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A HEALTH SCIENCES AUTHORITY (HSA) UPDATE

AN OVERVIEW ON THE ENHANCEMENTS TO THE MEDICAL DEVICE REGULATORY FRAMEWORK IN 2012 and 2013

In HSA's bid to increase knowledge sharing of our regulations and policies, we are pleased to provide an update on the enhancements to the medical device framework and how medical devices are affected by these enhancements.

It was through numerous communication and engagement sessions with industry and healthcare professionals, including the medical & dental community, from which HSA had received feedback that regulatory costs and access issues were important concerns of our stakeholders. Hence, taking in consideration these concerns, HSA has further streamlined processes to ensure medical devices continue to be optimally available for patient care through the recent enhancements of the medical device framework. These series of enhancements are as follows:

- In 2012, HSA enhanced the regulatory framework for product registration of the lower risk Class A and B medical devices. HSA has also announced lower fees for medical devices brought under the Special Authorization Routes (SAR) to facilitate greater access to unregistered medical devices necessary to fulfill unmet medical needs. Healthcare professionals and PHMC-licensed facilities may apply for SAR under GN-26 and GN-27.
- In 2013, there were further enhancements to the regulatory framework for product registration of the higher risk Class C and D medical devices. New change notification routes for registered medical devices were also introduced.

Background

HSA adopts a risk-stratified and confidence-based approach, in-line with international best practices to ensure that consumers have access to safe, good quality and efficacious devices, and to facilitate prompt recalls when defects are detected. The regulations were also implemented in phases since 2007 to allow stakeholders adequate time to transit to a full regulatory framework.

In the run up to the full implementation of medical device registration on 1 January 2012, HSA had intensified its dialogues with its stakeholders. Based on the feedback received and experiences gained with the initial implementation of the regulation, HSA further enhanced its framework to facilitate access for medical devices. To ensure that patient safety is not compromised while customising different levels of controls, the enhancements are based on the broad principles that include a confident based approach to further leverage on the works done by mature agencies through judicious referencing of key HSA's independent overseas agencies; consideration of a history of safe use; and a shift of focus from pre-market evaluation to greater post market surveillance, audit and enforcement. Highlights of the enhancements are outlined in Table 1 (on the next page).

Table 1: Overview of key initiatives announced in 2012 and 2013

Initiatives	Potential benefit(s) to HSA's stakeholders

Enhancements for product registration of medical devices
 	
Class A medical devices
From 1 May 2012
• All Class A medical devices, except sterile devices, will be exempted from registration.
  ➢ Examples of exempted Class A medical devices are: dental chairs, non-sterile reusable surgical instruments and hospital beds.
• Turnaround time for registration of Class A (sterile) medical devices will be reduced from 60 working days to 30 working days.
 	
Class B, C and D medical devices
HSA has implemented the following new registration routes in 2012 and 2013:
 	
• Immediate Registration Route (IBR) for Class B medical devices that have already been approved by two of HSA's independent regulatory reference agencies[1], marketed for at least three years in these jurisdictions and without safety issues globally.
  ➢ Upon successful submission of the necessary documents, devices meeting the IBR criteria will be listed on the SMDR.
 	
• Expedited Registration Routes for
  i. Class B and C devices which have already been approved by at least one of HSA's independent regulatory agencies[1] and marketed in this jurisdiction or in Singapore without any safety issues globally for at least three years; or
  ii. Class B, C and D devices which have already been approved by two of HSA's independent regulatory reference agencies[1]
• Regulatory fees and turnaround time for the new routes will be decreased as compared to the abridged/ full evaluation routes.
• Certain Class C and D devices are excluded from the new routes.
• For Class B, C and D medical devices that do not qualify for the new routes, the abridged and full evaluation routes remain open to them.
• For more information, kindly refer to GN-15 Guidance on Medical Device Product Registration which can be accessed at: http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html.
	The enhancements will result in immediate access to non-sterile Class A medical devices and expedited access for medical devices that qualify for the new routes. Industry will also benefit from reduced paperwork and/or lower regulatory fees.

