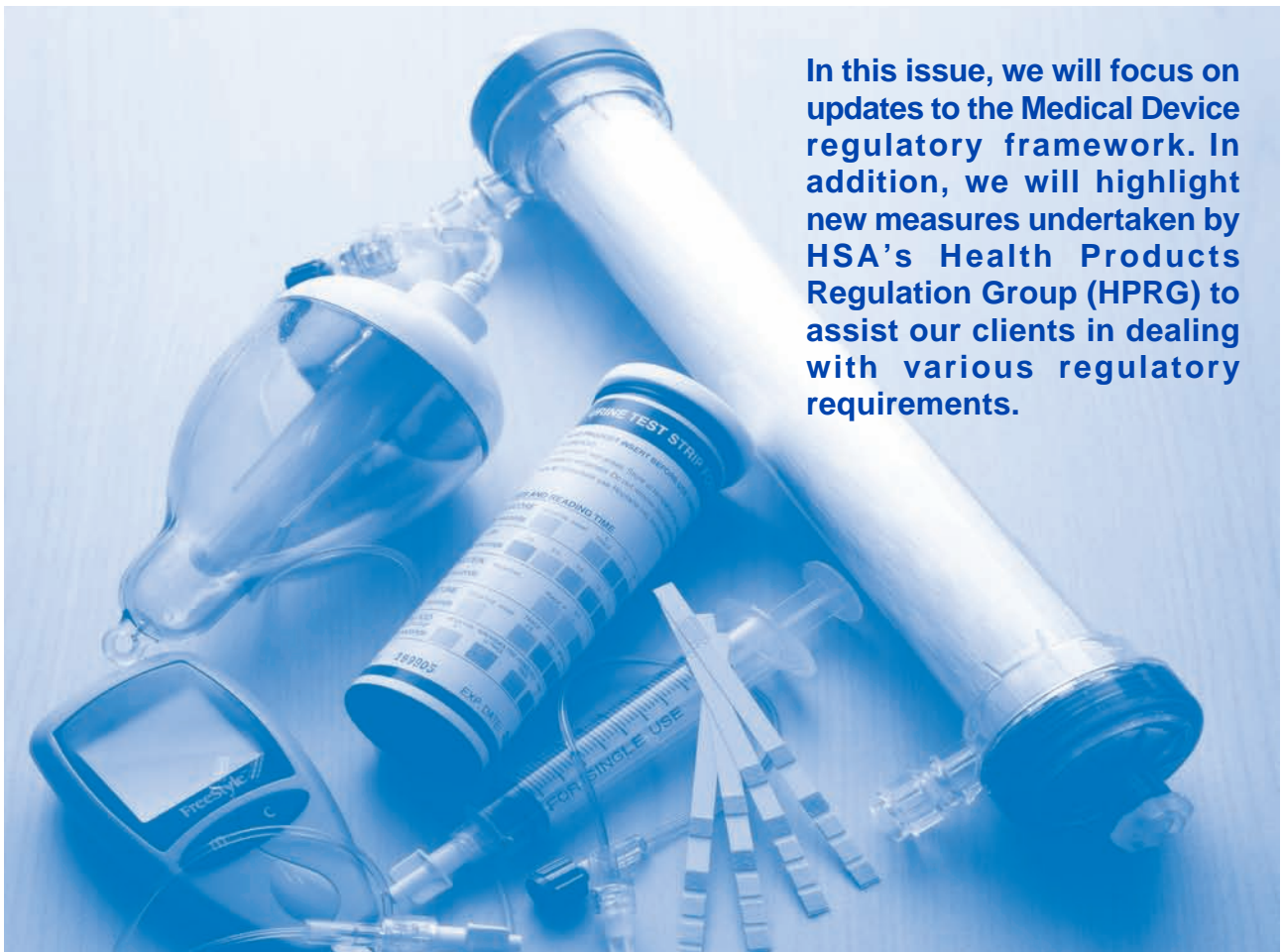


HSA

Health Sciences Authority | October 2010
www.hsa.gov.sg

Connects

HSA Connects is a regular communication update of present services available and future developments in the regulatory field for our industry clients.



In this issue, we will focus on updates to the Medical Device regulatory framework. In addition, we will highlight new measures undertaken by HSA's Health Products Regulation Group (HPRG) to assist our clients in dealing with various regulatory requirements.

