

BIODESIGN GLOBAL SOURCEBOOK: SG.02 SINGAPORE REGULATORY BASICS

Inventors seeking to supply medical devices in Singapore must register all classes of devices with the country's regulatory body for medical devices, the Health Sciences Authority (HSA). The requirement, which went into effect on January 1, 2012, is part of HSA's efforts in recent years to ensure medical devices supplied in Singapore meet international standards.

The Singapore government has taken a step-by-step approach to regulating medical devices, introducing a voluntary product registration scheme in 2002. In 2007, it passed the Health Products Act to begin mandating regulatory control over the industry. Since then, HSA has implemented the regulations that stem from the act in stages to give members of the medical device industry time to adjust to the new rules. This chapter explains the basics of Singapore's regulatory regime and product registration process, an understanding of which will help innovators design and develop medical devices that will meet regulatory requirements in Singapore.

Gaining an understanding of Singapore's regulatory environment may be worth the effort. Although the country's US\$575 million medical device market¹ is relatively small on its own, the Asia-Pacific market as a whole was worth roughly US\$55 billion in 2011.² Innovators developing devices for Asia-specific clinical needs and hoping to penetrate Southeast Asia's markets in particular may want to consider first obtaining approval for their devices in the city-state. Since HSA is often regarded as a thought leader for regulatory

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regimes in Southeast Asia, inventors who have successfully steered their device through Singapore’s regulatory system may find it easier to navigate those markets’ systems. Singapore-based inventors will also first want to seek registration approval in Singapore since foreign regulatory agencies are more likely to approve devices that have already obtained approval in their home market.

OBJECTIVES:

- ✓ Understand HSA’s initiatives and organization.
- ✓ Understand how medical devices are classified and the regulatory pathways they can take as a result of that classification.
- ✓ Understand some key differences between the Federal Drug Administration (FDA) in the United States and Singapore’s HSA.

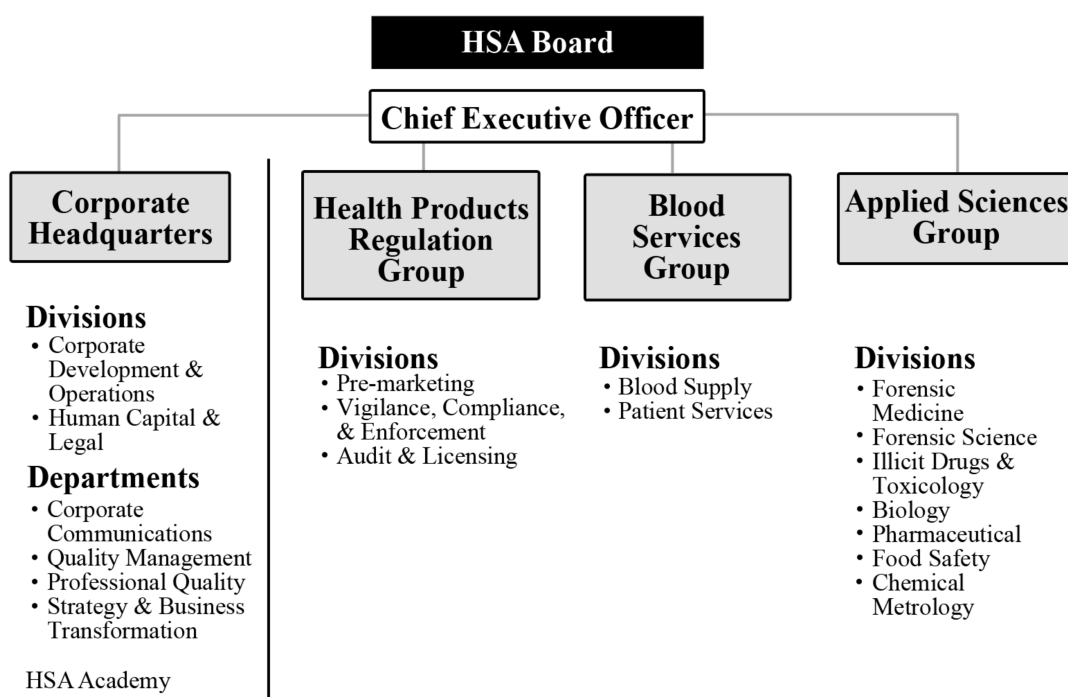
REGULATORY FUNDAMENTALS

Health Science Authority

Founded in April 2001 under Singapore’s Ministry of Health, HSA is a multidisciplinary agency with expertise in the health sciences. The goal of HSA is to ensure that the “quality, safety, and effectiveness of all medicines, medical devices, and health products in Singapore meet internationally benchmarked standards” such as those agreed upon by the founding members of the Global Harmonization Task Force (GHTF).³ The agency had 779 employees as of March 2010.⁴ HSA’s operating budget for Fiscal Year 2009 was approximately S\$71 million and its operating expenditure was roughly S\$136 million (US\$1:S\$1.26).

