HSA facilitates the access of respiratory devices for COVID-19 patients and implements "virtual desk-top audit process" to inspect new facilities manufacturing surgical masks in Singapore

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Dear Chief Executive Officers, Managing Directors and General Managers of Medical Devices Companies

I trust you are all keeping safe and well at work and at home.

In anticipation of the surge in demand for medical supplies with the global spread of COVID-19 cases, HSA is providing as much regulatory facilitation as possible to expedite and enhance the availability of medical devices that are critical to combat this pandemic.

As I had updated you earlier in March 2020, HSA had implemented the Provisional Authorisation for diagnostic test kits for COVID-19.

We have also worked on measures to facilitate the access to ventilators, as well as other respiratory devices, to mitigate any potential local shortage. To ensure that there is continual supply of surgical masks, we have also allowed "virtual desk top audits" to facilitate the inspections of new facilities that require a Manufacturing Licence to manufacture these products.

Facilitation of access to ventilators

Our measures to facilitate the access of ventilators include the following:

1) HSA will allow local anaesthesia machines to be used as ventilators for the duration of the COVID-19 pandemic, provided the manufacturers have developed the relevant instructions and are supporting the safe use of their anaesthesia machines as ventilators.

2) HSA will facilitate the implementation of changes to HSA-registered ventilators. For instance, software upgrades and alternative accessories for use with registered ventilators will no longer require HSA's prior approval before supply. The upgraded ventilators must continue to meet the Essential Principles of Safety and Performance as set out in the Health Products (Medical Device) Regulations, and the changes must not affect the registered performance specifications of the ventilators.

Facilitation of access to surgical masks

In tandem with the increasing interest of companies to set up surgical mask manufacturing in Singapore, HSA has implemented a "virtual desk-top audit process" to inspect new facilities. This allows the remote inspections of facilities that have not been audited or certified to the ISO 13485 standard or by third party certification bodies. To date, 3 companies siting manufacturing facilities in Singapore have been issued a Manufacturing licence (ML). This will contribute to ensuring a consistent supply of quality surgical masks in Singapore during this pandemic.

HSA has channelled significant resources in our medical devices cluster to focus on taking proactive and risk calibrated regulatory actions to expedite access to health products related to COVID-19. In addition to the above initiatives, HSA has stepped up our provision of timely regulatory guidance to the industry and the healthcare sector to support national efforts to combat COVID-19.

During this period, our priority will be to ensure that Singapore has continued access to critical and good quality health products to cope with the public health crisis. We endeavour to maintain our service delivery standards. Nonetheless, given our priorities related to COVID-19 balanced against current manpower resourcing, we seek industry's understanding if the expected turnaround times for some of the more routine applications are impacted during this pandemic.

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cc: Regulatory Affairs Managers
For further information pertaining to the regulatory measures for ventilators, please refer to this link.