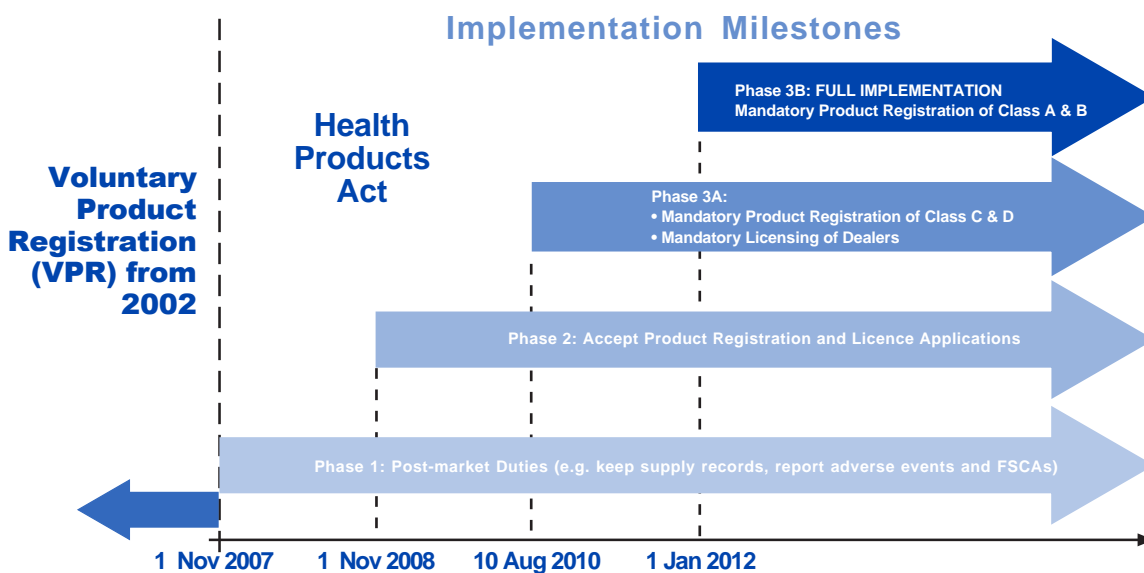
HSA Connects

Regulatory Control of Medical Devices in Singapore

In line with our mission to safeguard public health and safety, HSA's Medical Device Branch (MDB) implemented the medical device regulatory framework in 1 November 2007. HSA's objective is to ensure that medical devices available in Singapore are of acceptable standards with respect to both safety and performance. This will be done through various measures such as pre-market assessment of devices, dealers' controls and post-market compliance and vigilance.

A phased approach to implementation was adopted, allowing the Singapore medical device industry adequate time to prepare the necessary documentation and minimise impact on their business and market supply.

Implementation Milestones



Licensing Requirements (from 10 August 2010)

With effect from 10 August 2010, all Class C and D medical devices will require registration with HSA before they can be supplied locally. Medical devices that have been taken in before this date (e.g., devices already supplied in retail shops, hospitals or clinics) can continue to be supplied and used after this period.

It is important to note that only licensed dealers can manufacture, import or wholesale medical devices, regardless of risk class, except for devices used in clinical trials and those licensable under the Radiation Protection Act.

Transition List

Medical devices that are registered will be listed on the Singapore Medical Device Register (SMDR) and these can be imported and supplied in Singapore. Devices that were submitted by 30 April 2010 and are still under evaluation processing will be placed on a separate listing – Transition List (T-List). These devices can continue to be imported and supplied in Singapore, preventing the disruption of supply to the healthcare professional and patients. The T-list will be reviewed periodically.

There are certain devices which are considered to be of higher risk and these will not qualify to be on the T-list:

What is Abridged Evaluation?

Medical devices that have been approved by 1 of HSA's reference agencies will qualify for abridged evaluation:

1. US FDA
2. Health Canada
3. Australia TGA
4. European Notified Bodies
5. MHLW, Japan

- Devices that do not qualify for abridged evaluation
- Devices currently subjected to drug registration under Medicines Act before August 2010. Examples:
 - ▶ Lubricants for the eye
 - ▶ Viscoelastic material in ophthalmic products
 - ▶ Dialysate concentrate for hemodialysis (liquid or powder)
 - ▶ Solutions for irrigating, and/or non-injectable
 - ▶ Viscoelastic gels as fillers for joint lubrication
- Implantable devices with only 1 reference agency approval

After evaluation, if the device is approved, it will be removed from the T-list and listed on the SMDR. For a device which is withdrawn or rejected, it will be removed from the T-list and its import and supply will need to be stopped.

You may wish to refer to the HSA website for the devices that are on the T-List.