HSA currently consists of three key groups: Health Products Regulation, Blood Services, and Applied Sciences. Figure 1 shows the general organizational structure of HSA and the divisions within each of the three groups.

Figure 1 HSA’s organization structure.⁵



Medical device regulation falls under the Health Products Regulation Group (HPRG). HSA’s Medical Device Branch, under HPRG, is similar to U.S. FDA’s Office of Device Evaluation (ODE) under the Center for Devices and Radiological Health. As Table 1 shows, their objectives are similar, as both regulate the device lifecycle from pre-market to post-market.

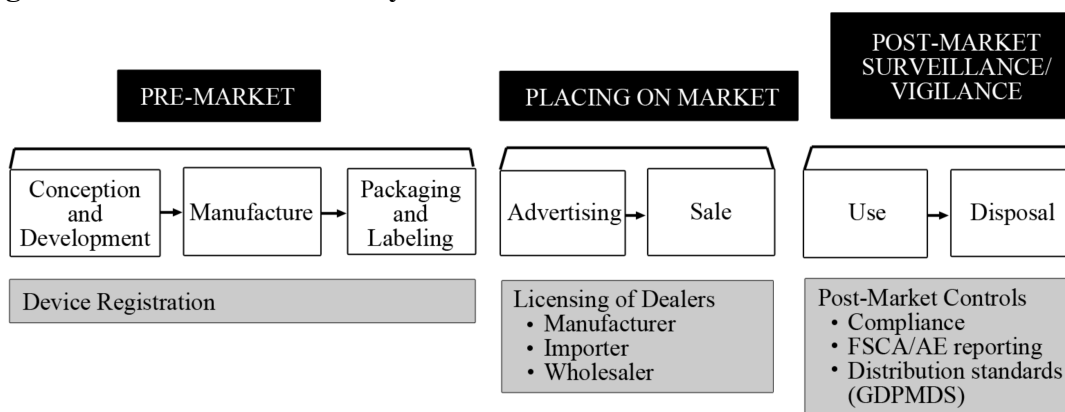
Table 1 HSA and FDA medical device evaluation regulatory groups

Singapore Medical Device Branch	U.S. Office of Device Evaluation
<ul style="list-style-type: none"> • Under the Health Products Regulation Group • Stated Objective: Ensure medical devices available in Singapore are of acceptable standard in accordance to the Health Products Act and Health Products (Medical Devices) Regulations • Pre-market assessment of devices, manufacturing controls, and post-market vigilance 	<ul style="list-style-type: none"> • Under the Center for Devices and Radiological Health • Stated Objective: Responsible for program areas through which medical devices are evaluated or cleared for clinical trials and marketing • Premarket notifications (510k), premarket approval applications (PMAs) and supplements, humanitarian device exemptions (HDEs), investigational device exemptions (IDEs), amendments and supplements, and product development protocols

HSA administers Singapore’s Health Product Regulations governing medical devices, which stem from the 2007 Health Products Act (HPA).⁶ The Act gives HSA flexibility to account for varying degrees of risk, allowing tighter control for higher-risk products and looser control for lower-risk products.

The new regulations impose controls over medical devices based on the Medical Device Life Cycle (see Figure 2). HSA’s purview thus covers early conception of the device in the pre-market phase, during which device companies need to register their products. The regulations also cover the placement-on-market phase, during which device manufacturers, wholesalers, and importers must meet mandatory licensing requirements. HSA also oversees post-market activities, such as requiring dealers to maintain distribution and complaint records.

