
CHAMBERS GLOBAL PRACTICE GUIDES

Life Sciences 2026

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Singapore: Law and Practice
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SINGAPORE



Law and Practice

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation

The Health Products Act 2007 (HPA) is the main legislation governing pharmaceuticals (which are referred to as “therapeutic products”) and medical devices. Therapeutic products and medical devices are also regulated under the following legislation and regulations:

- the Health Products (Advertisement of Specific Health Products) Regulations 2016;
- the Health Products (Medical Devices) Regulations 2010;
- the Health Products (Therapeutic Products) Regulations 2016;
- the Health Products (Clinical Research Materials) Regulations 2016;
- the Poisons Act 1938 and its subsidiary legislation; and
- the Sale of Drugs Act 1914 and its subsidiary legislation.

The Health Sciences Authority (HSA) – a statutory body under the Ministry of Health (MOH) – is the main regulatory body that administers, applies and enforces the aforementioned legislation and regulations. The HSA also publishes guidelines in its administration of the legislation and regulations. As a statutory body, the HSA has substantial independence and autonomy over its operations. Nevertheless, it generally operates in line with the policy directions set by the government.

1.2 Challenging Decisions of Regulatory Bodies

An appeal can be made in respect of any of the following decisions made by the HSA:

- refusal to register a health product;
- attachment of any condition to the registration of a health product;
- decision to recategorise or reclassify a health product;
- decision to suspend or cancel the registration of a health product;
- refusal to issue or renew a licence or to grant any approval;

- attachment of any condition to a licence; and
- decision to suspend or revoke a licence or to cancel an approval.

Any person aggrieved by these decisions can make an appeal in writing within the time specified in the decision notice to the Minister of Health, whose decision is final. The Minister may choose to refer the appeal to an Appeal Advisory Committee before making a decision and will have to take into consideration any report made to him or her by the Appeal Advisory Committee in making the decision.

This challenge procedure is specific to health products.

1.3 Categories of Pharmaceuticals and Medical Devices

Therapeutic Products

Therapeutic products in Singapore are classified as Prescription Only Medicines, Pharmacy Only Medicines and General Sale List Medicines. These categories of therapeutic products are regulated differently on the basis of the types of marketing authorisation required.

Medical Devices

The appropriate product registration requirements and evaluation route depend on the risk classification of the medical device.

Medical devices are classified into the following risk groups, based on guidance developed by the Global Harmonisation Task Force:

- Class A – low risk (eg, wheelchairs and tongue-depressors);
- Class B – low to moderate risk (eg, hypodermic needles and suction equipment);
- Class C – moderate to high risk (eg, lung ventilators and bone-fixation plates); and
- Class D – high risk (eg, heart valves and implantable defibrillators).

In vitro diagnostic (IVD) medical devices are separately classified on the basis of their risk levels, as follows:

- Class A (IVD) – low individual risk and low public health risk (eg, specimen receptacles);
- Class B (IVD) – moderate individual risk and/or low public health risk (eg, vitamin B12 and pregnancy self-tests);
- Class C (IVD) – high individual risk and/or moderate public health risk (eg, blood glucose self-tests and rubella tests); and
- Class D (IVD) – high individual risk and high public health risk (eg, HIV blood-donor screening and HIV diagnostic kits).

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials of therapeutic products are specifically regulated by the HSA under the Health Products (Clinical Trials) Regulations 2016.

Clinical trials of medical devices are not regulated by the HSA. Clinical trials of medical devices that involve human biomedical research are required to comply with the requirements of the Human Biomedical Research Act 2015, which is administered by the MOH. Clinical trials of medical devices that do not involve human biomedical research are currently unregulated in Singapore.

2.2 Securing Authorisation to Undertake a Clinical Trial

Therapeutic Products

In order to undertake a clinical trial of a therapeutic product, regulatory approval from the HSA and ethics approval from the relevant Institutional Review Board (IRB) must be obtained.

Applicants must first determine whether the clinical trial is subject to the requirements of a Clinical Trial Authorisation (CTA) or a Clinical Trial Notification (CTN). CTAs are required for higher-risk clinical trials involving therapeutic products that are unregistered in Singapore or uses of registered therapeutic products that are unapproved. CTNs are required for low-risk clinical trials involving only registered therapeutic products used in accordance with their approved labels.

