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 used locally.

Notice to Healthcare Professionals

Healthcare professionals who wish to obtain any unregistered medical devices for local clinical use shall make an application to the HSA via the following authorization routes ***prior to supply***:

- *GN-26: Authorisation Route for Import and Supply of Unregistered Medical Device on Request by Qualified Practitioner for Use on his Patient*
- *GN-27: Authorisation Route for Import and supply of Unregistered Medical Devices to a Private Hospital, Medical Clinic or Clinical Laboratory licensed under the PHMC Act for the use on their patients*

Further information regarding the Special Authorisation Routes of supply can be obtained via the weblink,
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Overview/Authorisation_Routes.html

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

Health Sciences Authority
Medical Device Branch
Email: HSA_MD_Info@hsa.gov.sg
Phone: (65) 6866 1111
[Registration of Health Products > Medical Devices Enquiry]
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 non-sterile medical devices categorised as Class A (low risk) are exempted from product registration and can be freely supplied without prior authorisation from HSA. 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. urine collection bottles, hospital beds, 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 http://www.hsa.gov.sg:

- *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*

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