Figure 2 Medical device life cycle⁷

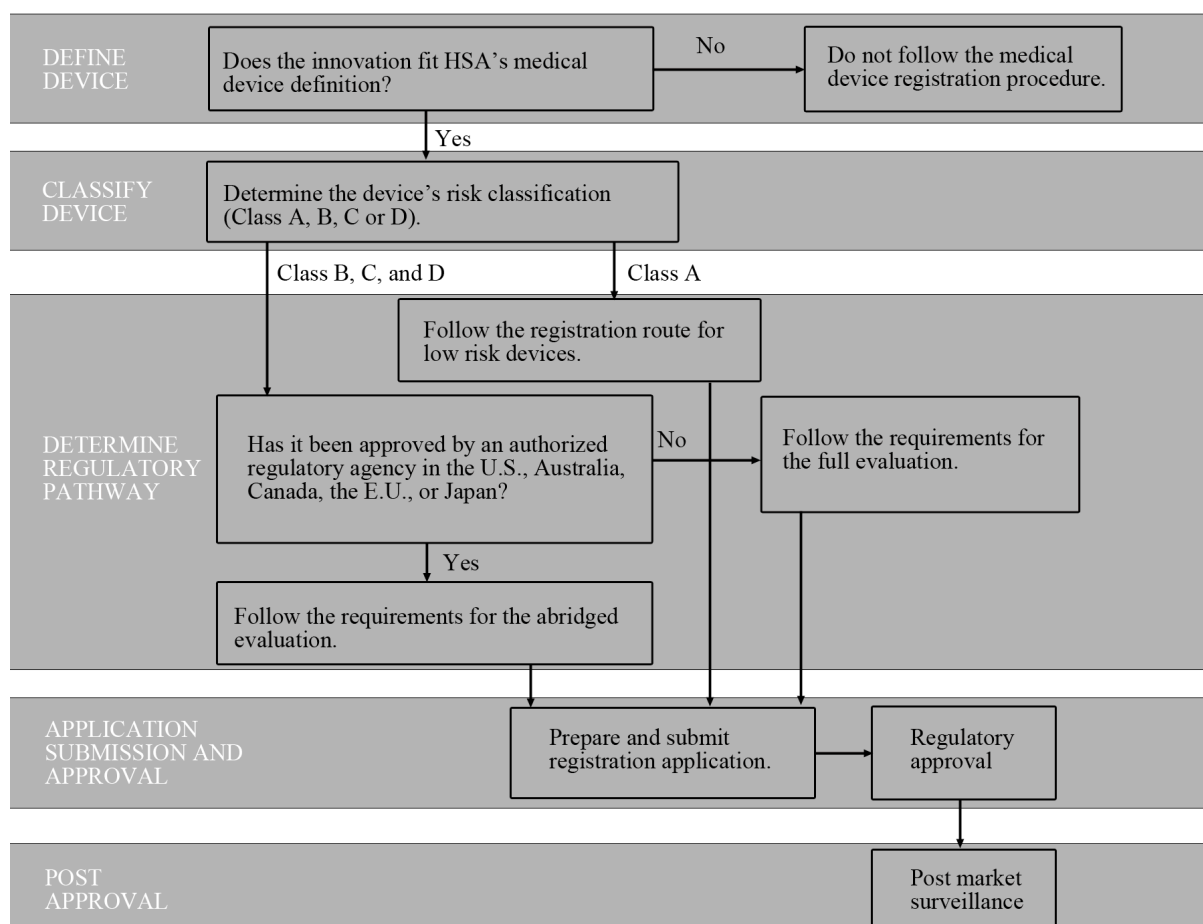


HSA has implemented the new regulatory controls in three phases. During the first phase, which began when the Health Products Act took effect on November 1, 2007, HSA started to carry out its post-market duties.⁸ Phase Two, beginning in 2009, required product registration and dealers licensing for certain classes of medical devices. Phase Three, beginning in 2010, extended those requirements to remaining medical device classes. This chapter will focus on device registration during the pre-market phase, which is particularly important for innovators to consider when conceiving their devices.

Device Registration

Before innovators can submit a product registration application to HSA and receive regulatory approval, they must first verify that their device meets HSA’s definition of a medical device, classify the device according to HSA’s classification system, and then select the appropriate regulatory pathway for the device. Figure 3 illustrates basic elements of the device registration process, which will be discussed in more detail in this section.

Figure 3 Basic elements of the device registration process⁹



Confirm Innovation as a Device

The first step in the product registration process is to make sure HSA considers the innovation a medical device. Medical devices are defined as “any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material, or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific purposes of

- a. Diagnosis, prevention, monitoring, treatment, or alleviation of any disease;
- b. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- c. Investigation, replacement, modification, or support of the anatomy or of a physiological process;
- d. Supporting or sustaining life;
- e. Control of conception;
- f. Disinfection of medical devices; or
- g. Providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and
- h. Which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.”¹⁰

Innovators can also find HSA’s definition of a medical device on its website (see Getting Started).

Singapore has aligned its definition with the definition from the Global Harmonization Task Force (GHTF), which was conceived in 1992 as a partnership to synchronize more closely the medical device regulatory systems of the European Union, United States, Canada, Australia, and Japan. Since Singapore follows GHTF principles, inventors may be able to use documents prepared for HSA as a guide when registering their devices in other countries.

In general, a medical device’s intended use must be to achieve a diagnostic, preventative, or therapeutic medical function, but the device cannot achieve this function by pharmacological, immunological, or metabolic action i.e., the device cannot be a drug. If inventors are uncertain whether their innovation is more device than drug or vice-versa, they should think about their product’s primary mode of action. For example, drug-eluting stents are considered devices since their main activity is to open blood vessels. Insulin pens, on the other hand, are deemed a drug since the drug insulin is the primary mode of action. If still unsure, inventors can contact HSA.

