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Healthcare
Singapore

Newsletter

May 2020

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Health Sciences Authority of Singapore clamps down on products making false COVID-19-related claims

The Health Sciences Authority of Singapore ("**HSA**") has been clamping down on the sale of products with false and misleading claims that purport to diagnose, prevent or treat COVID-19. Through intensified surveillance on online marketplaces and local retailers, the HSA has taken down more than 1700 listings of such products online, and issued more than 1600 warning letters to sellers and companies marketing such products.

Amongst the errant listings were various COVID-19 test kits for home use, which were accompanied by fraudulent claims such as "*positive results may be visible (in) as soon as 2 minutes*". The test kits sold were found to have inherent design and technological limitations that could result in inaccurate or misleading findings. The HSA has stressed that it has not approved any COVID-19 test kits for home use, and that testing for COVID-19 in Singapore could only be done by clinical laboratories or medical professionals in clinics and hospitals.

A large number of hand sanitisers and disinfectant sprays also included claims such as "*protects against Coronavirus*", "*kill viruses including coronavirus*" and "*stops coronavirus*". These were found to be misleading insofar as they inaccurately gave the impression that the sanitisers are sufficient to eliminate all germs and thereby protect the user from the virus.

The HSA has emphasised that claims relating to COVID-19 have to be supported by appropriate scientific evidence, and that products carrying such claims must be evaluated and registered by HSA before it can be supplied. The HSA further noted that there is currently no evidence that any health supplement, Chinese proprietary medicine, traditional medicine or herb can boost the immune system specifically to help prevent, protect against or treat COVID-19. Accordingly, dealers and sellers should not fraudulently give consumers the false impression that use of their products will protect the user from contracting the virus.

Retailers who falsely advertise products as preventing or treating COVID-19 may face a fine of up to S$20,000 and/or imprisonment of up to 12 months.

The swift action taken by HSA represents the strict stance that HSA has consistently taken towards false or misleading labels. Intensified surveillance efforts are expected to continue in the interest of public health and safety. Dealers and retailers of health products should familiarise themselves with the applicable regulatory requirements or restrictions on labelling for their products, so as to avoid inadvertently contravening health product laws and regulations during this critical period.

More information about the HSA's surveillance efforts can be found here.

Telemedicine services: The new normal?

As part of the stringent circuit breaker measures implemented in Singapore, the Ministry of Health ("**MOH**") has directed that medical clinics may remain open only to provide essential services, such as attending to COVID-19 related cases or acute illnesses. However, if services sought by the patient are suitable for tele-consultations, these should be delivered to patients remotely where possible, even if they are essential services.

To facilitate this, the MOH has introduced an initiative during this period, where patients will be able to attend their regular follow-ups on their chronic conditions through video consultations, and use Community Health Assist Scheme (CHAS) subsidies and their Medisave to offset the cost. As of 4 May 2020, a total of 115 clinics have been approved by the MOH to provide such video consultations under the initiative.

The MOH Regulation Group has also introduced a timely e-training course on telemedicine for doctors who intend to provide tele-consultation services. The course, although coincidentally introduced in the midst of the COVID-19 outbreak, is being conducted in anticipation of the Healthcare Services Act's ("**HCSA**") implementation, under which doctor-led tele-consultation services will be regulated as a licensable service by the end of 2022. The course will guide doctors on tele-consultation uses, limitations and implementation considerations to help them design and deliver telemedicine services in a manner that prioritises patient safety and welfare. Nearly a thousand medical practitioners and healthcare staff have completed the course within less than a month of its introduction in March 2020.

Presently, tele-consultation services are permitted if they are provided by qualified doctors registered with the Singapore Medical Council ("**SMC**"). Doctors also have to adhere to the existing National Telemedicine Guidelines and the SMC's Ethical Code and Ethical Guidelines.

Although Singapore has already been gearing up for the wide-spread use of telemedicine over the past few years, the COVID-19 outbreak presents an unprecedented example of the increasing relevance and importance of telemedicine in today's healthcare industry. As demand for remote services increases, leveraging on technology for healthcare will become less of a novelty and more of an industry norm or even a necessity.

Healthcare service providers and healthcare professionals intending to provide soon-to-be licensable services under the HCSA may wish to engage with MOH early in the process, be it through MOH's regulatory sandbox or through public consultations. This will help facilitate a smoother transition into the new licensing regime under the HCSA, particularly if new service models are being developed to meet the demands of a post-COVID-19 industry.

More information on the e-training course can be found here, and the latest developments regarding the HCSA can be found here.

Health Sciences Authority of Singapore issues guidance on 3-D printing of essential medical devices for use during COVID-19

On 8 May 2020, the Health Sciences Authority of Singapore ("**HSA**") issued guidance on the 3-D printing of medical devices for use during the COVID-19 period (the "**Guidance**"). The Guidance was published against the backdrop of companies increasingly turning to 3-D printing to address supply chain interruptions and meet increased demand for critical medical products such as personal protective equipment and accessories for respiratory ventilators in light of COVID-19.

As with all other medical devices in Singapore, 3-D printed medical devices ("**3-DP MDs**") are classified into four risk classes (Class A to D) depending on the nature of the device, degree of invasiveness, duration of contact with the user and its intended purposes. The HSA has provided examples of classification, as follows:

Class	Examples
A (lowest risk class)	External prosthetics, face shields and nasopharyngeal swabs
B	Breathing circuits, ventilator tubes and connectors
C	Dental or orthopaedic implants
D (highest risk class)	Cranial implants and heart valves

The key points of the Guidance are as follows:

1. Dealer Licensing: Organisations that manufacture, import or wholesale 3-DP MDs must hold the relevant dealer's licence from HSA. However, healthcare institutions which are manufacturing 3-DP MDs for use on their own patients and not for external supply will not require a manufacturing licence.

2. Product Registration & Notification: All 3-DP MDs must comply with the HSA's Essential Principles of Safety and Performance, which sets out certain key technical considerations, such as design, device validation and manufacturing considerations, which manufacturers may wish to consider when verifying if their 3-DP MD conforms to such requirements.

   Additionally, whether the 3-DP MD needs to be registered with the HSA prior to supply depends on the Class of the 3-DP MD, as well as the manufacturing entity:

   a. 3-DP MDs in Classes B, C and D must be registered with HSA before they can be supplied.

b. 3-DP MDs in Class A do not require registration, but manufacturers and importers will need to notify the HSA before they can be supplied.

c. 3-DP MDs manufactured by healthcare institutions for use only on their own patients do not require registration.

3. Post-Market Duties and Obligations: Specified changes made to 3-DP MDs as part of their product life cycle will need to be reported to HSA. Dealers of 3-DP MDs should also conduct post-market surveillance, and are required to report adverse events, defects and recalls to HSA. An investigation must be conducted thereafter and dealers will have to implement mitigation measures to correct such issues and prevent potential recurrence. Healthcare professionals and users of 3-DP MDs should also report any adverse events to HSA.

Given the increasingly important role that 3D printing plays in the medical manufacturing industry, the Guidance provides manufacturers with timely regulatory clarity amidst the rapid innovative developments in the healthcare space.

The Guidance is also the latest development in a series of measures implemented by HSA in response to COVID-19, such as the expedited approval process for COVID-19 test kits and the regulatory flexibility granted for respiratory devices. We have discussed these two measures in the Singapore chapter of our "COVID-19: Global Review of Healthcare and Life Sciences Industry Issues", which you can find here.

More information about the Guidance can be found here.

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