Baker McKenzie Wong & Leow.

Healthcare
Singapore

Medical Devices

In August 2010, Singapore implemented the Health Products (Medical Devices) Regulations 2010, pursuant to the Health Products Act.

The Regulations revoke the previous Health Products (Medical Devices) Regulations 2007. It retains the duties and obligations applicable to manufacturers, importers and wholesalers of medical devices set out in the 2007 Regulations, such as maintaining of records, adverse events reporting and recall requirements.

Additionally, the 2010 Regulations addresses the following regulatory issues (amongst other things):

- Renewed timelines, requirements and processes for product and dealer registration;
- Exemptions from registration requirements for the supply of certain medical devices such as custom-made medical devices, medical devices for patients' use, medical devices for non-clinical use and medical devices for export or re-export;
- Exemptions from licensing requirements for the manufacture of certain medical devices such as custom-made medical devices and medical devices manufactured by secondary assembly;
- Exemptions from registration and licensing requirements for medical devices used for clinical trials;
- Safety and performance requirements;
- Presentation requirements such as labelling and trade description requirements;
- Advertising requirements;
- Certificates that may be issued by the Health Sciences Authority of Singapore such as certificates of origin, certificates of issue of licenses, certificates or registration, certificates of free sale and certificates of export; and
- Other duties and obligations imposed on manufacturers, importers, wholesalers, and registrants.

Awards & Accolades

Band 1 for Life Sciences
Chambers Asia Pacific 2014 - 2024

Medical and Healthcare Law Firm of the Year
Asian Legal Business Southeast Asia Law Awards 2020 and 2021

Band 1 for Intellectual Property
Chambers Global 2009 - 2024

Band 1 for Intellectual Property
Chambers Asia Pacific 2010 - 2024

Tier 1 for Intellectual Property
Legal 500 Asia Pacific 2010 - 2024

Tier 1 for Patents and Copyrights/Trademarks in Singapore
ALB Asia IP Rankings 2018 - 2024

Asia Pacific Patents Firm of the Year
Asia IP Law 2023

Tier 1 for Copyright, Trademark Contentious and Trademark Prosecution in Singapore
Asia IP Law 2023

Asia Pacific IP Firm of the Year
Managing IP Asia Pacific Awards 2018 - 2022

Global IP Firm of the Year
Managing IP Asia Pacific Awards 2017, 2018 and 2022

Scope of 2010 Regulations

Like the 2007 Regulations, the 2010 Regulations utilizes a risk management approach to match the level of regulatory scrutiny to the degree of risk involved in using a particular medical device. Medical devices continue to be classified into four classes in ascending order of risk to the consumer.

A. (low risk);

B. (moderately low risk);

C. (moderately high risk); and

D. (high risk)

Implementation Phases

When the 2007 Regulations were implemented, the HSA adopted a phased approach in implementing the 2007 Regulations to provide sufficient response time for the industry to meet the new standards and requirements. Under the 2007 Regulations, Phase 1 was implemented from 1 November 2007 on the following:

- Imposition of duties and obligations to dealers to:
  - Report product defects and adverse effects;
  - Recall products upon HSA's instructions; and
  - Keep records of products supplied.
- Prohibition of false/misleading advertisements.

Phase 2 and 3 of the 2007 Regulations have been amended as follows by the 2010 Regulations:

Amended Phase 2 (From 1 November 2008)

- Acceptance of dealers' license applications from parties dealing in medical devices and registration of medical device products.

Amended Phase 3 (To be conducted in 2 stages)

- Stage 1 (10 August 2010 onwards)
  - Only licensed dealers can manufacture, import or wholesale medical devices.
  - Class C and D medical devices (but excluding those medical devices currently licensed under the Radiation Protection Act by the Centre for Radiation Protection and Nuclear Science of the National Environment Agency) that are imported and supplied must meet on of the criteria below:
    i. Listed on the Singapore Medical Device Register;
    ii. Listed on the Transition List;

iii. Authorised via one of the Authorisation Routes, which include:

(a) Authorisation Route for Supply on Named-Patient Basis;

(b) Authorisation Route for Supply on Request of Private Hospitals and Medical Clinics Licensed Facility;

(c) Authorisation Route for Export of Unregistered Medical Devices;

(d) Authorisation Route for Supply for Non-Clinical Purpose;

(e) Authorisation Route for Import on Consignment Basis (Consignment Registered Route); and

(f) Authorisation Route for Import on Consignment Basis (Consignment Unregistered Basis).

- Class C and D medical devices currently licensed under the Radiation Protection Act by the Centre for Radiation Protection and Nuclear Science of the National Environment Agency shall be exempted from product registration with HSA until 1 August 2011.

- Stage 2 (1 January 2012 onwards)
  - Unless exempted from product registration, all medical devices, including Class A and B medical devices, that are imported and supplied must meet one of the criteria below:
    - Listed on the Singapore Medical Device Register;
    - Listed on the Transition List; and
    - Authorised via one of the Authorisation Routes.