Classify device

Once innovators have determined that their innovation is considered a medical device, they need to ascertain the innovation’s risk classification. This risk classification indicates which regulatory approval route is open to the device (see Regulatory Pathways below).

Device classification in Singapore resembles GHTF and E.U. classification systems more than the system used in the United States. Singapore, GHTF, and E.U. classification systems consist of four classes: low risk (A), medium-low risk (B), medium-high risk (C), and high risk (D). The United States divides devices into only three classes: low (I), medium (II), high (III). For example, medium-low risk hypodermic needles and medium-high risk ventilators both fall into Class II in the U.S., whereas Singapore considers the former Class B and the latter Class C (see Table 2).¹¹

Table 2 Comparison of device classification models¹²

Singapore/ GHTF	E.U.	U.S.	Risk Level	Device Examples
A	I	I	Low Risk	Wheelchair, bandage, walking aid, simple wound dressing, surgical retractor
B	Ila	II	Low-Medium Risk	Hypodermic needle, non-absorbable skin closure, device, suction equipment, digital blood pressure monitor
C	Iib	II	Medium-High Risk	Orthopedic implant, lung ventilator, infant incubator, bone fixation plate
D	III	III	High Risk	Absorbable suture, implantable defibrillator, carotid artery shunt, stent

Singapore's model of splitting U.S. Class II into two separate classes (B and C) affects innovators under HSA's three-phase implementation of the city-state's new regulatory requirements. Class A and B medical devices were not subject to import or supply controls until January 1, 2012, whereas Class C and D devices have been since August 2010. Between April 1, 2009 and March 31, 2010, HSA received 3,830 product registration applications for medium to high risk devices and 2,862 applications for low risk Class A devices.¹³

Singapore exempts certain Class A devices from product registration, such as cotton balls and reusable surgical instruments, due to the low risk associated with their use. The exemption is only valid if the device is used for the specific intended purpose indicated in Singapore's Health Products Regulations. For the list of exempted Class A products, innovators can refer to regulatory guidance document GN-22 on HSA's website.¹⁴ (See Getting Started below for weblinks to this and other HSA guidance documents.)

For more general help determining a device's classification, innovators can refer to regulatory guidance document GN-13.¹⁵ Here is a checklist of questions that innovators may want to ask themselves about their device. Is their device:

- Non-invasive, invasive, or active? Surgically invasive (i.e., does the device penetrate inside the body through the surface of the body in the context of a surgical operation)?
- Intended for therapeutic or diagnostic use?
- Going to affect or involve the central circulatory system (major blood vessels)?

- Used for a duration that is transient (less than 60 minutes), short (between 60 minutes and 30 days), or long term (more than 30 days)?
- Implantable? Partially or wholly absorbed?
- Reusable?

After considering their answers to these questions, innovators should then follow the rules and flowcharts provided in GN-13 to classify their device.

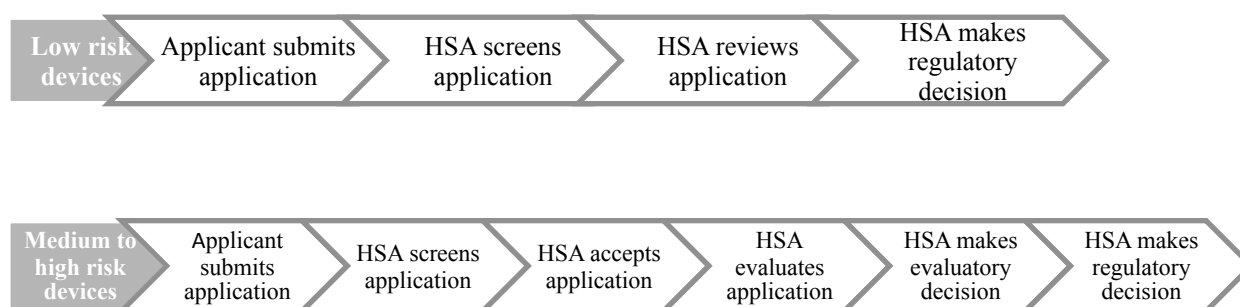
Innovators who wish to include software as a part of their device need to pay close attention to regulations governing software, which can be found in the same HSA guidance document.¹⁶ Under current regulations, software incorporated into the device itself e.g., embedded software to operate an electrocardiogram, is considered part of the device and does not need a separate classification. Standalone software, which is not embedded into the device itself, must be classified and registered separately. For instance, software applications for analyzing electrocardiogram signals on a computer independent of the electrocardiogram need their own classification. Innovators should note that software classification is currently under debate globally, so Singapore's policies toward it could change.

