

Regulatory Agility in a Post-Pandemic World

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Head, Regulatory and Government Affairs, APAC
26 November 2021

In Partnership with the Philippines Association of
Medical Device Professionals (PAMDRAP)



My Affair with Regulatory Affairs – 20 Years

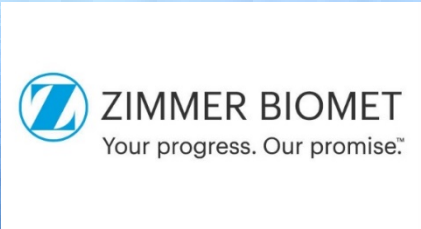


Regulator



Industry

Sakit Ulo kasi
“It’s Complicated”



The Deep Blue Sea

About me...on a personal note...



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About me...on a more serious note...



- Drafted the ASEAN Medical Device Directive, ASEAN Common Submission Dossier Template (CSDT)
- Head-of-Delegation (HoD) in the Medical Device Product Working Group (MDPWG)
- Secretariat to the ASEAN Medical Device Technical Committee (MDTC)
- Ex-Chair of Asia Harmonization Working Party (AHWP) Working Groups 1 (Pre-Market Submission and CSDT) and 6 (Capacity Building and Regulatory Training)
- Liaison Member of Study Group 1, Global Harmonization Task Force (GHTF)
- Trainer to regulators/industry under capacity building programs
- Vice Chair, Capacity Building Working Group, APACMed
- Appointed lecturer for the Graduate and Advanced Certificate for Medical Devices Regulatory Affairs Programmes from the National University of Singapore.

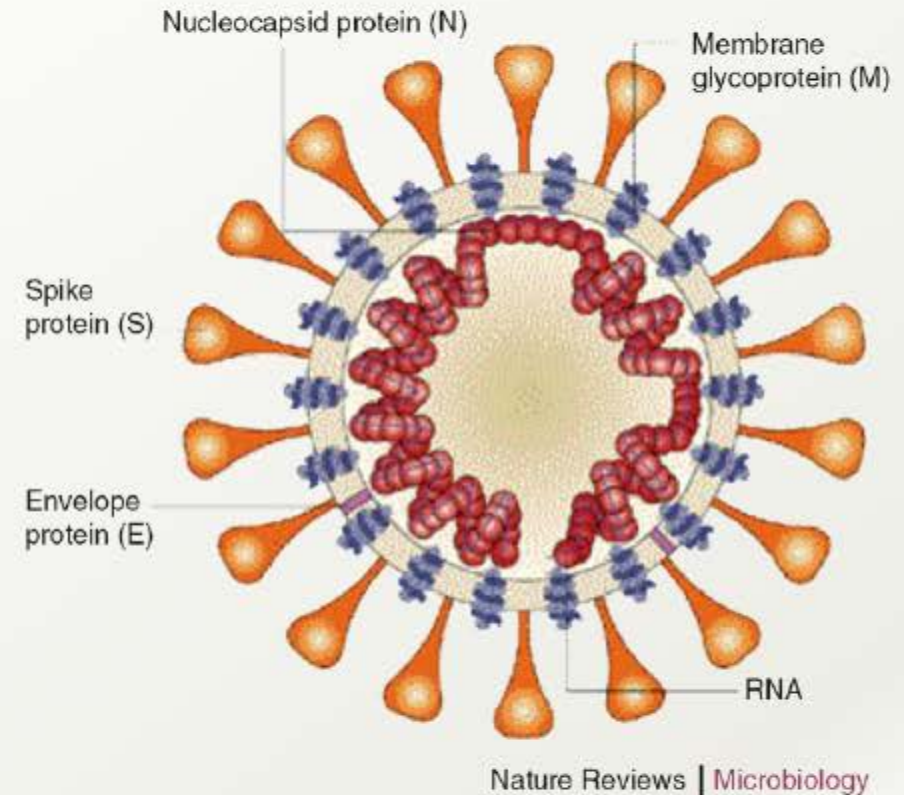




Stage 5

New emerging SARS-CoV-2 variants and their implications

- **New SARS-CoV-2 variants:**
 - Sept. 2020, a variant emerged in Denmark related to mink farming
 - Variant detected in the United Kingdom in December 2020
 - Variant detected in South Africa in December 2020
 - 9th January 2021, variant detected in Japan among persons coming back from Brazil
- All these variants involve **genetic mutations coding for the spike protein**
- The spike protein of SARS-CoV-2 is targeted by most vaccines currently approved or in development; mutations of the spike protein are closely monitored
- **The mode of transmission of the virus variants has not changed**
- **The same preventive measures continue to be effective and should continue to be implemented¹**