HSA has indicated to the industry that the timeline (calculated from the date of submission of product registration applications to attaining registration) is 60 working days, subject to additional time as may be required for HSA to request, and the applicant to respond, to any input requests. Therefore, the timeline for attaining registration (on the basis that there are no input requests) is 3 calendar months. Realistically, additional time has to be taken into account for input requests from HSA, which may significantly increase the timeline for attaining registration.

For products which have been evaluated and approved in at least one of the Global Harmonisation Task Force countries, the evaluation of the submission will take the form of an abridged evaluation and the timeline is likely to be shorter in these cases.

Submissions of applications for low-risk product registration (i.e. Class A medical devices) do not undergo a substantive pre-market evaluation by HSA and the timeline for attaining registration is correspondingly reduced.

Enhancements to Regulatory Framework

Faster and Expedited Access for Lower Risk Devices

HSA announced on 20 April 2012 that its regulatory framework will be enhanced for lower risk Class A and B medical devices to facilitate expedited access and lower regulatory fees for these products. Further enhancements are also being planned for the higher risk Class C and D devices.

From 1 May 2012, all Class A medical devices, except sterile Class A medical devices, have been exempted from product registration. Dealers manufacturing and importing products that are exempted from product registration are required to declare the list of such products in the importer's and manufacturer's licences and update the list half-yearly. 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.

From 1 September 2012, HSA has created two new registration routes, in addition to the Full and Abridged registration routes.

The new Immediate Registration route for Class B medical devices allows immediate access to medical devices that have already been approved by at least 2 of HSA's independent reference regulatory agencies (i.e. US Food and Drug Administration, EU Notified Bodies/Australian Therapeutic Goods Administration, Health Canada, Japan Ministry of Health, Labour and Welfare) and marketed for at least 3 years without safety concerns.

The new Expedited Registration Route comes with a turnaround time of 60 working days excluding stop-clock. Product registration applications will quality for this new route if the medical device meets one of the following criteria:

(a) Approval by at least two of HSA's independent reference regulatory agencies; or

(b) Approval by one of HSA's independent reference regulatory agencies 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 from $2,300 to $1,400.

There has been industry consultation on Guidance for Change Notification for Class A and B Medical Devices and Registration of Class C and D Medical Devices as of 19 October 2012.

Enhancement of the Special Authorisation Routes

With effect from 1 March 2012, validity period of all approved Special Authorisation Routes applications have been extended from 3-6 months to 12 months.

SAR have been re-costed and the following revised fee structure with reduced fees has been implemented with effect from 1 August 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): SGD 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): SGD 350
- GN-28 (import for re-export; Requests by licensed importers to import unregistered medical devices for re-export purposes): SGD 250
- GN-29 (non-clinical use; Requests by licensed importers to import unregistered medical devices for non-clinical purposes, e.g. training purposes, in-vitro diagnostic medical devices for research-use only purposes, etc.): SGD 250

Submission of Applications

The Singapore Medical Device Register is a database of medical devices that are imported into or exported from Singapore. HSA has also developed the Medical Device Information & Communication System, a web-based system that provides an electronic environment for interaction between medical device establishments and HSA.

Currently, users can access several key documents through MEDICS@HSA, including the establishment license application, the market clearance application for higher-risk devices and the notification of export-only unregistered medical devices.

The following sets out a summary of the steps to be taken for the submission of a product registration applicant ion for a medical device:

1. Ascertain if the product in question falls within the definition of a "medical device";
2. Determine the risk classification of the medical device;

3. If the medical device falls under Class A (low risk), check if it falls under the list of exempted low risk medical devices published by the HSA for which registration is not required;
4. Determine if the medical device may be submitted as a group medical device;
5. Prepare the documentation required for the registration application (with the exception of low risk medical devices, all medical devices need to be submitted in the ASEAN Common Submission Dossier Template);
6. Apply for a Client Registration and Identification Service account (this is not required if the company has participated in the Voluntary Product Registration Scheme);
7. Apply for a Registrant Account under the MEDICS@HSA system; and
8. Submit the product registration applications online via the MEDICS@HSA system and respond to any subsequent input requests by HSA.

In view of the aforementioned regulations, medical device companies should manage the timelines for product launches so as to allow adequate time to procure all necessary product registrations for medical devices prior to their supply on the Singapore market.

Contact Us

Andy Leck
Principal
Tel: +65 6434 2525
Fax: +65 6337 5100
andy.leck@bakermckenzie.com

Ren Jun Lim
Principal
Tel: +65 6434 2721
Fax: +65 6337 5100
ren.jun.lim@bakermckenzie.com

bakermckenzie.com

Baker McKenzie Wong & Leow
8 Marina Boulevard #05-01
Marina Bay Financial Centre, Tower 1
018981 Singapore
Tel: +65 6434 2606
Fax: +66 6338 1888