HSA Circular to Exhibition Attendees

Legal Control for Medical Devices in Singapore

In Singapore, medical devices are subject to regulation under the Health Products Act. Under this law, all medical devices are required to be registered before any supply can be legally carried out, unless otherwise exempted under the provisions of the law. Thus, the supply of an unregistered medical device is an offence under Singapore's law and is liable on conviction to a fine not exceeding $50,000 or to a jail term not exceeding 2 years or to both.

With this, the Health Sciences Authority would like to remind all exhibition attendees that any unregistered medical device which is permitted for display at the exhibition shall not be taken as samples or purchased for use locally.

Notice to Healthcare Professionals

Healthcare professionals (e.g. dentist and doctors) who wish to obtain any unregistered medical devices for unmet medical need such as in situations where a registered treatment option is absent, and the patient's health will be clinically compromised without the use of the unregistered medical device, will require a **prior** authorisation from HSA. You may apply via the following Special Access Routes (SAR):

- GN-26: For licensed Qualified Practitioner (QP) to seek approval for the import and supply of unregistered medical devices for use on his patient.
- GN-27: For laboratories and medical facilities licensed under the Private Hospitals and Medical Clinics Act (PHMCA) / Healthcare Services Act (HCSA) to seek approval for the import and supply of unregistered medical devices for use on their patients.

For more information and eligibility of the above routes, please refer to SAR Guidance available at: https://www.hsa.gov.sg/medical-devices/guidance-documents

For further queries on the regulatory framework and process for registration of medical devices in Singapore, please contact:

Health Sciences Authority
Email: HSA_MD_Info@hsa.gov.sg
Phone: (65) 6866 1111
Fax: (65) 6478 9028

Or visit our website at:
http://www.hsa.gov.sg

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Annex: Class A medical devices exempted from product registration

All medical devices categorised as Class A (low risk) are exempted from product registration. The import and wholesale of such medical devices, however, must be performed by **importers and wholesalers licensed with HSA.**

The following are some examples to aid in identification of an exempted Class A medical device:

- Non-medicated wound dressings, adhesives and bandages for minor cuts and abrasions
- Non-active devices that are not intended to be invasive to the human body (e.g. non-sterile syringes)
- Simple devices that do not touch the patient or contact intact skin only (e.g. hospital beds, surgical face masks)
- Non-active devices that are transiently invasive to body orifices (e.g. Examination gloves, enemas)
- Non-active, non-sterile, reusable surgical instruments
- Examination lights/lamps, operation lights

Please note that these are only general examples for ease of reference. For further information, please refer to the guidance documents available on HSA website at https://www.hsa.gov.sg/medical-devices/guidance-documents

- *GN-13: Guidance on the Risk Classification of General Medical Devices*
- *GN-22: Guidance for Dealers on Class A Medical Devices Exempted from Product Registration*