The clinical trial application, together with the relevant supporting documents, should be submitted by the sponsor to the HSA via its online platform, PRISM. The study may be initiated after the HSA accepts the notification of clinical trial or authorises the clinical trial.

Medical Devices

Authorisation is generally not required for clinical trials of medical devices. However, a notification must first be submitted to the Director of Medical Services before the commencement of any clinical trial of medical devices involving human biomedical research.

2.3 Public Availability of the Conduct of a Clinical Trial

Particulars of ongoing clinical trials are made publicly available online on the Clinical Trials Registry. All information in the Clinical Trials Register is maintained and updated by the local sponsors at least once every six months. The results of the trials are not made publicly available.

2.4 Use of Online Tools to Support Clinical Trials

There are no restrictions for using online tools to support clinical trials, as long as the use complies with the requirements and guidelines set out in the International Council for Harmonisation (ICH) E6 (R3) Good Clinical Practice Guidelines.

2.5 Use of Data From Clinical Trials

Data from clinical trials is considered personal data under the Personal Data Protection Act 2012 (PDPA), Singapore's primary data protection legislation. While there is no express categorisation of sensitive data in Singapore, the Personal Data Protection Commission (PDPC), which administers the PDPA, has taken the position in several enforcement decisions that medical data is more sensitive in nature and requires a higher standard of protection.

Resulting data may be transferred to a third party or an affiliate if consent has been obtained from individuals involved in the clinical trials. Data transfers are required to comply with the requirements of the PDPA.

2.6 Personal or Sensitive Data

The creation of a database containing personal or sensitive data would not be subject to requirements beyond those already set out in the PDPA.

3. Marketing Authorisations

3.1 Product Classification

The classification of a health product is assessed when an application for registration is screened to determine whether it should be accepted for evaluation.

Therapeutic Products

A therapeutic product is any substance that is intended for use by and in humans for any of the following purposes:

- preventing, diagnosing, monitoring, treating, curing or alleviating any disease, disorder, ailment, injury, handicap or abnormal physical or mental state, or any symptom thereof;
- investigating, modifying or replacing any physiological process;
- influencing, controlling or preventing conception; or
- inducing anaesthesia.

A therapeutic product must have any of the following active ingredients as a constituent:

- any chemical or botanical element, naturally occurring chemical or botanical material, or chemical product obtained by chemical change or synthesis;
- any metabolite from a micro-organism;
- any macromolecule extracted from an organism; or
- any substance derived from a biological system.

A therapeutic product must also exert an inherent effect either pharmacologically, chemically or by other physiological means, leading to its use for a therapeutic, preventative, palliative or diagnostic purpose.

Medical Devices

A medical device is any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, 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 following specific purposes:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury;
- investigation, replacement, modification or support of the anatomy or of a physiological process, mainly for medical purposes;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices; or
- providing information by means of in vitro examination of specimens derived from the human body, for medical or diagnostic purpose.

Medical devices must not achieve their primary intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in their intended function by such means.

Medical devices also include:

- any implant for the modification or fixation of any body part;
- any injectable dermal filler or mucous membrane filler; or
- any instrument, apparatus, implement, machine or appliance intended to be used for the removal or degradation of fat by invasive means.

3.2 Marketing Authorisation for Biologic Medicinal Products

Biologic medicinal products are generally classified as therapeutic products and are not subject to any specific obligations in relation to the granting of a marketing authorisation.

Biosimilars are “follow-on” versions of biologic medicinal products and are required to be submitted under a new drug application, rather than a generic drug application. The registration of biosimilar products involves a comprehensive comparability exercise, where similarity to an existing biologic medicinal product registered in Singapore in terms of physico-

chemical characteristics, biological activity, safety and efficacy needs to be established.

3.3 Period of Validity of Marketing Authorisations

Registrations of therapeutic products and medical devices generally remain valid for a year and may be renewed by paying an annual retention fee, unless the registration is suspended by the HSA or cancelled by either the HSA or the product registrant. There is no requirement to market the health product once it is registered by the HSA. However, under the Singapore Association of Pharmaceutical Industries Code of Conduct, the first use of all promotional materials circulated to the market may not occur more than two years from the date of approval. Materials used beyond this time period are required to be re-approved.

