

<b>TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)</b>
<b>Author(s):</b> Benjamin Gaw and Cherlyn Seah  <b>Firm:</b> Drew & Napier, Singapore  <a href="mailto:benjamin.gaw@drewnapier.com">benjamin.gaw@drewnapier.com</a> ; <a href="mailto:cheryl.seah@drewnapier.com">cheryl.seah@drewnapier.com</a>
<b>REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES</b>
<b>1. What are the principal statutes, regulations and competent authorities that govern the import, wholesale distribution, retail sale and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?</b>
<p>In Singapore, the main legislation governing therapeutic products and medical devices is the Health Products Act 2007 (HPA).</p> <p>Under the HPA, therapeutic products and medical devices are regulated separately. In addition to the HPA, subsidiary legislation also applies to health products. For example, therapeutic products are also regulated under the Health Products (Therapeutic Products) Regulations 2016 (HPTPR), medical devices are also regulated under the Health Products (Medical Devices) Regulations 2010 (HPMDR) and active ingredients, commonly known as active pharmaceutical ingredients, are also regulated under the Health Products (Active Ingredients) Regulations 2023.</p> <p>The Health Sciences Authority (HSA), a statutory body within the Ministry of Health (MOH), is the main regulatory body which administers, applies and enforces the aforementioned legislation and regulations.</p>
<b>2. How are therapeutic products classified for regulatory purposes (eg, prescription only, over the counter, hospital use, risk classes for devices, etc) and what legal consequences attach to each classification with respect to trade and distribution? In particular, is the conclusion of a premarket review and approval process required by a competent authority?</b>
<p>Therapeutic products in Singapore are classified as prescription-only medicines (POMs), pharmacy-only medicines (Ps) and general sale list (GSL) medicines, and the category that a therapeutic product falls under determines the corresponding level of access control for the therapeutic product, as follows:</p> <ul style="list-style-type: none"><li>• POMs may only be supplied by a registered medical practitioner or pharmacist in accordance with a valid prescription;</li><li>• Ps may be supplied by a pharmacist at a retail pharmacy without the need for a prescription, subject to the retailer maintaining a record of every supply; and</li></ul>

- GSL medicines can be freely obtained from any retailer without medical supervision.

Prior to the import, manufacture or wholesale of therapeutic products in Singapore, they must be registered with the HSA, and a licence must be obtained. Please see Questions 3, 4 and 5 for more information on licensing.

Medical devices are classified into the following risk classes:

- 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 the level of risk posed, as follows:

- Class A (IVD) – low individual risk and low public health risk (eg, specimen collection tubes and general culture media);
- Class B (IVD) – moderate individual risk and/or low public health risk (eg, pregnancy tests, anti-nuclear antibody tests and urine test strips);
- Class C (IVD) – high individual risk and/or moderate public health risk (eg, blood glucose tests, human leukocyte antigen typing tests, prostate-specific antigen screening tests and rubella tests); and
- Class D (IVD) – high individual risk and high public health risk (eg, HIV screening and ABO blood grouping tests)

All medical devices must be registered with the HSA before they can be supplied in Singapore, except Class A low-risk medical devices, which are exempted from product registration, or in regard to specific conditions, as approved by the HSA. In addition, a licence must also be obtained prior to the manufacture, import or supply of medical devices in Singapore.

## LICENSING, AUTHORISATIONS AND DISTRIBUTION CHANNELS

### **3. Which licences, authorisations, registrations or other official permissions are required for businesses to engage in the wholesale distribution of therapeutic products, and what key conditions (such as good distribution practices, facility standards, personnel-related requirements and insurance or financial guarantees) are attached to them?**

Businesses are generally required to hold a valid wholesaler's licence issued by the HSA to engage in the wholesale distribution of therapeutic products and medical devices.

According to the HSA, wholesale distribution is defined as the supply of health products:

- 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 lawful trade;
- to the Singapore government or a department/statutory body of the 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.

To obtain a wholesaler's licence for the distribution of both therapeutic products and medical devices, the applicant must show that it is able to provide and maintain, or ensure the provision and maintenance of, the relevant staff, premises, equipment and facilities for the handling, storage and distribution of the therapeutic product/medical device as are necessary to prevent the deterioration of the therapeutic product/medical device, while it is in the applicant's ownership, possession or control.

For therapeutic products, the applicant must also show that it can comply with the HSA's Guidance Notes on Good Distribution Practice (GDP).

For medical devices, the applicant must also show that it can comply with the requirements set by the Good Distribution Practice Standard for Medical Devices or ISO 13485. In its application to the HSA, a distributor is required to submit to the HSA any one of the following:

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

However, a wholesaler's licence is not required if the wholesaling of medical devices is for a clinical purpose in regard to any type of clinical research.