Enhancement of the Special Authorisation Routes (SAR) • Fees for special authorisation routes (SAR) will be temporarily offset and absorbed by HSA if all the medical devices listed in the SAR application are the subject of pending product registration or change notification applications that have been submitted by 31 December 2012. • The validity period of all approved SAR applications will be extended to 12 months (instead of the previous 3-6 months). • Qualified medical practitioners could import unregistered medical devices for the treatment of unmet medical needs in their patients via GN-26 and/or GN-27. • The process for the GN-27 (for applications to import unregistered devices for supply to clinical laboratories, medical clinics or private hospitals licensed under PHMC Act) has been enhanced to allow consolidation of an identical list of unregistered medical devices for different healthcare facilities into a single application. • SAR routes have been re-costed and the following revised fee structure with reduced fees has been implemented as of 1 Aug 2012: ➢ GN-26 (named-patient; requests by healthcare practitioners to import unregistered medical devices for use in specific named patients due to lack of registered alternatives): $150 ➢ GN-27 (PHMCA licensed facility; requests by licensed importers to import unregistered medical devices for use in specific PHMC-licensed healthcare institutions due to lack of registered alternatives): $350 ➢ GN-28 (import for re-export; requests by licensed importers to import unregistered medical devices for re-export purposes): $250 ➢ GN-29 (non-clinical use; requests by licensed importers to import unregistered medical devices for non-clinical purposes e.g. exhibition, training purposes etc.): $250	Healthcare professionals, PHMC-licensed facilities and industry members will benefit from reduced regulatory cost associated with applications to import and supply unregistered medical devices via the Special Authorisation Routes (SAR) for unregistered medical devices necessary to fulfil unmet medical needs. This includes low cost, low volume medical devices.
Enhancement of Change Notification Routes for Registered Class A and B medical devices • A closed list of changes to registered devices can now be submitted via the Minor Administrative Change (MAC) Notification. This route is applicable to all risk classes of registered medical devices with effect from 1st May 2012 and there are no fees payable. • For changes that are authorized for marketing in HSA's reference agencies, they will qualify for the new CN1 and CN2 routes. Further enhancements to change notification routes for registered medical devices are planned for implementation in 2014.	The enhancements will result in lower regulatory fees and faster turn-around time for change notification applications that qualify for the new routes.
Importation of medical devices on the Transition List (T-List)[2] • Medical devices placed on the T-List can continue to be imported and supplied while product registration applications	Healthcare professionals and users of medical devices will not face any disruptions in the access

are being evaluated. • The T-list can be found at: http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/Transition_List.html	and supply of essential medical devices.

(Details are available on the HSA website at: http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_updates.html)

More information

Annex A provides some examples on the risk classification of medical devices.

Annex B provides a guide on navigating the Singapore Medical Device Register (SMDR) for medical devices registered with HSA.

Information on medical device license fees & charges can be found via this URL: http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/fees_and_charges0.html

Feedback/ enquiries

HSA views healthcare professionals as important partners in the successful implementation of the medical device regulatory framework. Feedback or enquiries on the enhancements to the regulatory framework may be made through email (HSA_MD_Info@hsa.gov.sg). There is also a dedicated phone line for clinicians at 63045861.

Healthcare professionals play an important role to help safeguard public health by reporting adverse events suspected to be related to medical devices to HSA's Compliance Branch via the web-link: www.hsa.gov.sg/ae_online.

We look forward to our continued partnership in ensuring that safe, effective and quality medical devices continued to be introduced and used in Singapore.

More information on the enhancements of medical device framework can also be found in the

- *ADR Bulletin August 2012 (Vol.14 No.2)*
  - *http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/safety_information/adr_bulletin.html*
- *NEX2US Newsletter May 2012 (1st issue)*
  - *http://www.hsa.gov.sg/hsa_nex2us_newsletter*

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[1]US Food and Drug Administration (FDA), EU Notified Bodies or Australian Therapeutic Goods Administration (TGA), Health Canada and Japan Ministry of Health, Labour and Welfare

[2]The Transition List (T-List) was one of the measures implemented in November 2009 during the rolling out of the regulatory framework to facilitate continued access to medical devices while their applications were reviewed.

ANNEX A: RISK CLASSIFICATION FOR MEDICAL DEVICES

Table A1: Possible risk classes of medical devices

Class A	Class B	Class C	Class D
- Reusable surgical instruments - Dental examination chairs - Dental impression materials - Hospital beds - Blood collection tubes - Syringes without needles	- Dental drills/ hand-pieces - Blood pressure monitors - Thermometers - Pregnancy test kits - Needles for biopsy/ aspiration	- Transgingival dental implants (dental abutments) - Endosseous dental implants - Blood glucose meters - Contraceptive diaphragms - Catheters (for long-term, >30 days use)	- Bio-active implantable bone reconstruction materials (e.g. those containing collagen) - Absorbable wound dressings (e.g. those containing collagen) - Drug-eluting stents - Prosthetic heart valves

Actual risk class may differ based on intended use. Please refer to GN-13 Guidance on the Risk Classification of General Medical Devices for more information on risk classification (http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html)

ANNEX B: GUIDE TO NAVIGATING THE SINGAPORE MEDICAL DEVICE REGISTER (SMDR)

E-SERVICES & FORMS

Singapore Medical Device Register

The Singapore Medical Device Register (SMDR) is a database of all medical devices registered for use in human being under the Health Product Act (Medical Device Regulation). The register also includes medical devices registered with HSA before 31 March 2007 under the Voluntary Product Registration Scheme (VPRS) and evaluated in accordance to VPRS requirements.