The registration of a health product may be suspended or cancelled by the HSA on the following grounds:

- the registration has been obtained by fraud or misrepresentation;
- the registrant of the health product has contravened or is contravening any provision of the HPA, any condition attached to the registration, or any other prescribed requirement;
- the formulation, composition, design specification, quality, safety or presentation of the health product has changed in such a way as to render it unsuitable to continue to be registered;
- the health product no longer complies with a prescribed requirement; or
- it is in the public interest to do so.

3.4 Procedure for Obtaining a Marketing Authorisation

Therapeutic Products

Registration procedure

- Pre-submission: at the pre-submission stage, applicants may submit a pre-submission enquiry to the HSA for any clarification, and may also request a pre-submission meeting with the HSA where necessary to address specific submission issues.
- Application submission: the application form must be submitted online via the HSA's portal, PRISM, and the technical dossier accompanying the appli-

cation must then be submitted within two working days of the PRISM application submission.

- Application screening: the application is screened to ensure that the application type is correct and the technical dossier is complete. Where any changes are required or where there are deficiencies in the application, the HSA will request that the applicant take the necessary action via an Input Request. In the case of certain major deficiencies, applicants will be requested to withdraw the application.
- Application evaluation: the evaluation stage begins when the application is accepted. Evaluation queries may be issued to the applicant if clarification or additional information is required. The applicable evaluation route depends on the type of therapeutic product and whether the therapeutic product has received reference agency approvals. Please see **4.1 Fast-Track Registration Routes** for more details.
- Regulatory decision: the HSA will notify the applicant of whether their application has been approved, is approvable or non-approvable, or has been rejected, after evaluation.

Where the applicant receives an approvable regulatory decision, they will be informed of the conditions for approval and will receive a grant of a final approval if the conditions are fulfilled within a stipulated timeframe.

Where the applicant receives a non-approvable regulatory decision, they will be informed of the deficiencies leading to said decision. The applicant may address the specified deficiencies by furnishing a response based on the original data set submitted to the HSA within the stipulated timeframe in order to continue with the application.

Variation procedure

Variation applications of registered therapeutic products are split into major variation applications (MAV) and minor variation applications (MIV). Each application type may be subject to different evaluation routes and different variation procedures.

As a whole, the procedure to vary a therapeutic product registration is largely similar to the registration procedure.

- At the pre-submission stage, applicants may submit a pre-submission enquiry to the HSA for any clarification, and may also request a pre-submission meeting with the HSA where necessary to address specific submission issues.
- Only MAV applications will be screened, to ensure the correctness of the application type and the completeness of the technical dossier.
- During the evaluation stage, applicants who have incorrectly selected an application type or evaluation route will be requested to make the appropriate changes. In such cases, the applicant will be required to withdraw and resubmit the application if they intend to pursue the application.

Transfer procedure

A registrant for a registered therapeutic product may be changed from one company to another.

Before the submission of a transfer application, the existing registrant should conclude all pending variation applications and pay the annual retention fee. To make a transfer application, the existing registrant first initiates the application via the [HSA's portal](#). The new registrant will receive an email notice with a PRISM transaction number. The new registrant is then required to retrieve the draft application on the same website, using the transaction number, and submit the completed application in PRISM within 30 calendar days of receiving the email notice.

Medical Devices

Registration procedure

The registration requirements and evaluation route for medical devices depend on their risk classification, whether they have received reference agency approvals, and their prior safe marketing history. Generally, medical devices that have not received prior reference agency approvals will have to undergo the full evaluation route. Please see **4.1 Fast-Track Registration Routes** for more details.

Medical device registration applications are submitted online via the HSA's portal, SHARE. Applications

under the full or abridged evaluation routes will first be verified for eligibility and completeness before they are accepted for evaluation. If the application does not qualify for the selected evaluation route, it will be re-routed accordingly. A regulatory decision is made after the HSA's evaluation of the application. Only applications that satisfy the registration requirements will be registered and listed on the Singapore Medical Device Register (SMDR). For applications under the immediate evaluation route, the medical device is registered immediately and listed on the SMDR within an hour.