Pandemic Dashboard



Numbers at a glance

239 007 759

Confirmed cases

Last update: 14 October 2021, 11:08 pm
GMT+8

4 871 841

Confirmed deaths

Last update: 14 October 2021, 11:08 pm
GMT+8

6 471 051

151
Vaccine doses
administered

Last update: 14 October 2021

COVID-19 and the Critical Role of Medtech



COVID-19 and the Critical Role of Medtech

Novel Coronavirus COVID-19

Personal Protective Equipment (PPE)
According to Healthcare Activities
FOR HEALTHCARE WORKERS

PPE

medical gloves

medical mask

eye protection

face shield OR goggles

gown

filtering respirators

N95 or FFP2 or FFP3 standard or equivalent

apron

closed shoes

heavy-duty gloves

Items for specific procedures

Triage / Points of entry screening personnel/ Ambulance drivers that are not handling patients

Medical mask

Collecting respiratory specimens

Eye protection

Filtering respirator

Gown

Medical gloves

Caring for a suspected/confirmed case with NO aerosol-generating procedure (including ambulance staff)

Eye protection

Medical mask

Gown

Medical gloves

Caring for a suspected/confirmed case of COVID-19 WITH aerosol-generating procedure

Eye protection

Filtering respirator

Gown

Medical gloves

Apron

Cleaning the room of COVID-19 patients

Eye protection

Medical mask

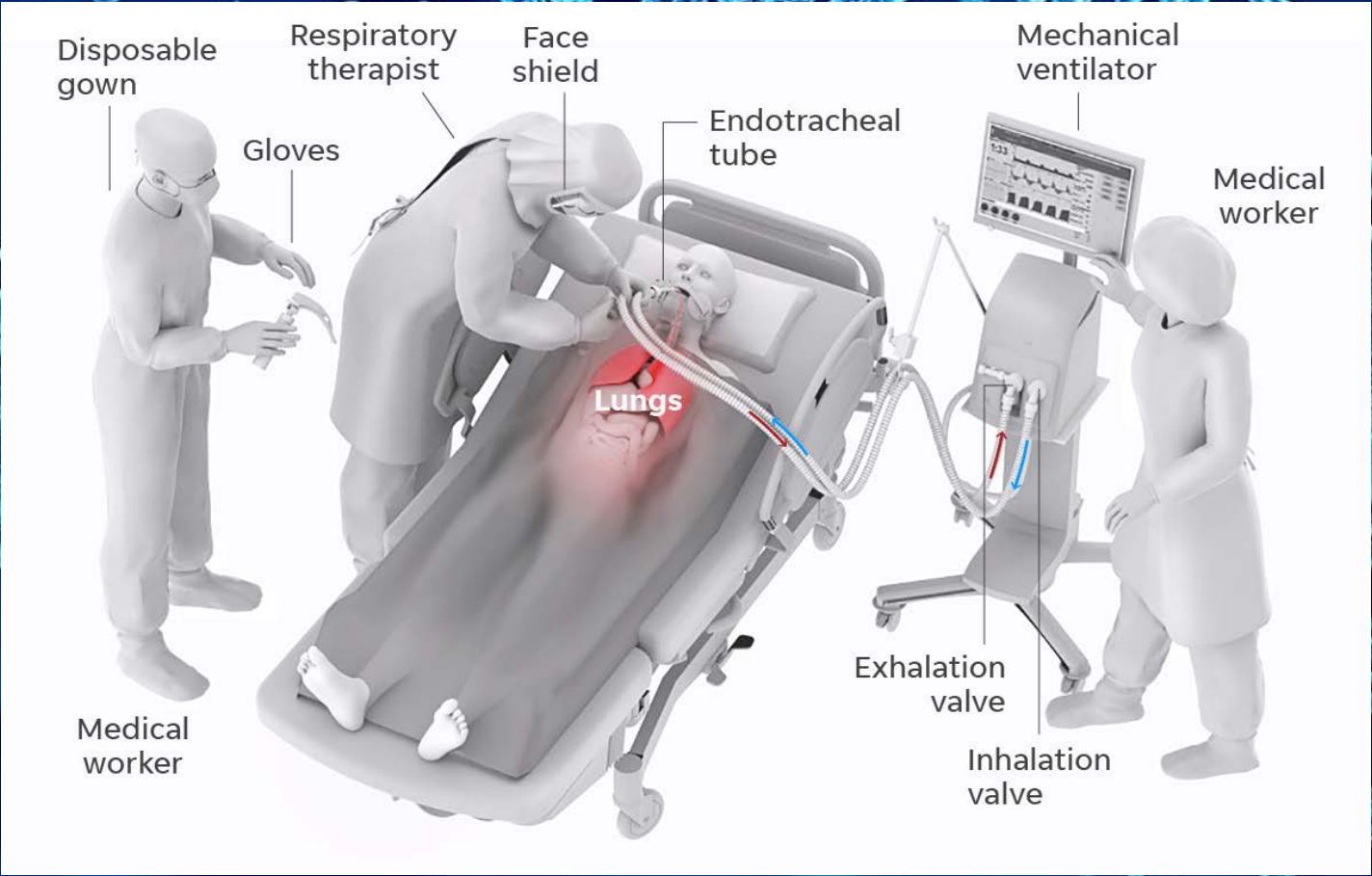
Gown

Heavy-duty gloves

Closed work shoes

General public/ Staff working in other areas than health facilities

Cloth mask (non-medical mask)



COVID-19 and the Critical Role of Medtech



The Rise of Technological Advancements



Technologies That Will Shape The Post-Virus World

First patient-controlled nasal swab robot

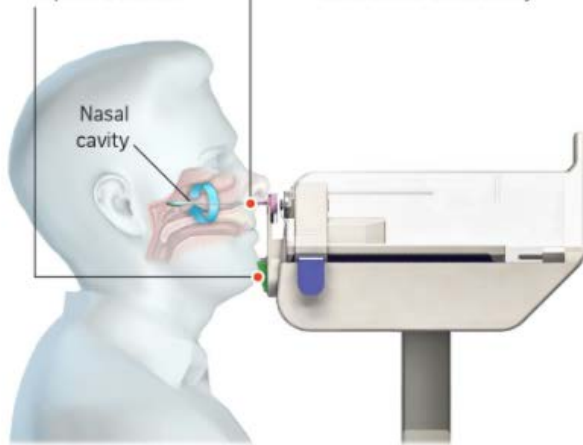
