yun, QARA manager at EndoMaster Pte Ltd and chair of the new *Singapore Chapter* of ARPA. The official opening of the Singapore Chapter was announced as a preface to the main discussion, which is reported below.

Q **Medtech Insight: We live in very dynamic times, with regulatory systems transforming and stakeholders adapting to deal with COVID-19. How has the pandemic impacted the medical device markets in the ASEAN countries?**

A Jack Wong: COVID-19 has brought many challenges to our regulatory world. It meant an extra-large workload for regulators, who had additional tasks to do in processing urgent approvals for COVID-19 related products. This meant more meetings for them. In the past, it has been very difficult to organize meetings with regulators. Now, they are always reachable by phone or email. For expert panel meetings in China, for instance, a call can be made instead of flying overseas experts into the country for in-person meetings. So there are pros and cons.

I would add that, because of the very tight timelines that must be adhered to under COVID-19, the regulators need to be creative and develop very express pathways for the approval of some products, be they medical devices or pharmaceuticals. These pathways will be very important reference points in the future, in the case where we have another crisis.

A May Ng (ArQon regulatory consultancy global director): Under COVID-19, ArQon consultancy has tried to help as many companies as possible to bring in PPE and ventilators, given the huge demand at the beginning of the crisis. We were seeking approvals within three weeks, including doing the product file. During this period, the authorities were in fact able to use fast track approaches and digitized their processes. The demand for PPE led to the introduction of exemption orders in some of the region's countries.

It was good to have a lot of products available from a safety point of view. However, there were cases of sub-standard products that were not authorized, including masks, getting into circulation. And it was down to the public to differentiate between compliant and non-compliant products. The aim must be to source products from reliable sources, based on good, transparent information. For instance, lists of

approved COVID-19 tests were published on local health care regulators' websites, including those in Singapore and the Philippines.

In terms of manufacturing COVID-19 products, some non-device manufacturers—shipping companies for instance—were able to convert their operations and help out in product manufacturing. Some start-up companies also tried to convert their technologies and output, from non-COVID to COVID-related respiratory products, for example.

And regarding software-related applications, companies should take this opportunity to see what changes they can make to their products, and add new intended purposes to products to help meet the public needs.

Q **You're speaking of a mood of collaboration and a need for compliance, but who is driving the changes we are seeing under COVID, and what is industry's role in ensuring health system success, both now and post-pandemic?**

A Wong: We are learning both that governments can be flexible, and that governments themselves are learning that they can operate under super-quick pathways. The need for an express pathway is always there. Today, it is COVID, but we have had SARS, for instance. And it can be applied to cancer, or indeed any area where there is a clinical need and a good product that meets that need and therefore should be eligible for fast approval.

I think lot of governments and officials are now willing to approach industry, talk to companies and seek justification why certain products should be fast-tracked. A similar crisis might happen again. Normally, it can take one year to approve a product; now, with justification, approvals are happening within a month or even less. We are in a "golden moment," and the good thing is that governments are willing to listen about COVID-19 needs, and learn from the situation.

A Ng: Manufacturers have also been very understanding, trying to distribute needed products among many countries, for instance in the case of surgical gloves. The

regulators are also trying to cooperate with industry to approve needed products. Industry and governments are tending to cooperate well in the current environment.

Q How should we have prepared differently for the pandemic situation, with the benefit of hindsight?

A Wong: We must ensure we benefit from a lot of good learning, as we don't know what might happen next year – a COVID-20 perhaps? With that in mind, I come back to the point that governments and regulators should be proactively creating express pathways now. They don't need to wait for new crises; companies and governments can quickly get together and do something about it. Right now, everyone is still in crisis mode, busy with their current situations, but we can learn from this crisis.

We can't meet face to face, but via digital platforms that allow industry and governments to come together when problems arise. Many companies have switched focus to COVID-related opportunities. Some companies, either intentionally or by chance, realized that their product had a COVID-19 function, and went for it, creating a new indication, or "new intended use."

A Ng: I think that communications between the authorities can be improved. For instance, in the Philippines, where they have approved COVID-19 tests, virtual reports can be shared among the whole region's regulatory authorities, preventing duplication of efforts and information. An authority in one country should be able to give approval to a product, and then all other countries can use that as a reference and allow that product to be available in their countries.

Q Can you give some detail about experiences and actions in individual ASEAN members states?

A Ng: During COVID-19, ASEANMed initiated a project on legalization removal, or exemptions for some countries like Vietnam, Thailand and Indonesia. Some countries temporarily removed the requirement for the legalization of documents during COVID-19, and we think this is something that the local authorities should consider.

Some other countries do not require legalization, a process that takes time at the Embassies, some of which have been closed during COVID-19. ASEANMed is driving forward that idea for all ASEAN countries.

For instance, in the Philippines, work on device submissions was held up for a few months, but that restarted [as of late September]. At this point, companies registering a class A (low risk) device applications will not require a Certificate of Exemption (COE).

Myanmar entered into lockdown in September, and the ministry of health decided on special regulatory rules, but the regulator still had not implemented them [by late September], meaning industry could not file submissions during the lockdown.

Malaysia in lockdown was still doing device product reviews, and there were approvals ongoing. New guidance was issued for post-market surveillance, including a new form on which to record adverse events. New device advertising requirements have been delayed until 2021.