Determining the classification of an innovation that combines drug and device can also be challenging. A combination product, such as a drug-eluting stent mentioned earlier, is defined as a "product that combines a medicinal product and a medical device such that the distinctive nature of the medicinal product component and device component is integrated in a singular product."¹⁷ HSA expects to publish a guidance document on registering combination products.

Determine Regulatory Pathway

Once applicants have determined their device's classification, they then choose a product registration route for their device based on its risk classification. There are two possible regulatory pathways: one for low risk devices and one for medium to high risk devices.¹⁸ Innovators should note that the processes within these pathways are subject to change.

Figure 4 Comparison of Singapore's two regulatory pathways¹⁹



Low risk (Class A) route: As one can see in **Figure 4**, the process for low risk devices involves fewer steps. Applications for low risk devices move straight to the regulatory decision stage after HSA reviews the application. Unlike for high risk devices, HSA does not conduct a premarket evaluation of the safety, quality, and performance for low risk devices. It simply determines that the applicant classified the device correctly and that the application does not make misleading or exaggerated claims regarding what the device does.²⁰ If

regulators decide the application does not meet these criteria, then they may request full technical documentation.

Medium to high risk (Class B, C, and D) routes: The registration process for medium to high risk devices in Singapore is more complex. This is especially the case for devices that undergo full evaluation rather than abridged evaluation (see **Table 3**). Full evaluation, unlike abridged evaluation, requires applicants submit in-depth pre-clinical studies as well as actual clinical trial data or a performance comparison with a predicate device e.g., a device that is already legally marketed. Reasons for rejection include safety and quality concerns.²¹

Table 3 Requirements for abridged evaluation versus full evaluation²²

Requirements	Abridged	Full
Executive summary <ul style="list-style-type: none"> • Overview • Intended uses and indications • Global post-market records for the past five years 		Required
Essential principles and evidence of conformity		Required
Device description/labeling		Required
Risk analysis and risk management report		Required
Manufacturer information and manufacturing process flow		Required
Executive summary <ul style="list-style-type: none"> • Registration status in reference agencies 	Required	Not applicable
Pre-clinical studies <ul style="list-style-type: none"> • Including biocompatibility, biological safety, animal studies, software verification and validation, and sterilization validation 	Summary reports	In-depth study of: <ul style="list-style-type: none"> • Study design • Methodology • Acceptance criteria • Results • Interpretation of the results
Clinical evidence <ul style="list-style-type: none"> • Including literature review, clinical experience, and clinical evaluation 	Emphasis on clinical experience	Actual clinical trial data OR performance comparison to established predicate devices

To be eligible for the abridged route, the device must have already been approved by an authorized regulatory agency in the United States, Australia, Canada, the European Union, or Japan. Innovators need to include in their applications the same packaging, labeling (including instructions), and intended purpose information as in the application approved by the foreign agency.

A device-drug combination product can take the abridged evaluation route if an approved overseas regulatory agency has already approved it or if an approved overseas drug regulatory authority has signed off on the device's drug or biologics component. Innovators should note that evaluation applications for *device-drug* combination products are submitted to HSA's medical devices branch, since the device is the primary mode of action. If the

combination product's main mode of action is the drug, it would be labeled as a *drug-device* combination product and its evaluation application would go to the pharmaceutical and biologics branch.

Abridged evaluations are less costly and time-consuming than full evaluations (see Table 4).²³ For example, abridged evaluations for Class C devices normally take 160 days and cost S\$3,500, whereas full evaluations take 220 days and cost S\$5,700. Evaluation fees for drug-device combination products are much higher: Abridged evaluation costs S\$10,000 and full evaluation, S\$75,000.²⁴

Table 4 Fees and duration in abridged and full evaluation routes²⁵

Risk Classification	Abridged Evaluation		Full Evaluation	
Class B	S\$1,800	100 working days	S\$3,500	160 working days
Class C	S\$3,500	160 working days	S\$5,700	220 working days
Class D	S\$5,700	220 working days	S\$11,400	310 working days

Prepare and Submit Application

Once innovators have determined their device's regulatory pathway, they can prepare a product registration application for the device. Applications for Class B, C, and D devices must be prepared based on the ASEAN Common Submission Dossier Template (CSDT). Innovators can again refer to regulatory guidance documents (GN-15-R4, GN-17, and GN-18) on HSA's website. They may apply for a pre-submission consultation with regulators if they are uncertain whether their application dossier meets HSA's submission requirements. They can only apply for the consultation by submitting a form available on the agency's website. HSA limits each company to one pre-submission consultation per device.