Clinicians and patients who have used SwabBot say that the machine is safe, faster and more comfortable compared with a manual swab test.

1 Activation

Patient will latch his nostril firmly onto the disposable nosepiece. When ready, he will activate the robot by using his chin to push a button.

2 Swabbing

The nosepiece moves slightly upwards to widen the nostril, and the swab will extend and rotate safely and gently through the patient's nose to the back of the nasal cavity.



Duration

The whole process takes about **20 seconds**.

Safety

The robot has a **built-in feature** that withdraws the swab stick if there is resistance when moving deeper into the nasal cavity. The individual can also terminate the process by moving his head away from the robot.

Sources: NATIONAL CANCER CENTRE, SGH
STRAITS TIMES GRAPHICS: LEE HUP KHENG

- Crisis can either be a catalyst or can speed up changes that are on the way.
- It almost can serve as an accelerant.
- Robot That Conducts Swab Tests For Covid-19 Is **Safe, Faster And More Comfortable** For Patients
- It **reduces swabbers' risk of exposure** to the virus and the need for training people, standardises the consistency of swabs taken, and increases the efficiency of conducting swab tests.
- This made-in-Singapore bot is the first that allows patients to fully control the swab process so they are more comfortable. Patients can activate and terminate the machine at will.

A New Era for MedTech industry

AUG 10 | MORE ON MEDICAL DEVICES

COVID-19 pandemic changing regulatory picture around medical devices, technology in healthcare

Some of these changes have presented opportunities for entrepreneurs and product developers.



