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Health Products Regulation Group
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Dear Members of the Medical Device Industry

ENHANCEMENTS TO THE MEDICAL DEVICE REGULATORY FRAMEWORK

The Health Sciences Authority (HSA) is pleased to announce further enhancements to the regulatory framework to facilitate expedited access and lower regulatory fees for these devices.

This letter serves to provide an overview of the key enhancements while the relevant regulatory guidances are being updated.

1. Enhancements to the regulatory system for Class A and B medical devices

1.1 Exemption of Class A medical devices from registration, except for sterile Class A devices (with effect from 1 May 2012)

Currently, all Class A medical devices must be registered before importation and supply, except for products that are exempted from product registration in accordance with GN-22.

From 1 May 2012, all Class A medical devices, except sterile Class A medical devices, will be exempted from product registration. Dealers manufacturing and importing products that are exempted from product registration will, however, be required to declare the list of such products in the importer's and manufacturer's licences and update the list every half-yearly. All Class A applications for non-sterile devices which are currently pending approval will be eligible for refund. Applicants will be informed of the refund mechanism by the end of May 2012.

All sterile Class A medical devices will require product registration, with a target turn-around time of 30 working days excluding stop-clock. Product registration fees remain at $25 per application.

1.2 Additional expedited routes for registration of Class B medical devices (with effect from 1 September 2012)

Currently, product registration applications may be submitted through the full evaluation or abridged evaluation routes.

From 1 September 2012, HSA will be creating a new Immediate Registration route for Class B medical devices to allow immediate access to medical devices that have already been approved by at least 2 of HSA's independent reference regulatory agencies (i.e., US FDA, EU/TGA, Health Canada, Japan MHLW) and marketed for at least 3 years without safety concerns.

HSA will also be creating an Expedited Registration route, with a turnaround time of 60 working days excluding stop-clock. Product registration applications will qualify for this new route if the medical device meets one of the following criteria:

1. Approval by **at least two** of HSA's independent reference regulatory agencies

OR

2. Approval by **one** of HSA's independent reference regulatory agency and **marketed** in Singapore or that reference agency's jurisdiction for **at least 3 years** without safety concerns

Product registration fees for the new immediate registration and expedited registration routes will be reduced to $1,400 (from the current $2,300).

1.2.1 Interim measures to cater for the new routes of applications while upgrading MEDICS (from 20 April 2012 to 1 September 2012)

(a) For Class B (abridged) applications pending approval:
If the medical device meets the immediate registration or expedited registration criteria, the difference in evaluation fees between the abridged route and the immediate registration/expedited registration routes (i.e., $900) will be refunded to the applicant upon approval of the application.

(b) *For New Submission of Class B applications:*
While the MEDICS system is being enhanced, new applications eligible for the above 2 routes may be submitted under the abridged route. Refunds will be made to reflect the new fee structure. For example, if the medical device meets the immediate or expedited registration criteria, the difference in evaluation fees between the abridged route and the immediate registration/expedited registration routes (i.e., $900) will be refunded to the applicant upon approval of the application. Applicants are to include supporting evidence that the application fulfills the criteria in the dossier submission.

2. Special Authorisation Routes

2.1 Offset of fees

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. Refunds will be given for eligible SAR applications that have yet to be approved as at 20 April 2012.

2.2 Enhancement of application process for GN-27 special authorisation route

HSA has enhanced the GN-27 route to allow consolidation of an identical list of unregistered medical devices for different healthcare facilities into a single application.

2.3 Validity period

All approved SAR applications now carry a validity period of 12 months.

2.4 Fee review

HSA is looking into more tiered costing for SAR to take into consideration innovative, low cost and low volume medical devices. These will be announced on 1 August 2012 after reviewing the key products of concern with our stakeholders.

3. Change Notification

3.1 Introduction of a notification route for minor administrative changes

With effect from 1 May 2012, minor administrative changes may be implemented immediately upon submission to HSA, without awaiting regulatory approval. The usual documentation requirements apply and the fee collected upon submission will be refunded.

Refunds will be given for eligible administrative change notification applications that have yet to be approved as at 20 April 2012.

Minor administrative changes refer to the following changes:

Category	**Type of Change**
1. Labels including Instructions for Use (IFU)	Other labelling changes: • Layout • Colour • Font size and design • Addition and/or removal of languages not required by HSA
2. Software version	Changes to software version number that are not due to changes affecting safety, quality or effectiveness of the medical device, such as a) Software changes solely to correct an inadvertent software error which does not add new functions, does not pose any safety risk and is intended to bring the system to specification b) Software changes which augment interfacing to other non-medical peripherals such as printers or VDUs and which has no diagnostic or therapeutic function c) Software changes which only modifies the appearance of the user interface with no risk to diagnostic or therapeutic function of the device
3. Changes in package size	Changes which increase or reduce the number of devices in a pack of the device
4. Model Listing – Deletion only	Reduction in the number of models listed due to obsolescence or line rationalisation
5. Certificates	Update of validity dates of a. Regulatory approval certificates from reference agencies b. QMS documents such as ISO 13485

4. Updates to pending applications

To facilitate access of medical devices, changes to pending product registration or change notification applications (e.g., addition of models) will be allowed. Companies may write to HSA_MD_Info@hsa.gov.sg to request for an input request to include the updates or changes if the application is pending approval. Companies should, however, be aware that such requests may delay approval of the application, depending on the stage of evaluation.

5. HSA SMaRT E-Guide

The HSA-SMaRT E-Guide is a step-by-step guide on the medical device controls. The modules are being introduced in phases and the first module on product registration is now available on the HSA website and may be assessed by clicking on the following icon on the HSA homepage.

Alternatively, the E-Guide may be assessed directly through the URL http://www.hsa.gov.sg/mdbsmartguide.

6. Appeals

Appeals on submissions may be made in writing to the Group Director's Office at email address HSA_MD_Query@hsa.gov.sg.

7. Feedback and enquiries

The press release on the proposed enhancements is attached for your reference. More details will be shared with industry in the coming weeks.

Feedback or enquiries on the enhancements to the regulatory framework may be made through email (HSA_MD_Info@hsa.gov.sg) or by contacting the Medical Device Branch at telephone hotlines 6866-3560 or 6866-3566.

We thank the industry for your valuable feedback, and look forward to our continued partnership in ensuring that safe, effective and quality medical devices are used in Singapore.

Yours Faithfully,

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