Innovators then submit applications via the product registration route that accords with the device classification appropriate for their innovations. They must use HSA's online Medical Device Information and Communication System (MEDICS) to submit the document.²⁶

Application Screening, Acceptance, and Approval

No matter which regulatory pathway devices take, HSA screens registration applications to make sure they fulfill certain basic requirements (see **Figure 4** above). Causes for rejection at the screening stage include:

- The application is for a product that is not a medical device;
- The application is not submitted in the required format; and
- The applicant did not select the correct product registration route (e.g., a low risk medical device application submitted via the medium or high risk product registration route, or vice versa).

If HSA accepts the application, HSA then bills the innovator an evaluation fee in advance. HSA will only begin its evaluation of a device's suitability for product registration after it receives payment.²⁷

Once HSA has approved a medical device for product registration, the device is clear for use in Singapore and is entered into the Singapore Medical Device Register (SMDR) via

MEDICS. SMDR is a public database consisting of medical devices for human use that have obtained marketing clearance in the city-state.

Device owners must pay an annual listing fee for their device to remain in the SMDR database. This annual listing fee currently applies to Class C and D devices only, but will be implemented for Class A and B devices in January 2013. The fee is S\$25 for Class A, S\$35 for Class B, S\$60 for Class C, and S\$120 for Class D.²⁸

Post-Market Vigilance

Once their device is approved, innovators can use SMDR to view device information and carry out transactions with HSA's Medical Device Branch. For instance, they can use the database to track recalls or adverse health events related to medical devices. They can also refer to it for updates on requirements for safety, quality, and performance related to their device. Note that HSA only keeps one medical device database, rather than multiple databases like U.S. FDA, which manages separate databases for medical device reporting, recalls, product classification, etc.²⁹ Innovators can visit HSA's website for more details regarding online forms and other e-services.

HSA requires medical device makers and dealers report adverse events associated with their device as part of its post-market surveillance system. An adverse event (AE) is an incident that reveals a defect in the medical device. It can also be an incident during which the device's use harms or is likely to harm human health. Innovators can find HSA's official definition and criteria for reportable adverse events in regulatory guidance document GN-05.³⁰ Reporting timelines for adverse events generally follow GHTF guidelines: 10 days to report an AE that has resulted in death or serious injury and 30 days to report AEs that could cause death or serious injury if they were to reoccur. Additionally, HSA requires device makers and dealers to report AEs that potentially pose a serious threat to public health. It also asks them to submit a follow-up report within 30 days of their initial report. HSA then analyzes AE reports for trends.

Device makers that suspect their device may harm users are responsible for taking corrective action and submitting a Field Safety Corrective Action Report to HSA. Corrective actions can range from refining directions for the device's use to recalling the device altogether. HSA can also advise device makers to take corrective action based on its AE report analyses. For more information, see HSA guidance documents GN-10 and GN-04.³¹

Clinical Trials

Device trials

HSA is in the process of developing new regulations for conducting clinical trials for medical devices, which it expects to implement in early 2013. Until then, the current Medicines (Clinical Trials) Regulations apply. Unlike for medicinal products, innovators under existing regulations are not required to obtain HSA approval (via a Clinical Trial Certificate, CTC) for trials evaluating a medical device's effectiveness, safety, or performance. They are, however, responsible for obtaining ethics approval for the trial from their institution's ethics committee or Institutional Review Board.³²

Once in force, HSA's new regulations will govern Class C and D devices only. HSA is implementing them in phases, with full implementation taking place in Phase Two. In Phase One, the clinical trial's sponsor needs to inform HSA that it is conducting trials on a medical

device, under the Clinical Trials Notification (CTN) system. The trial can start only after HSA accepts the CTN and other requirements have been met, such as ethics approvals.³³

In Phase Two, the sponsor of a trial for a *registered* Class C and D device i.e., a device listed on SMDR, continues to operate under the CTN system. However, sponsors of trials for *unregistered* Class C and D devices need to submit an application to HSA for approval to conduct a trial, under the Clinical Trial Authorization (CTA) system. They cannot begin a trial without that authorization, which HSA expects to take 30 business days.³⁴

Device imports for use in clinical trials

While HSA prohibits the import and supply of unregistered medical devices, it may approve the import of unregistered medical devices for clinical trials. Clinical trial sponsors need to provide HSA's Clinical Trials Branch a completed Application for Import of Clinical Trial Test Materials (CTM for Medical Devices), which HSA normally processes in five business days. Approval is valid for six months.³⁵

GETTING STARTED

Get an overview of the registration process

What to cover - Consult HSA's website for tutorials and other aids to help innovators navigate Singapore's medical device registration process.

Where to look

- HSA-SMaRT E-Guide
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/mdbsmartguide.html

Confirm innovation as a medical device

What to cover - Confirm that the product concerned is a medical device, using the appropriate definition. Document the device's intended purpose.