Jeff Lagasse, Associate Editor



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COVID-19 IS ACCELERATING THE RISE OF THE DIGITAL ECONOMY



Home > News > Research & Innovation News > How the COVID-19 pandemic will accelerate mobile medtech innovation

News Research & Innovation News

How the COVID-19 pandemic will accelerate mobile medtech innovation

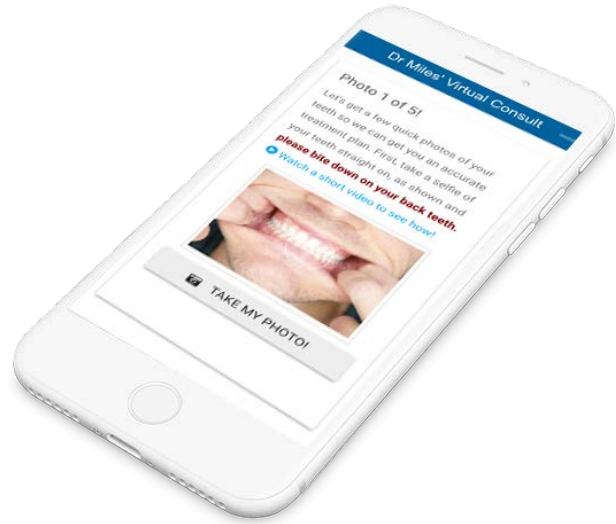
26th March 2021



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A New Era for MedTech industry



"Digitally Transforming Practice"

Covid-19 pandemic: example teledentistry services satisfy the need for social distancing and minimize physical contact

Continuity of care: monitoring patients' progress remotely to ensure their treatment is tracking to plan

Singapore authorizes four COVID-19 antigen rapid test self-use kits

Singapore authorises four COVID-19 antigen rapid test self-use kits

11 June 2021 | News

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HSA is working with the Ministry of Health (MOH) to make these tests widely available through designated local retail pharmacies



- HSA is working with the Ministry of Health (MOH) to make these tests widely available through designated local retail pharmacies.
- The Health Sciences Authority (HSA) in Singapore has granted interim authorization for four antigen rapid test self-test kits.
- These are antigen rapid tests (ARTs) that can be used by consumers (untrained lay-users) for self-testing to detect active SARS-CoV-2 infection in nasal swab samples. ARTs detect the viral proteins in the nasal swab samples of infected individuals and usually work best in the early stages of infection. ARTs can achieve a sensitivity of about 80% for cases with higher viral loads and a specificity range of 97-100%.

Technological Agility: Fundamental Shifts in a Post Covid-19 World

COVID-19 has accelerated the following trends which are reshaping the future of healthcare.

TELEMEDICINE: ACCELERATION OF ONLINE-OFFLINE INTEGRATION

China's Ping An Good Doctor

- New registrations grew by **10 times**
- Average daily consultations increased by **9 times**



US Centres for Diseases Control and Prevention

- Collaborated with **Microsoft Azure Healthcare** on Coronavirus Self Checker Bot, Clara

Singapore's Doctor Anywhere

- Raised **S\$27million** in funding digital-first "front-door" concept



ROBOTS WILL BE COMMONLY DEPLOYED IN HEALTHCARE

Singapore hospitals deploy robot, BeamPro



3D PRINTING COMBATS MEDICAL SUPPLY SHORTAGES



A.I. DEPLOYMENT



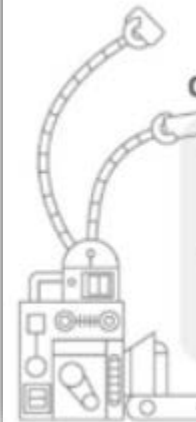
Development of online tools

- Model and chart medical scenarios
- Set parameters like population size and transmission rate

BlueDot, Canadian health-monitoring platform (AI-driven algorithm)

- Model and chart medical scenarios
- Set parameters like population size and transmission rate

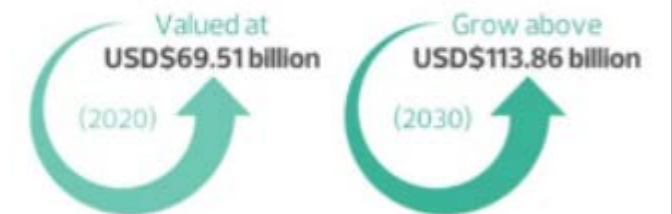
DIAGNOSTICS & POC TESTING



COVID-19 pandemic

- A new era for diagnostic testing
- Allows for rapid, point-of-care ("POC") testing

Global IVD market



How Singapore is Embracing Innovative Technology and Robots in Healthcare

Interest in medtech set to grow as S'pore healthcare firms digitalise



More doctors and users have signed up to use telehealth platform Doctor Anywhere, which allows users to consult a doctor through video on an app. PHOTO: DOCTOR ANYWHERE



Sue-Ann Tan

UPDATED APR 19, 2021, 3:27 PM



SINGAPORE - The Covid-19 pandemic has spurred many firms and sectors to transform themselves digitally, and even the healthcare sector with its high degree of human touch is not exempt.