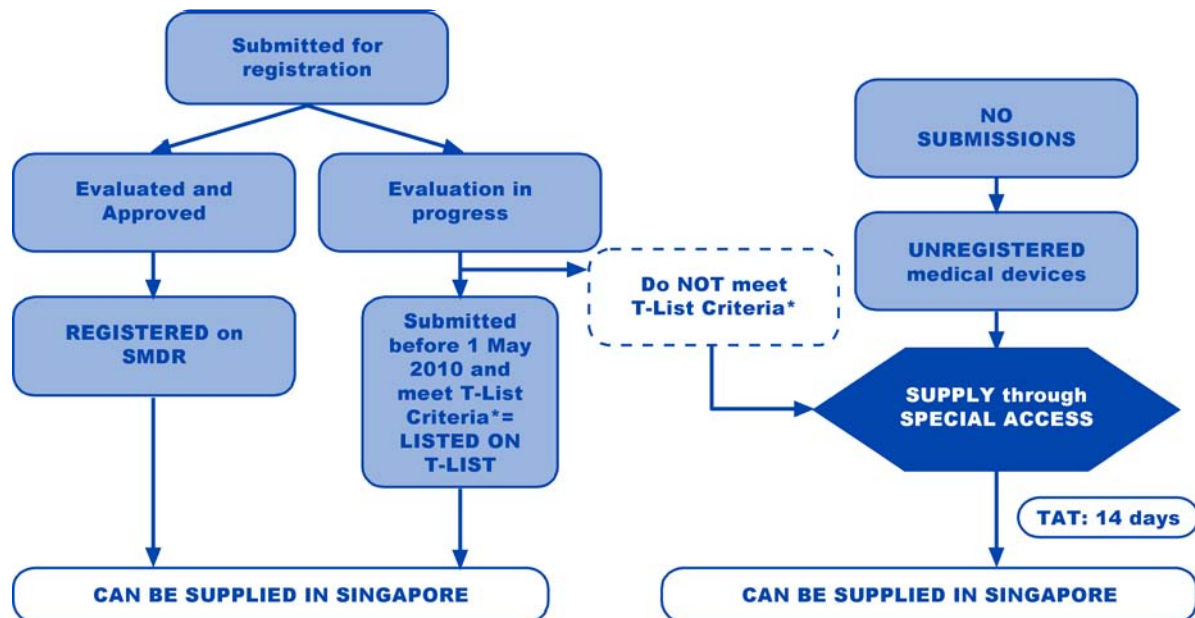
Authorisation Routes for Unregistered Medical Devices

To facilitate the supply of existing medical devices not intended for registration, HSA has implemented a number of special "Authorisation Routes". This allows qualified medical practitioners and patients to have timely access to novel medical devices. These routes do not mean automatic approvals and HSA will monitor the volume of import very closely to minimise misuse of this scheme.

There are 6 authorisation routes available to cater to different scenarios. Please refer to our guidance documents on the HSA website.

HSA Connects

This following diagram shows the overview of the required steps for the supply of Class C and D devices to the local market.



Moving Ahead

HSA has been actively involved in engaging our various stakeholders through briefing sessions and focused group discussions. As regulators, HSA needs to protect public health and at the same time we are aware of the need to accommodate technological innovations. We will continue to communicate openly with our industry and share any latest updates on the medical device regulatory controls.

DID YOU KNOW that as of May 2010, MDB received:

- 5045 product registration applications (including 2134 “C & D” registration applications)
- 1562 enquiries
- 796 licence applications

Frequently Asked Questions

Question:

I have not received any response from MDB since I first submitted my Class C and D product registration applications. When will my medical devices be approved so that I can supply them in Singapore?

HSA Connects

Answer:

Although the applications for Class C and D medical devices have yet to be approved, your business will not be disrupted as you can continue to import and supply these medical devices if they qualify to be on the Transition List. The Transition List is published online at http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/Transition_List.html Companies who have yet to submit the declaration letter for the Transition List are reminded to do so.

Question:

My company only deals with Class A and Class B medical devices, which will be controlled from January 2012. Does this mean that we do not require an importer, wholesaler or manufacturer's licence between August 2010 and January 2012?

Answer:

All dealers of medical devices require a valid dealer's licence to continue to import, wholesale or manufacture their products from 10 August 2010. This is regardless of the product's risk classification.

Importation of Medical Devices for Use in Clinical Trials in Singapore

With effect from 10 August 2010, an import permit for clinical trial material (CTM) will be required for the import of unregistered Class C and D medical devices for use in clinical trials, including regulated drug trials. The import permit, which is study-specific, will be issued in the form of a CTM (Medical Devices). Details on the application process, including the application form, may be found on the HSA website.

The table below summarizes the various scenarios in which sponsors of clinical trials will be required to apply for a CTM (Medical Devices).