Variation procedure

Registrants may be required to submit a "Change Notification" application to the HSA upon changes to the medical device registrations. A Change Notification to the HSA can be categorised into Notification, Administrative, Technical and Review changes.

Some changes may not qualify for a Change Notification and will require the submission of a new registration. These include:

- a change to the intended purpose of the registered medical device;
- a change to the risk classification of a registered medical device;
- a change to the medicinal substance in a device that incorporates a medicinal product in an ancillary role;
- any addition of a model or models that do not fulfil the grouping criteria, including permissible variants, as per the GN-12 guidance documents on Grouping of Medical Devices for Product Registration; and
- any addition of medical devices with device proprietary names that are different from the registered devices into a device listing, unless permitted to be listed together under one SMDR listing based on the GN-12 guidance documents on Grouping of Medical Devices for Product Registration.

A Change Notification application is submitted to the HSA via SHARE. The following changes must be evaluated by the HSA first, prior to implementation:

- all Technical changes;
- all Review changes; and

- Administrative changes involving changes to administrative documents and information submitted at the point of registration of the medical device.

Where the HSA determines that the Change Notification is approvable, the change to the registered device may be implemented.

All other applications (ie, all Notification changes and all other Administrative changes to device particulars that are published on the public SMDR listing) may be implemented immediately upon receipt of the acknowledgement email from the HSA.

Transfer procedure

A transfer application can only be made to the HSA after the medical device is listed on the SMDR and there are no pending applications in the HSA's system in relation to the device.

The new registrant is responsible for making the transfer application, by emailing the application form and required supporting documents to the HSA. The new and existing registrants will then be notified of the outcome of the application for the change in registrant.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Unregistered therapeutic products may be imported and supplied for patients' use via the Special Access Route (SAR) under certain circumstances, including the following:

- a licensed hospital or medical clinic importing the drug for use by its own doctors or dentists on patients under their care;
- a licensed retail pharmacy acting on behalf of, and in accordance with, a valid prescription issued by a registered doctor or dentist; or
- a company acting on behalf of a licensed hospital or clinic.

However, any such use of unregistered therapeutic products should only be considered for life-saving therapies, and is to be done through either a named-patient application or a buffer stock application.

Note that if the therapeutic product consists of controlled drugs or psychotropic substances, the respective licences will also have to be obtained in order to import the product.

Unregistered medical devices may be supplied via SAR under a number of exceptions, including the following:

- for non-clinical purposes;
- for export or re-export; or
- for patients' use by qualified practitioners or licensed healthcare facilities, subject to approval.

3.6 Ongoing Obligations Imposed by Marketing Authorisations

In general, health products may be registered subject to post-approval commitments.

Therapeutic Products

Ongoing obligations for registrants of therapeutic products include:

- maintaining records of every receipt and supply of the therapeutic product;
- maintaining records of defects and adverse effects, and reporting them to the HSA within certain timeframes;
- notifying the HSA before any intended recall;
- informing the HSA of any information that adversely affects the validity of any data furnished to the HSA;
- submitting benefit-risk evaluation reports periodically to the HSA;
- implementing risk-management plans; and
- informing the HSA of any regulatory actions taken by other regulatory authorities, or actions taken by the company arising from significant safety issues of the therapeutic product.

The Regulatory Guidance on Post-Marketing Vigilance Requirements for Therapeutic Products and Cell, Tissue and Gene Therapy Products, revised by the HSA in March 2021, sets out further guidance relating to the submission of relevant safety information during the post-marketing phase.

Medical Devices

Ongoing obligations for registrants of medical devices include:

- ensuring and maintaining objective evidence to establish that the medical device complies with safety and performance requirements;
- maintaining records of every supply of the medical device;
- maintaining records of complaint reports and of actions taken in response to these reports;
- reporting defects in the medical device or adverse effects arising from the use thereof;
- reporting information that adversely affects the validity of any data furnished to the HSA relating to the quality, safety or efficacy of the medical device;
- notifying the HSA prior to any intended recall and furnishing a report of that recall; and
- notifying the HSA prior to carrying out any field-safety correction in relation to a medical device and furnishing a report thereon.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations

The Health Products (Medical Devices) Regulations 2010 and Health Products (Therapeutic Products) Regulations 2016 allow the disclosure of information relating to applications for registration. Trade secrets and information of commercial value that would be, or would be likely to be, diminished by disclosure are excluded from any such disclosure requirements.