The interest in medical technology, or medtech, has grown markedly over the past year, industry experts said.

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When COVID-19 evolved rapidly across the world, hospitals had to leverage new technologies, such as artificial intelligence (AI) and analytics, to develop tools that can be swiftly deployed, and enable teams to find new ways to combat the virus and manage the situation efficiently

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Harnessing Artificial Intelligence

- Doctors in Singapore developed an AI predictive tool to determine the likelihood of whether a patient has mild or severe pneumonia, based on chest x-ray images.
- Intended use: Community- Acquired Pneumonia and COVID-19 Artificial Intelligence Predictive Engine (CAPE), this system alerts doctors to pneumonia patients who are likely to become critically ill.



- Predictive tool used to determine the likelihood of whether a patient has mild or severe pneumonia.
- The risk of patients requiring critical care can be calculated almost instantaneously.
- Doctors at the emergency department and wards can receive an early warning for possible clinical deterioration, and prescribe the appropriate measures to improve patient outcomes.

Source: <https://www.singhealth.com.sg/news/singapore-health/embracing-innovative-tech-and-robots-in-healthcare>

Robots on the Frontline

Meet the robots that have been on the frontlines of the COVID-19 battle, "SwabBot" and "temi".



Availability of Antigen Rapid Test (ART) Self Test Kits Over The Counter

Every S'pore household to receive 10
ART Covid-19 self-test kits: MOH



Alcon

Source: TodayOnline, Yahoo News



The distribution will be done via SingPost and each household will receive a package containing 10 ART self-test kits. PHOTO: ST FILE



Clara Chong

PUBLISHED OCT 9, 2021, 3:47 PM SGT



SINGAPORE - The Health Ministry will be conducting another round of distribution of antigen rapid test (ART) kits, as Singapore heads towards a new normal where frequent testing for Covid-19 becomes common.

frequent testing for Covid-19 becomes common

Catalyst for Regulatory Agility



- Formulate **emergency exemption/approval pathways** (sometimes called provisional/conditional approval) to allow **fast access** with limited preliminary clinical evidence and conditions attached to request for post-authorization submission of ongoing or additional safety and performance evidence.
- Leveraging **regulatory reliance models** and/or authorizations from overseas reference authorities (such as those in IMDRF member countries or the WHO Emergency Use Listing procedure), to minimise duplication of efforts.

Enablers of Regulatory Agility in Philippines

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On the other hand the COB has issued Customs Administrative Order No. 7-2020 ("CAO 7-2020"), which provides that:

- The importation of health equipment and supplies to carry out the objective of Republic Act No. 11469 shall be exempt from duties, taxes and fees, including:
 - PPE, such as gloves, gowns, masks, goggles, face shields, surgical equipment and supplies;
 - Laboratory equipment and its re-agents;
 - Medical equipment and devices;
 - Support and maintenance for laboratory and medical equipment;
 - Surgical equipment and supplies;
 - Medical supplies, tools and consumables (i.e., alcohol, sanitizers, tissue, thermometers, hand soap, detergent, sodium hydrochloride, cleaning materials, povidine iodine, common medicines (e.g., paracetamol tablet and suspension, mefenamic acid, vitamin tablet and suspension, hyoscine tablet and suspension, oral rehydration solution, and cetirizine tablet and suspension);
 - COVID-19 testing kits; and
 - Others as may be determined by the DOH.
- Manufacturers included in the Master List of the Department of Trade and Industry and other incentive granting bodies of the National Government may avail of the tax and duty free importation under Section 4(o) of Republic Act No. 11469 for their importation of materials necessary for the production of health equipment and supplies deemed as critical or needed to carry out the objectives of Republic Act No. 11469.
- Importers of medical equipment and supplies for commercial purposes are exempt from the presentation of Certificate of Product Notification ("CPN") or Certificate of Product Registration ("CPR") issued by the FDA prior to release from the BOC provided, that they are able to provide a copy of their LTO and proof of application for product notification with the FDA. For ventilators, respirators and their respective accessories imported for commercial purposes, importers only need to present a copy of their LTO.
- Foreign donations of PPEs (face masks including N95 Masks, Shoe Covers, Gloves, Head Covers, and Gowns), imported not for commercial purposes, and foreign donations of ventilators, respirators and their respective accessories to be used in the treatment of COVID-19 patients, shall not be required clearance from the FDA prior to release.
 - Head Covers, and
 - Gowns