Vietnam is planning to implement new device price control rules, with the relevant text being drafted at present. Indonesia's e-Catalogue will be back in use soon, having not been available to use for the past year. Indonesia has reduced its timeline for approvals. The Thai medtech industry is having briefings from the Thailand FDA about the new device regulation, which has not yet come into use. Industry has been eager for updates on when to submit applications under the new regulation.

A Rhoel Laderas (*Baxter International Inc.* associate director regional regulatory affairs Asia-Pacific): Many regulatory agencies have shown that they can work under pressure and they can support the needs of the population and support industry as well. The main pathway used by ministries of health in ASEAN in order to support a COVID device or IVD is the emergency exemption, which is notified rather than registered. A good example is the Philippines, which allowed the direct import of PPE and ventilators by simply showing the import permit or approval pathway.

Separate fast tracks, requiring specific reviews, are also in place. Their requirements are the same as for all products, but they put a real focus on the review and on a reduction in approval time. And one other important mechanism is "regulatory reliance," i.e. using the approvals from other reputable regulatory agencies as acceptable proof of a product's quality. The Philippines, Singapore and Malaysia have utilized this route. These are the most important learnings for regulators during this period.

Q **Can you provide an update on new requirements relating to PPE and deployments regionally?**

A Laderas: Industry knew that governments were seeking secure supplies through emergency channels, and they were also supporting the import, manufacture and sourcing of goods and raw materials. Some countries are at the stage of continuing to import products now that supplies have stabilized, and some form of registration is being required. The Philippines drew up regulations on this. These products were initially exempted from registration, but now a time limit on that has been set, after which the registration process will apply. This will happen in other countries too.

A Romeo Ongpoy (regulatory affairs specialist, Philippines and Cambodia, Perkin Elmer Instruments): The Philippines eased regulations for PPE and hand sanitisers. It also had a one-stop shop for PPE business regulation and license issuing. In addition, the Philippines froze prices on PPE early in the pandemic. Locally manufactured COVID-19 test kits and donated products were subject to relaxed commercial rules in terms of licenses to operate. Masks and respirators benefited from faster regulation.

On the negative side, there was a proliferation of unregistered or not-notified PPE, especially in May, June and July in the country. This is one thing the FDA has been trying to control and in fact highlighted on its website. The main source was online outlets. Online sale are in the process of being regulated.

Q **How are markets adapting to the need for devices manufactured and packaged under strictly controlled conditions?**

A Loy Khang Yang (deputy director, sales and marketing, Mentor Media Ltd): The pandemic compelled brand owners to adopt a more careful approach towards the "wellbeing" of their products, in order to protect them from possible contamination. There has been much emphasis on ensuring zero risk, and localizing sterile packaging within the logistics supply chain.

In the past, it was purely medical logistics supplies. Now it is also about clean rooms, sterile packaging, sterilization and outsourcing. But many brand owners don't want to go through these tedious and time consuming processes that need special skill sets, and are very costly. Outsourcing is what they want to do, a business need that Mentor Media serves.

A lot of customers prefer to use pre-validated medical packaging. But new product lines still need the requirements of a cleanroom, which is why outsourcing is the trend. There are commercial reasons as well. Global markets need to adapt. Today we have COVID-19, but we need to be nimble to change, and brand owners do too.

A Jackie Tey (senior QA engineer, Mentor Media): The fundamentals are on minimizing risk factors. The very last mile is vital—sterile packing must be done properly, and clean rooms are a critical step. A technical approach is needed, given the many standards involved, including Asian standards. In short, it's a new perspective and focus on risk.

Q **Finally, can we explore how local businesses have been affected by COVID-19?**

A James Chan (SMF MTIG): For SMEs, it depends on the types of medical devices they supply, for instance, companies in elective device procedures have for the most part seen a negative impact on their sales, as government hospitals and patients too have been avoiding such procedures.

Chronic care and critical care are doing fairly well, as governments and hospitals are preparing for worst case scenarios and have been stocking up to ensure that there will not be a situation where they run out of supplies. Companies involved in PPE are

doing really well, with masks rising in price. Singapore has encouraged local companies to source more masks. The Health Sciences Authority (HSA) requires notification of import quantities, and in many cases, these can come into the country without registration.

A Lim Jing (*Osteopore Ltd.* chief technology officer): Osteopore specializes in bone fillers, and a lot of elective cases were postponed in the Singapore circuit breaker period. Some patients still need to be treated, however, with the ministry of health assessing how their quality of life is affected.
Over this period, a major pain point has been supply chain and logistics, and whether goods get held up at customs. We need to ensure that deliveries can still take place and that hospitals still have products. COVID-19 heralded much innovation and led to business pivots. Industry took a real hard look at digitization and automation, and how to innovate their products.

Business teams were all in one location for the first time – and that helped drive lot of innovative ideas. Use of Teams and Zoom platforms allowed us to stay in contact with customers and keep up some level of communication, although it's not the best option.

One of the positives to come out of COVID-19 was that companies were able to see how much they could streamline processes, or drive operational excellence to ensure business sustainability. These are some of the key things that we discovered along the way, and these are the silver linings of COVID-19.

A Laderas: This situation has proven that there is a need to look for new treatment options, given that so many new medical devices have online or remote capabilities. This will definitely be the trend in the next few years. COVID has called on us to accelerate the development of these technologies.