The HSA makes publicly available, on an online database, information submitted to it in support of health product registration applications for registered health products. Information relating to pending applications is currently not publicly available.

Confidentiality

Disclosure of any confidential information obtained in the administration or enforcement of the HPA is generally prohibited, except with the consent of the person from whom the information was obtained. However, the HSA may disclose any confidential information relating to the quality, safety or efficacy of a therapeutic product or medical device if the disclosure is, in the HSA's opinion, necessary to protect the health

or safety of members of the public, or if the disclosure is to a government body.

In addition, confidential supporting information given in relation to an innovative therapeutic product application is protected by the HSA for a period of five years after the application is received by the HSA, subject to exceptions. An innovative therapeutic product application can be made for a substance that is an ingredient in the manufacture or preparation of the therapeutic product to which the application relates and that has not been referred to as an ingredient in the manufacture or preparation of any other therapeutic product in any previous application.

4. Regulatory Reliance and Fast-Track Registration Routes

4.1 Fast-Track Registration Routes Therapeutic Products

Depending on the type of therapeutic product and whether it has been approved by any overseas drug regulatory agencies, different evaluation routes apply for the registration of a therapeutic product.

For instance, if a therapeutic product has been approved by the HSA's reference drug regulatory agencies – ie, the European Medicines Agency (EMA), the US Food and Drug Administration (FDA), Health Canada (HC), the UK Medicines and Healthcare products Regulatory Agency (MHRA), Swissmedic or the Australia Therapeutic Goods Administration (TGA) – it will be assessed under the verification evaluation route, which is subject to the lowest fees among the evaluation routes and has the shortest turnaround time.

Medical Devices

Similarly, different evaluation routes apply for the registration of a medical device, depending on the class of medical device and whether it has been approved by any overseas referenced regulatory agencies.

For instance, if a Class B, C or D medical device has received approval from at least one of the HSA's overseas reference regulatory agencies, it will be assessed under the abridged route.

For Class C and Class D medical devices, there are also expedited routes. For example, the ECR-1 route is available for Class C medical devices that have approval from at least one of the HSA's overseas regulatory agencies, and that have been marketed for at least three years in the respective agencies' jurisdictions, provided there are no safety issues globally and no prior rejection/withdrawal by the HSA or any overseas reference regulatory agencies. The ECR-2/EDR route is available for Class C and Class D medical devices that have approval from at least two of the HSA's overseas regulatory agencies, and that have no prior rejection/withdrawal by the HSA or any overseas reference regulatory agencies.

There are also immediate registration routes for Class B medical devices that meet certain conditions, and for Class B and Class C standalone medical mobile applications.

Notwithstanding the above, there are some medical devices that do not qualify for the expedited routes, such as hip, knee and shoulder joint replacements, active implantable devices (eg, pacemakers, neurostimulators) and implantable devices in direct contact with the central circulatory system or central nervous system, among others. These devices will have to be registered via the full or abridged routes.

Typically, the full route will take the longest time and have the highest fees, followed by the abridged routes, then the expedited route, and finally the immediate route (if applicable).

Separately, there is also a Priority Review Scheme for Class B, C and D devices that are submitted under the full evaluation route (excluding Class D devices with a registrable drug in a secondary role). This is more expensive than going by the normal full evaluation route, but gives registrants the option to gain faster device registration and market entry for medical devices, with a 35% shorter turnaround time.

If the medical device belongs to one of five focused healthcare areas (ie, cancer, diabetes, ophthalmic diseases, cardiovascular diseases, infectious diseases) and is designed and validated for an unmet clinical need, the fees associated with such an application

are lower than those for a medical device that does not meet these two criteria.

4.2 Regulatory Reliance

Please see 4.1 Fast-Track Registration Routes.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants

Manufacturers of therapeutic products and medical devices are generally required to obtain a manufacturer's licence from the HSA. The manufacture of a health product means to make, fabricate, produce or process the health product, and includes:

- any process carried out in the course of so making, fabricating, producing or processing the health product; and
- the packaging and labelling of the health product before it is supplied.