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Enablers of Regulatory Agility in USA

Initiatives to speed up market access	Tenets of Regulatory Mechanisms
New Mechanism	The key mechanism that the FDA is employing to facilitate the urgent need for medical products is the Emergency Use Authorization (EUA). EUAs allow the use of unapproved drugs and other medical products, or unapproved uses of those products in an emergency.
Faster Review	FDA is reviewing and granting EUAs in as little as 24 hours of receiving applications.



Enablers of Regulatory Agility in UK



Initiatives to speed up market access	Tenets of Regulatory Mechanisms
New Mechanism	<p>The MHRA may authorize manufacturers to supply a non-CE marked device in the interest of the protection of health (see here). This will be under regulations 12(5), 26(3) and 39(2) of the Medical Devices Regulations 2002, and is likely to be relevant for manufacturers of ventilators and PPE. The Department of Health and Social Care (DHSC) can grant its approval so that manufacturers may submit applications for exemption from the regulations to the MHRA. The DHSC may grant its approval regarding ventilators as long as they comply with the necessary minimum specifications which have been set out by the UK Government for ventilators.</p>
Faster Review	<p>The focus has been on a faster review for medicines and medical devices that are related to COVID-19, and the UK's Medicines and Healthcare products Regulatory Agency (MHRA) may authorize manufacturers to supply a non-CE marked device in the interest of the protection of health.</p>



Enablers of Regulatory Agility in Australia



Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Administration

An introduction to the work of Australia’s regulator of therapeutic goods



Initiatives to speed up market access	Tenets of Regulatory Mechanisms
New Mechanism	<ul style="list-style-type: none">• Relaxation from the requirement to obtain marketing approval for COVID-19 diagnostic test kits imported by, supplied to or used by accredited pathology laboratories• Relaxation in requirements to obtain marketing approval for certain other medical devices such as face masks, disposable gowns and protective eyewear that are supplied under a contract with the Australian Government for the purposes of the national stockpile;• Relaxation of requirements (relating to marketing approval and other technical requirements), for ventilators manufactured in Australia in accordance with minimum technical requirements prescribed by the TGA, provided that such ventilators are only supplied to Australian hospitals; and• Manufacture and supply of hand sanitizers.
Faster Review	Expedited approvals for all medical devices associated with the detection, prevention and treatment of COVID-19.

Enablers of Regulatory Agility in Japan

Initiatives to speed up market access	Tenets of Regulatory Mechanisms
New Mechanism	<ul style="list-style-type: none">• The government has introduced a subsidy to businesses which intend to make investment in facilities to manufacture surgical masks.• MHLW announced measures to provide manufacturers in non-medical industries with easier access to the medical devices market to promote the manufacture of medical devices for COVID-19 (such as ventilators). The measures include the following:<ul style="list-style-type: none">• If a manufacturer manufactures only parts of medical devices and supply them to marketing authorization holders of such devices, regulatory procedures will not apply to such manufacturer.• If a manufacturer is to be involved in assembly and other important manufacturing processes:• regulatory registration as medical devices manufacturer will be handled on a priority and expedited basis; and• a change to the product approval resulting from the addition of manufacturing sites will also be handled on a priority and expedited basis and physical QMS inspection of the manufacturing sites will be conducted after the approval of such change.
Faster Review	A foreign-manufactured test kit was approved as an IVD on 27 March on an expedited basis with a small amount of support data but subject to the condition that post-approval clinical assessment be conducted.