The SMDR can be publicly accessed on the HSA website via the URL: http://eservice.hsa.gov.sg/medics/md/mdEnquiry.do?action=getAllDevices

Disclaimer: The listing of medical devices in the SMDR should not be construed as an explicit endorsement of the products by HSA.

A Step-by-step Guide on How to Search for a Medical Device in the SMDR

(i) Using Search Keyword(s)

The public can search for the medical device in the various tabs which list the medical devices in alphabetical order or search for the medical device in the "Advanced Search" tab using different key words.

For example, under "Device Proprietary/Brand Name", enter "Search Entry" or Search Keywords , for example, "cement", (as shown in Image 1), change the "Search Mode" to "Contains" and click on the "Search" button below, a list of device names containing "cement" will be shown (Image 2).

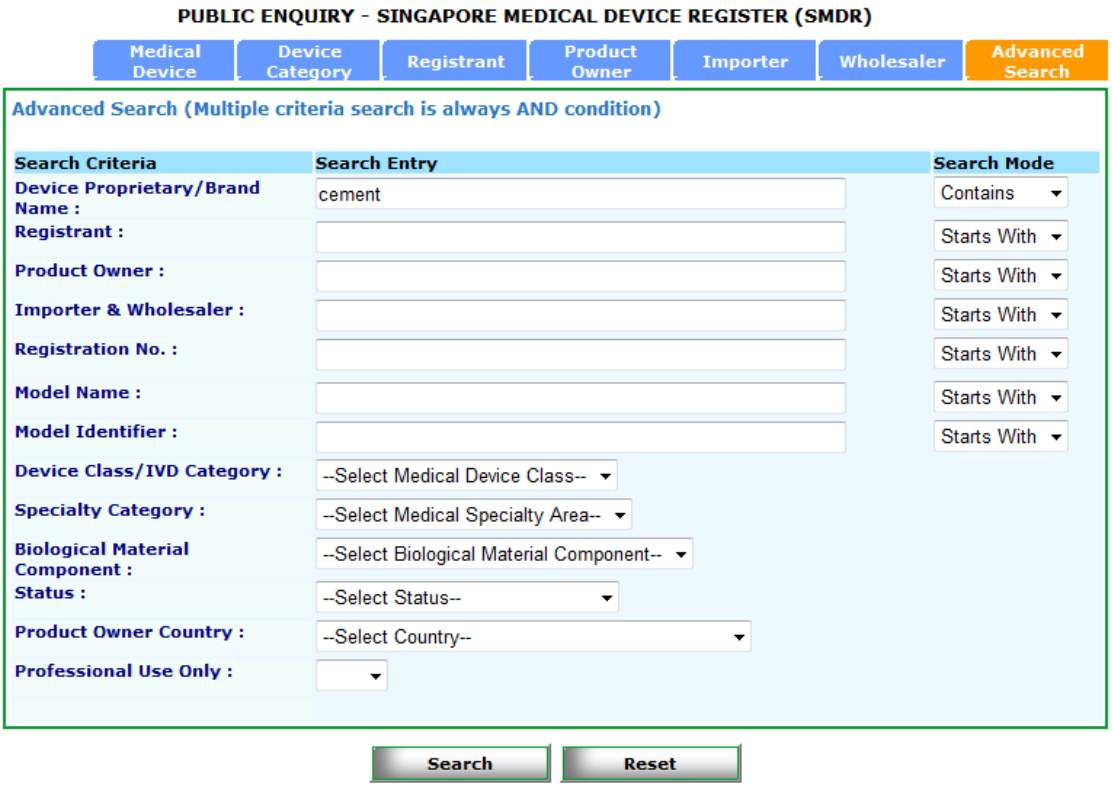

Image 1: Using "cement" as a search keyword on SMDR

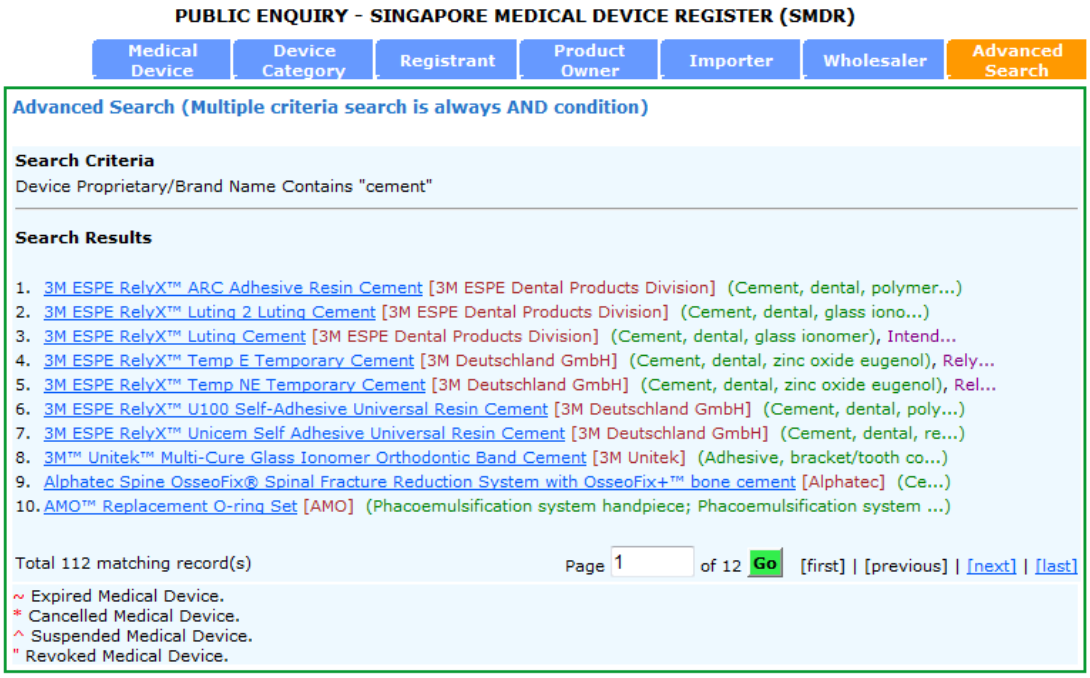

Image 2: Search results of using “cement” as a search keyword

(ii) Using ‘Medical Specialty Area’ search

Alternatively, the public also can search for medical device based on Medical Speciality Area.

For example, under the “Speciality Category”, select the appropriate category (for example, “Cardiovascular”) and click on the “Search” button. All the registered medical devices categorized under the “Cardiovascular” specialty category will be listed (Image 3).

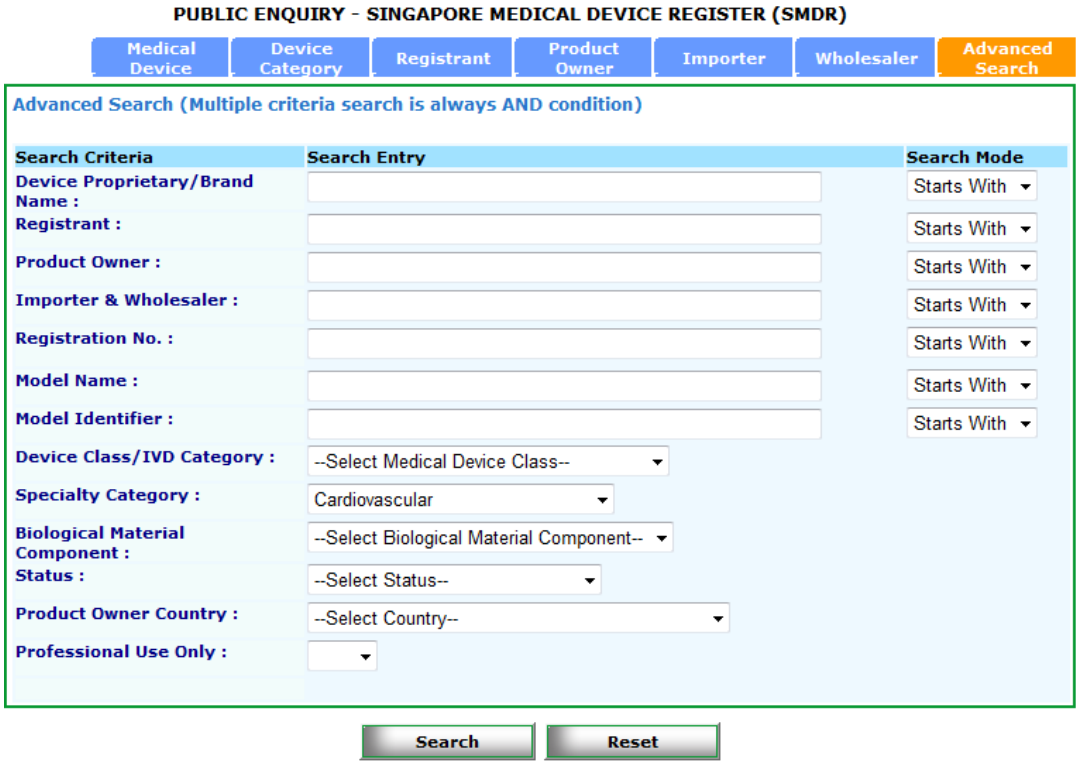

Image 3: Using “cardiovascular” as the medical specialty category on SMDR

To start with a new search, click on the “Search Again” button located at the bottom of the search results page.