Where to look

- HSA website
 - "Overview"
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/Overview.html

Classify device

What to cover - Determine the medical device's risk classification according to Singapore's risk classification system. If the medical device has features that fit into more than one risk class, base the risk classification on the *highest* risk class indicated.

Where to look

- HSA website
 - "Overview"
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/Overview.html
- HSA Guidance Documents
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html
 - GN-13-R1: Guidance on Risk Classification of General Medical Devices

Determine appropriate regulatory pathway

What to cover - Select a product registration route based on your medical device's risk classification. One route is for low risk (Class A) devices and the other is for medium to high risk (Classes B, C, or D) devices. For medium to high risk devices, determine if your device is eligible for an abridged evaluation or if it must undergo a full evaluation.

Where to look

- HSA Guidance Documents
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html
 - GN-15-R4.1 Guidance on Medical Device Product Registration

Prepare and submit product registration application

What to cover - For Class A devices, check to see if the device is exempt from product registration. Prepare the submission dossier based on the ASEAN Common Submission Dossier Template (CSDT) format. Use HSA's online Medical Device Information and Communication System (MEDICS) to submit the product registration application at <http://www.hsa.gov.sg/publish/hsaportal/en/services/medics.html>.

Where to look

- HSA Guidance Documents
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html
 - GN-15-R4.1 Guidance on Medical Device Product Registration
 - GN-17 Guidance on Preparation of Product Registration Submission for General Medical Devices using the ASEAN CSDT, and
 - GN-18 Guidance on Preparation of Product Registration Submission for In Vitro Diagnostic (IVD) Medical Devices using the ASEAN CSDT
 - GN-22 Guidance to the List of Medical Devices Exempted from Product Registration

Application screening, acceptance, and regulatory approval

What to cover – Make sure to pay in advance HSA's evaluation fee following the agency's preliminary screening and acceptance of your application. After your device receives regulatory approval and is listed on the Singapore Medical Device Register (SMDR), pay an annual listing fee to keep the device in the public database.

Where to look

- HSA Guidance Documents
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html
 - GN-15-R4.1 Guidance on Medical Device Product Registration
- HSA website
 - "Fees and Charges"
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/fees_and_charges0.html

Conduct post-market vigilance

What to cover - Use SMDR to view device information (such as recalls, adverse events, and changes in requirements) and carry out transactions with HSA's Medical Device Branch. Report adverse events and corrective actions.

Where to look

- HSA Guidance Documents
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html
 - GN-05-R1 Guidance on Reporting of Adverse Events for Medical Devices
 - GN-10-R1 Guidance on Medical Device Field Safety Corrective Action
 - GN-04-R1 Guidance on Medical Device Recall

- HSA website
 - “Adverse Event Reporting” and “Field Safety Corrective Action Reporting”
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/adverse_event_reporting.htmlhttp://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/adverse_event_reporting.html, and
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/Field_Safety_Corrective_Action_Reporting.html

Clinical trials

What to cover - Keep abreast of new regulations for conducting clinical trials on medical devices as of early 2013. Until then, follow current Medicines (Clinical Trials) Regulations. To import unregistered medical devices for use in clinical trials, submit a completed Application for Import of Clinical Trial Test Materials (CTM for Medical Devices) to HSA’s Clinical Trials Branch.

Where to look

- HSA website
 - “Clinical Trials: FAQs,” see sections D1-7
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/clinical_trials/faqs.html
 - “Clinical Trials: Guideline on Application for Import of Clinical Trial Test Materials (CTM for Medical Devices)
http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/clinical_trials/guidelines/ctm_md_application.html

Consult regulatory experts

- Innovators unsure of any aspect of the product registration process in Singapore may want to consult a specialist. Unlike when dealing with U.S. FDA or Notified Bodies of the European Union, however, inventors will find Singapore’s pool of regulatory consultants with specific expertise limited.³⁶ They can instead consult directly with regulators within HSA or regulatory consultants who are familiar with the approval processes in the United States or European Union.

Endnotes

¹ Figure is for 2010. Ames Gross and Arthur Chyan, “Updates on Singapore’s Transition to Medical Device Regulation,” Today’s Medical Developments, October 20, 2010, <http://www.onlinetmd.com/medical-device-design-manufacturing-singapore-102010-tmd.aspx> (August 7, 2012).

² Ames Gross, “Asian Regulatory Update: Asia-Pacific Medical Device Market Gets Healthier,” www.massdevice.com, March 3, 2011, <http://www.massdevice.com/blogs/ames-gross/asian-regulatory-update-asia-pacific-medical-device-market-gets-healthier> (July 25, 2012).