厚生労働省
Ministry of Health, Labour and Welfare

Enablers of Regulatory Agility in China



NATIONAL MEDICAL PRODUCTS ADMINISTRATION

国家药品监督管理局

Initiatives to speed up market access	Tenets of Regulatory Mechanisms
New Mechanism	<ul style="list-style-type: none">Emergency approvals have been available under existing regulations to allow expedited market access of medical devices if: (i) they are urgently needed for public health incidents; and (ii) there are no similar products marketed in China, or that any similar products marketed in China are insufficient to meet the particular urgent needs.Under the <i>Opinions on the Urgent Importation of Unregistered Medical Devices</i> issued by the NMPA on 27 January 2020, medical devices that are in compliance with relevant standards in the US, EU, Japan, Australia, Korea and Canada can be urgently imported during the COVID-19 epidemic. Exemption of documents for import.In line with these emergency measures, the PRC Customs also set up a "green channel" under which donated medical devices that are not registered or recorded in China can be released based on local MPA's approvals.
Faster Review	<p>Urgent approvals have been heavily utilized in response to the COVID-19 pandemic. Examples include the following:</p> <p>a) In vitro testing reagents for COVID-19 virus: A total of 19 testing reagents had received urgent approvals as of 16 March 2020.</p> <p>b) Hospital beds and isolating cabins: The Guangdong Medical Product Administration (MPA) granted conditional urgent approval for an isolating hospital bed and the Jiangsu MPA granted conditional urgent approval for an isolating cabin, both for use in preventing and controlling the spread of COVID-19. In the case of Guangdong, the approval was granted within three days from filing.</p> <p>c) Medical masks and protective clothing: As of 24 February 2020, 153 medical masks and 93 medical protective clothes had been urgently approved.</p> <p>□ It is worth noting that for personal protective equipment such as masks and protective clothing, the production has stabilized in China and some provincial-level MPAs have already stopped accepting applications for urgent approvals.</p>

Enablers of Regulatory Agility in Singapore



Initiatives to speed up market access	Tenets of Regulatory Mechanisms
New Mechanism	<p>From 31 January 2020, importers of the following medical devices will not require an importer's licence from HSA:</p> <ul style="list-style-type: none">• Surgical masks;• Particulate respirators (e.g. N95 masks);• Thermometers for measuring human body temperature; and• Any protective gear for medical professionals (e.g. isolation gowns and gloves). <p>Importers of such medical devices for commercial purposes (and not personal use) will only need to notify HSA of their intention at least 24 hours before importation, and provide information on the brand and quantity of the devices to be imported into Singapore.</p> <p>The HSA has also implemented greater regulatory flexibility to manage the increase in demand for respiratory devices for COVID-19 patients.</p> <p>The Pandemic Special Access Route (PSAR) is an interim authorization to supply an "emergency medical device" under regulation 13C of the Health Products (Medical Devices) Regulations.</p>
Faster Review	<p>HSA has created an alternative regulatory pathway where registrants will not need to undergo the standard change notification process for upgrades or modifications made to registered ventilators and accompanying accessories that do not create undue risk to users, or for registration of new models of accessories for use with the registered ventilators. Registrants may implement these changes without waiting for HSA's approval.</p>

In Summary

- MedTech continues to evolve and develop a risk-based Covid-19 Response Plan
- How to qualify for emergency use authorization?
- Enhance collaboration amongst stakeholders to enable regulatory agility

Fighting COVID-19 To Build A Global Community Of Health For All



A press conference on the release of a white paper on fighting COVID-19 held by China's State Council Information Office in Beijing, capital of China, June 7, 2020.

BY DINO PUGLIONE

The Covid-19 global pandemic is the most extensive to afflict humanity in a century. A serious virus for the entire world, and a daunting challenge, it poses a grave threat to human life and health. This is a war that humanity has to fight and win. China is waging intense efforts, day for day, to ensure success in cutting off channels for the transmission of the virus. Having forged the idea that the world is a global community of shared fate, and believing that it must act as an inseparable member, China has fought shoulder to shoulder with the rest of the world.

On June 7, 2020, the State Council Information Office of China published a white paper titled "Fighting COVID-19 in China in Action". The 17,000-word document records the Chinese people's battle against the virus, shares with the international community China's experience in curbing the virus and victory was secured in the battle to defeat Hubei Province and its capital city of Wuhan. As of the end of May, a cumulative total of 13,177 confirmed cases had been reported in the Chinese mainland. 78,307 infected had been cured and discharged from hospital, and 4,634 people had died. This demonstrates a cure rate of 98.3 percent and a fatality rate of 3.4 percent.