Manufacture of Therapeutic Products

To issue a manufacturer's licence, the HSA must be satisfied that the applicant is able to comply with the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice (GMP) for Medicinal Products in relation to the manufacture of the therapeutic product in question. The HSA enforces these standards by conducting pre-approval and routine GMP audits to ensure conformance to the standards. The details of the audit process may be found in the Regulatory Guidance published by the HSA on the Licensing, GMP Certification, and Inspection of Therapeutic Products Manufacturers in January 2022.

If the therapeutic products contain controlled drugs or psychotropic substances, the respective licences will also have to be obtained.

Manufacture of Medical Devices

Applicants for a manufacturer's licence are required to provide information on their Quality Management System through the submission of an ISO 13485 certificate, the scope of which must include distribution

of the categories of medical devices and the activities performed, a Medical Device Single Audit Program (MDSAP) certificate, or a declaration of conformity to a Quality Management System (for companies dealing with Class A medical devices only).

A manufacturer's licence is not required for certain activities, including:

- manufacture at the request of a qualified practitioner practising at the licensed healthcare institution intended for the use of a particular patient of the licensed healthcare institution;
- manufacture by way of fitting or adjusting the medical device to meet the requirements of the end user;
- manufacture to enable the continued use of the medical device by the end user;
- secondary assembly where the company holds an importer's licence or wholesaler's licence and is able to comply with the requirements of the Good Distribution Practice Standard for Medical Devices or ISO 13485;
- manufacture for use in clinical research;
- manufacture of laboratory-developed tests;
- manufacture of Class A medical devices for a charitable purpose; or
- manufacture of specified dental medical devices.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

Establishments are generally required to obtain a wholesaler's licence from the HSA in order to engage in the wholesale of therapeutic products and medical devices. The wholesale of a health product includes the supply of the product:

- to a person who obtains the product for the purposes of supplying it to another person;
- to a person as a commercial sample in the normal course of a lawful trade;
- to the Singapore government where it is required for the purposes of public service or use in connection with the exercise of any statutory power;

- to a person or an institution concerned with scientific education or research requiring the health product for such a purpose;
- to a person who requires the health product for the purpose of complying with any written law with respect to the medical treatment of individuals employed by that person in any business or trade carried out;
- to a person who requires to use the health product, other than by way of administration to one or more individuals, for the purpose of business or trade; or
- by export to a party outside Singapore.

Wholesale of Therapeutic Products

To obtain a wholesaler's licence for therapeutic products, the establishment must first be audited to comply with the HSA's Good Distribution Practice standards, which are set out in the HSA's Guidance Notes on Good Distribution Practice, revised in December 2023.

Where the establishment intends to export codeine cough preparations or therapeutic products containing psychotropic substances, additional approval must first be obtained from the HSA.

Certain activities may not require a licence if the exceptions available in the Health Products (Therapeutic Products) Regulations 2016 apply.

Wholesale of Medical Devices

To be granted a wholesaler's licence for medical devices, the establishment is generally required to submit any of the following to the HSA:

- an ISO 13485 certificate, the scope of which must include distribution of the categories of medical devices and the activities performed at the facility, where applicable;
- Medical Device Single Audit Program (MDSAP);
- a declaration of conformity to a Quality Management System (for companies dealing with Class A medical devices only); or
- a Good Distribution Practice Standard for Medical Devices certificate issued by a certification body accredited by the Singapore Accreditation Council, or a declaration of exemption thereof.

A wholesaler's licence is not required if the wholesaling is for a clinical purpose in clinical research.

A wholesaler's licence is generally valid for 12 months from the date of licence approval. Renewals must be submitted and processed before the expiry of the licence.