³ Health Sciences Authority (HSA), “About Our Work,” http://www.hsa.gov.sg/publish/hsaportal/en/for_public/about_our_work.html (January 30, 2011).

⁴ Presentation by Christina Lim, Group Director, Health Products Regulation Group, HSA on June 27, 2011.

⁵ Ibid.

⁶ See “Health Products Act 2007,” *Republic of Singapore Government Gazette Acts Supplement*, March 16, 2007, www.hsa.gov.sg (August 7, 2012).

⁷ Ibid. and World Health Organization, “Medical Device Regulations: Global Overview and Guiding Principles,” 2003, p. 10, http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf,

⁸ “New Age of Singapore’s Regulations of Medical Devices,” Sidley Austin LLP, June, 9, 2011, p.3, http://www.sidley.com/files/News/6b2948d4-3000-455e-9c47-0fe45306fcfd/Presentation/NewsAttachment/ea679911-2896-40d9-ae77-12f433b1a2df/GLS-Singapore%2006_09_11.pdf (August 12, 2011).

⁹ HSA, “GN-17 Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT,” October 2008, http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html (March 14, 2012); and HSA, “GN-15-R4.1 Guidance on Medical Device Product Registration,” November 2011, http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html (August 6, 2012).

¹⁰ HSA, “Overview,” http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/Overview.html (August 3, 2012).

¹¹ For more information on U.S. and E.U. classification systems, see U.S. FDA’s website <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm> (August 3, 2012) and the relevant E.U. guidance document at http://ec.europa.eu/health/medical-devices/files/meddev/2_4_1_rev_9_classification_en.pdf (August 3, 2012).

¹² HSA, “Overview,” op. cit. and GHTF, “Principles of Medical Devices Classification,” <http://www.ghtf.org/documents/sg1/SG1-N15-2006-Classification-FINAL.pdf> (May 10, 2011).

¹³ HSA, “HSA Annual Report 2009-2010,” 2012, http://www.hsa.gov.sg/publish/hsaportal/en/publications/annual_reports/annual_report_fy2009.html (August 3, 2012).

¹⁴ HSA, “GN-22 Guidance to the List of Medical Devices Exempted from Product Registration (Draft),” (January 2011), http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html (September 11, 2011).

¹⁵ HSA, “GN-13-R1 Guidance on the Risk Classification of General Medical Devices,” October 2008, http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html (September 6, 2011).

¹⁶ Ibid., p.9.

¹⁷ HSA, “GN-15-R4.1 Guidance on Medical Device Product Registration,” op. cit., pp. 21-22.

¹⁸ Ibid., pp. 10-18.

¹⁹ Ibid., pp. 10, 15.

²⁰ Ibid., pp. 15-18.

²¹ Ibid., pp. 20-21.

²² Presentation by Christina Lim, Group Director, Health Products Regulation Group, HSA, op. cit.

²³ HSA, “GN-15-R4.1 Guidance on Medical Device Product Registration,” op. cit., pp. 19-20.

²⁴ HSA, “Fees and Charges,” November 29, 2011, http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/fees_and_charges0.html (August 3, 2012).

²⁵ As of August 2012. Table was compiled from data in HSA, “Fees and Charges,” *ibid.*, and “GN-15-R4.1 Guidance on Medical Device Product Registration,” *op. cit.*, p. 36.

²⁶ The Internet address for MEDICS is <http://www.hsa.gov.sg/publish/hsaportal/en/services/medics.html>

²⁷ HSA, “GN-15-R4.1: Guidance on Medical Device Product Registration,” *op. cit.*, p. 12.

²⁸ HSA, “Fees and Charges,” *op. cit.*

²⁹ U.S. FDA, “Medical Device Databases,”

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm> (August 28, 2011).

³⁰ HSA, GN-05-R1 Guidance on Reporting Adverse Events for Medical Devices,” October 2008, pp. 5-8, http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html (August 1, 2012).

³¹ HSA, “GN-10-R1 Guidance on Medical Device Field Safety Corrective Action,” October 2008, and “GN-04-R1 Guidance on Medical Device Recall,” October 2008, http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html (August 1, 2012).

³² HSA, “Clinical Trial: FAQ: Clinical Trials on Medical Devices,” June 26, 2012, sections D1-D2, http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/clinical_trials/faqs.html (August 2, 2012).

³³ HSA, “Clinical Trial: FAQ: Clinical Trials on Medical Devices,” section D4.

³⁴ *Ibid.*

³⁵ See HSA, “Clinical Trials: Guideline on Application for Import of Clinical Trial Test Materials (CTM for Medical Devices), http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/clinical_trials/guidelines/ctm_md_application.html (August 12, 2012) and HSA, “Clinical Trial: FAQ: Clinical Trials on Medical Devices,” *op. cit.* section D5.