Type of Clinical Trial	Clinical Trial Certificate (CTC)	CTM (Drugs)	CTM (Medical Devices)
Drug (only) Trial	✓	✓	✓ (if unregistered medical devices will be imported)
Drug-Device Combination Trial (*PMOA: Drug)	✓	✓	✓
Drug-Device Combination Trial (*PMOA: Device)	Pending implementation of the Health Products (Clinical Trials) Regulations	✓	✓
Medical Device (only) Trial	Pending implementation of the Health Products (Clinical Trials) Regulations	N.A.	✓

*PMOA: Primary mode of action

HSA Connects

In addition, manufacturers, importers or wholesalers of all medical devices, whether used in routine clinical practice or in clinical trials, have a duty and obligation to:

- report defects and adverse effects to HSA
- notify HSA concerning recalls
- maintain records of import and supply
- maintain records of complaints

Under the current clinical trials regulatory framework administered under the Medicines Act and Medicines (Clinical Trials) Regulations, it is not a requirement for the sponsor or Principal Investigator of a clinical study assessing a medical device to apply for a Clinical Trial Certificate (CTC). However, approval from the healthcare institution's Institutional Review Board should be obtained before commencement of the study.

The regulatory framework for clinical trials involving investigational medical devices is currently under development. Regulatory control of medical device clinical trials will commence in phases upon implementation of the revised Clinical Trials Regulations, which is targeted to be in 2011. The initial phase will be a notification system requiring sponsors to inform HSA of the medical device clinical trial prior to conducting the study.

Implementation of ASEAN Stability Requirements

Implemented on 1 January 2009, the ASEAN Guideline for Drug Product Stability Study stipulates that a larger safety margin for medicinal products marketed in Climatic Zone IVb is necessary. This is to provide assurance that product quality will not be affected when it is stored under "normal" conditions (i.e., non air-conditioned room).

Upon feedback from industry, HSA has adopted a phased approach to implementation of the ASEAN guideline. The second phase before full implementation will be effective from 1 July 2010 to 31 March 2011. The objectives of this second phase are to:

- give sufficient time for manufacturers to adopt the ASEAN guideline
- facilitate registration of products that do not meet the guideline requirements
- continue to move forward towards full implementation

ASEAN DRUG PRODUCT STABILITY DATA REQUIREMENTS

(Details of the second phase before full implementation of the ASEAN guideline)

HSA Connects

1. At time of submission of the application:

Application type	Drug product stability data requirement
NDA, GDA	Minimum of 6 months stability data as per ASEAN guideline
MIV	Minimum of 3 months stability data as per ASEAN guideline

Applications that do not meet this stability data requirement will not be accepted for screening.

2. Before approval of the application:

Application type	Drug product stability data requirement
NDA, GDA	Minimum of 12 months stability data as per ASEAN guideline
MIV	Minimum of 6 months stability data as per ASEAN guideline

Applications that do not meet this stability data requirement will not be approved until the data becomes available.

For further information, please contact Mr David Woo, Regulatory Consultant, at Tel: 6866 3551 or email: david_woo@hsa.gov.sg.

What's New?

E-versions of Package Inserts Now Available!

We are pleased to announce that the electronic versions of Package Inserts (PI) / Patient Information Leaflets (PIL) for all new medicinal products that are registered since 2003 are now available online.

The public and industry stakeholders can now gain easy access to the current list of approved PI and PILs for more than 1,000 medicinal products on HSA website via this link: <http://www.hsa.gov.sg/infosearch>.

Please contact **Ms Sherly Tanjung at 6866 - 1040** or email us at HSA_PBB_Productlabels@hsa.gov.sg, if you have any feedback on the above new e-service.

HSA Connects

Legislation Administered by HSA Now on HSA Website

For your easy access and reference, we have uploaded Acts of Parliament and subsidiary legislation administered by HSA onto our website:

http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/legislation.html

Upcoming Events

Inaugural HSA Joint Regulatory Workshop in January 2011

HSA will be organising a Joint Regulatory Workshop from 17 to 20 January 2011. This inaugural joint Workshop aims to provide a platform for industry participants to better understand the regulatory control requirements for health products in Singapore. Participants will also get to hear the latest updates on regulatory matters pertaining to western medicines, medical devices, cosmetics and clinical trials.

A workshop not to be missed!

More information will be made available in the coming months. Mark these dates on your calendar!

Going Green

HSA supports “Going Green”, and we hope that you will be our partner in this effort.

Future issues of HSA Connects will be emailed to all CRIS-registered companies. In order to receive your electronic copy of HSA Connects, please ensure that your company’s particulars are up-to-date. CRIS updates may be made at cris@hsa (<http://www.hsa.gov.sg/publish/hsaportal/en/services/cris.html>). However, if you prefer to continue receiving a hardcopy of HSA Connects, please contact Ms Soong Soon Chow at 6866 3497 or email Soong_Soon_Chow@hsa.gov.sg to tell us your preference.

For your convenience and reference, an electronic copy of **HSA Connects** is also available on the HSA website.



Tel: 65 6866 3400
Fax: 65 6478 9076
Email: hsa_industry_news@hsa.gov.sg
Address: 11 Biopolis Way #11-01 Helios
Singapore 138667
Website: www.hsa.gov.sg