6.2 Different Classifications Applicable to Pharmaceuticals

Therapeutic products in Singapore are classified as Prescription Only Medicines, Pharmacy Only Medicines and General Sale List Medicines. Prescription Only Medicines may only be supplied by a registered medical practitioner or pharmacist in accordance with a prescription. Pharmacy Only Medicines may be supplied by a pharmacist without a prescription, and General Sale List Medicines can be freely obtained from any retailer.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law and Relevant Enforcement Bodies

The import and export of therapeutic products and medical devices are governed by the Health Products (Therapeutic Products) Regulations 2016 and the Health Products (Medical Devices) Regulations 2010, respectively. In addition, all goods imported into Singapore are regulated under the Customs Act 1960, the Goods and Services Tax Act 1993 and the Regulation of Imports and Exports Act 1995.

The Singapore Customs applies and enforces import regulations at the point of entry; thereafter, the regulations are applied and enforced by the HSA.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

A licensed importer or licensed wholesaler of therapeutic products has to appoint a responsible person who is able to implement and maintain the quality system to meet the Good Distribution Practice (GDP) Standard. For Pharmacy Only Medicines or Prescription Only Medicines for local use, or unregistered therapeutic products for patients' use, only a qualified

pharmacist may act as the responsible person under an importer's licence. There are no specific requirements regarding the importer of record of medical devices.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

An importer's licence is required to import therapeutic products and medical devices. In general, only registered therapeutic products and medical devices may be imported.

There are certain exemptions from holding an importer's licence, including the following:

- a healthcare institution may import an unregistered therapeutic product without a licence, on a named-patient basis with the prior approval of the HSA;
- a person may import a therapeutic product that does not contain psychotropic substances or amounts of codeine and dextromethorphan greater than that specified by the HSA without a licence for personal use with the prior approval of the HSA;
- a licensed manufacturer may import any therapeutic product or medical device if required for the purpose of carrying out the licensed manufacture of a therapeutic product or another medical device; and
- medical devices may be imported without a licence for personal use subject to conditions set out by the HSA or for use in a clinical purpose in any clinical research.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

Harmonised System (HS) codes are required in Singapore in the permit declaration of goods, and are used to determine the tariffs, controls and rule of origin applicable to the relevant goods. The HS code of goods used in Singapore is an eight-digit code known as the ASEAN Harmonised Tariff Nomenclature code. The HS codes are listed in the Singapore Trade Classification, Customs and Excise Duties, published by the Singapore Customs.

7.5 Trade Blocs and Free Trade Agreements

Singapore is part of the ASEAN trade bloc and is a party to free trade agreements containing provisions

on trade/regulatory facilitation with numerous jurisdictions, including the European Union, China and New Zealand.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

In general, prices for therapeutic products and medical devices are not regulated in Singapore. However, it should be noted that public healthcare institutions in Singapore procure medicinal products in bulk by way of tender contracts through Group Procurement Offices to achieve economies of scale.

8.2 Price Levels of Pharmaceuticals or Medical Devices

Price levels of therapeutic products and medical devices generally do not depend on the prices for the same product in other countries, as prices are generally not regulated in Singapore. However, this may be a factor considered in negotiations with drug companies.

8.3 Reimbursement From Public Funds

The Singapore government provides direct subsidies of up to 75% for subsidised medications at specialist outpatient clinics and polyclinics. Patients receive drug subsidies and assistance based on their subsidy and means-test status, and the scheme under which the drug is covered (eg, Standard Drug List, Medication Assistance Fund).

The Singapore government has also implemented the Seniors' Mobility and Enabling Fund, which provides subsidies to offset the costs of assistive devices and home healthcare items.

The government also provides multiple tiers of financing for Singapore citizens and permanent residents for their healthcare expenditure, which includes a basic health insurance plan and a medical endowment fund.

8.4 Cost-Benefit Analyses

The Agency for Care Effectiveness (ACE), under the purview of the MOH, is the national health technology assessment agency in Singapore and works to lower the prices of health technologies, including drugs, medical devices and medical services, by evaluating their clinical and cost-effectiveness and negotiating with companies based on their proven outcomes. The evaluations made by the ACE also guide policy-makers in making subsidy decisions. Summaries of the rationale for subsidy decisions, as well as the key clinical and economic evidence supporting such recommendations, are published by the ACE to increase the level of transparency in decision-making.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

There are generally no regulations restricting pharmaceutical spending with regard to prescriptions by physicians and dispensing by pharmacies. However, medical practitioners are increasingly reminded to prescribe medications which are the most cost-effective for patients.

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