The Covid-19 is currently raging all over the world, and lives are being lost every day. The situation in Nigeria and Africa remains grave as well. In the face of this serious crisis, humanity once again stands at a crossroads. Every country has a choice to make. China

cooperation with the United Nations, the establishment of a cooperation mechanism for Chinese hospitals to pair up with 30 African hospitals, the building of the Africa Center for Disease Prevention and Control headquarters to help the continent ramp up its disease prevention and control capacity, the Covid-19 vaccine to be used as a global public product once it is developed and deployed in China, and the implementation of the Data Service Suspension Initiative for the poorest countries together with other G20 members.

China has shared information and experience with the international community. China is active in releasing information such as the whole country's epidemic sequence and the specific prompts and probes for detecting the coronavirus to the WHO and other relevant countries and regional organizations, and has kept them informed with regular updates. The "dilemma" and "coverage" accusations fabricated by politicians from certain countries are totally groundless and scapegoating. The National Health Commission has worked out diagnosis, treatment, prevention and control solutions, had them translated into three languages, and shared them with over 180 countries including Nigeria. China has held video conferences with health experts from over 170 countries to share its proven protocols of diagnosis, treatment and control to ensure any deviation. Among them, Chinese medical experts have held over 30 virtual exchanges with the African side. Nigerian Health Minister Dr. Ogbeke Chibari has consecutively attended all 4 video conferences on the local exchange on Covid-19 between China and Africa.

China has provided humanitarian assistance to the international community. Even while under the tremendous pressure of coronavirus control, China has donated quickly to provide as much assistance to the international community as it can. It has provided two batches of such support totaling 1,330 million to the WHO. China has been active in providing medical aid to other countries. As of the end of May, China had sent 26 medical expert teams to 27 countries, and offered assistance to 130 countries and 4 international organizations. A total of 8 teams with 148 medical workers have been sent to 13 African countries and 2 patches of governmental medical supplies have been donated to the Nigerian government. The medical teams so far regional over 400 African and African training centers in the region. Local governments, enterprises, non-governmental organizations and individuals in China have also been active in providing 150 countries and regions, and international organizations through various channels.

As the White Paper said, "The pandemic will have a significant impact on the development of humanity, but the people's longing for a happy life will remain unchanged. Peace, development and win-win cooperation will go on." The joint force running through this global pandemic is the common desire of all countries to end the epidemic, to provide greater support for Africa to strengthen global governance in public health, to restore economy and social development, and to strengthen international cooperation. The idea encompasses a series of major measures that China would take in supporting the global fight, including US\$2 billion of international and over two years' humanitarian relief again stands at a crossroads. Every country has a choice to make. China

A Technological and Innovative Approach to COVID-19 in Uruguay

BY GASTÓN MILANO, DIEGO VALLESPÍR, AND ALFREDO YOLA

THIS ARTICLE PRESENTS A technological and innovative approach developed to help the Uruguayan government in their fight against COVID-19. The first version of the system built only the most urgent services at that time was released only seven days after the first case of COVID-19 was reported in Uruguay. At press time, some months after its first release, the fourth version is operative. Part of the system is a cellphone app available freely to the public, and it was downloaded by half a million people in a country with a population of 3.5 million.



The project is innovative because it is the only world-wide solution that, that we are aware of, that integrates in a unified way for patients, all the health services of a country, the Ministry of Health, self-monitoring, remote patient monitoring, and telemedicine. Furthermore, the system makes full tracking possible from end to end to follow citizens' and patients' situation. Because of this, Uruguay was one of the first three countries and the first in Latin America to incorporate exposure notifications for COVID-19.

As we write this article (July 2020), the world is immersed in a context of total uncertainty regarding health issues caused by the coronavirus. In Uruguay, the first case of COVID-19 was confirmed on March 13, 2020. The same day, a Coronavirus UY App was launched by the Uruguayan government, where telemedicine was never seen before, at least in Uruguay.

Uruguay is one of the first countries to incorporate contact tracing for COVID-19.

FEATURE 23

Covid-19 crisis: Through solidarity, we will prevail

Now as the US is facing a severe situation domestically, many Chinese companies and localities have been offering assistance to the American people. The two peoples have shown mutual understanding and support in this joint fight against the pandemic.

Embracing the Future: Role of RA Professionals like ikaw at ako



Anticipate
Agility
Resilience
Empathy
Collaboration
Advocacy
**Game
Changer**

Source: <https://www.greenlight.guru/blog/author/jon-speer>

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