**4. Are there distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies or other retailers), and what key conditions are attached to them?**

We highlight some of the requirements for the retail sale of specified health products, including POMs and Ps:

- pharmacies that supply specified health products must hold a pharmacy licence issued by the HSA;
- the supply of the specified health products must be carried out at or from the retail pharmacy specified in the pharmacy licence and in accordance with the conditions of the pharmacy licence;

- a proper record of every supply of the specified health product must be made and kept for at least two years after the date it was supplied to the consumer;
- only in-store pharmaceutical officers may have access to specified health products (other than a controlled drug) stored at the retail pharmacy; and
- only a qualified pharmacist may have access to any controlled drug stored at the retail pharmacy.

In addition, POMs can only be supplied by a qualified doctor or by a qualified pharmacist according to a prescription issued by a doctor, while Ps can be supplied by or under the supervision of a pharmacist at or from a licensed retail pharmacy.

In relation to Ps, in the record of every supply, retail pharmacists must include particulars in relation to each supply, such as the date of supply; identification and contact details of the buyer; the name, strength and total amount of Ps to be supplied; as well as the dosage and frequency of the treatment.

Specifically, for the sale of codeine cough preparations, additional restrictions exist, such as sale quantity limits and the requirement that a qualified practitioner or qualified pharmacist provide professional counselling on the use of codeine cough preparation to the buyer on each occasion that such products are supplied.

In relation to the provision of e-pharmacy services, HSA-licensed retail pharmacies and wholesalers in Singapore with a good track record in handling POMs and Ps may apply for a retail pharmacy licence, or include such e-pharmacy services in their existing retail pharmacy licence.

For GSL medicines, these can be freely obtained from any retailer without a prescription or licence. GSL medicines are typically self-limiting, they are used for common and easily recognised ailments and they are reasonably safe to be used without medical supervision. They are also generally supplied in small pack sizes, so they are appropriate for self-treatment.

As for medical devices, there are additional requirements for the supply of professional use-only medical devices and trained user-only medical devices.

Professional use-only medical devices can only be supplied to persons who are also licensed wholesalers of medical devices or qualified practitioners.

Trained user-only medical devices can only be supplied if the supplier provides, or ensures the provision of, training on the safe and efficacious use of the medical device as the manufacturer of the medical device determines is necessary, to every user of the medical device, or ensures that every user of the medical device has received such training.

Additionally, if there are any conditions in the wholesaler's licence, the wholesaler must also comply with such conditions.

**5. What rules govern the sale of therapeutic products to consumers over the internet (including social media and marketplace platforms)?**

For therapeutic products, only GSL medicines may be sold online.

For medical devices, most medical devices except professional use-only and trained user-only medical devices can be sold online. However, the medical devices must be registered with the HSA prior to such sale, except for Class A medical devices.

Any sale of health products, whether over the internet or not, must also comply with the HPA and any conditions stipulated in the wholesaler's licence. For instance, it is illegal to sell any adulterated, counterfeit, tampered with or unwholesome health product.

For completeness, additional requirements apply to the advertisement of health products. The definition of 'advertisement' under the HPA includes advertisements on all types of media, including the internet. This includes corporate websites, e-commerce platforms, microsites, as well as mobile applications and advertisements presented on digital interactive platforms and social media channels.

Generally, businesses that advertise their products to consumers over the internet will have to abide by the general principles of advertisement controls set out in the HPA. For example, a person must not advertise any product or cause any product to be advertised as a health product if that product is not a health product or advertise any registered health product that represents the registered health product as being usable for any purpose other than that for which it has been registered. In addition, advertisements cannot be false or misleading.

The Health Products (Advertisement of Specified Health Products) Regulations 2016 (the 'Advertisement Regulations') also apply to therapeutic products.

Under the Advertisement Regulations, an advertisement of a specified health product must not, among other restrictions:

- encourage self-diagnosis or self-treatment of any serious disease;
- give the impression that advice from qualified healthcare professionals is not necessary;
- promote excessive or inappropriate use;
- mislead any person with regard to the quality or efficacy of the health product;
- exploit the lack of knowledge of consumers;
- claim or suggest that the health product is infallible, unfailing, magical or miraculous, or that the effect of taking the specified health product is certain, guaranteed or a sure cure, or that the specified health product is not accompanied by any side effects; or
- contain or give the impression of any endorsement or recommendation of the health product by any healthcare professional or any person who, because of the person's celebrity, social or professional status, is likely to encourage the use of the health product.

In addition, POMs cannot be advertised and Ps must prominently display an advisory or a warning statement required by the HSA to be displayed in connection with advertisements for that medicine.

In relation to medical devices, advertisements on professional use-only medical devices are not allowed, unless the advertisement is distributed only to, or contained in, a publication intended to be circulated to qualified practitioners.

Advertisements for medical devices for specified diseases and conditions (ie, blindness, cancer, cataracts, drug addiction, deafness, diabetes, epilepsy or fits, hypertension, insanity, kidney diseases, leprosy, menstrual disorders, paralysis, tuberculosis, sexual function, infertility,

impotency, frigidity and conception and pregnancy) must not expressly or implicitly claim, indicate or suggest that the medical device will prevent, alleviate or cure the disease or condition unless the advertisement is distributed only to, or is contained in a publication intended for circulation mainly among, one or more of the following classes of persons:

- qualified practitioners;
- registered pharmacists;
- registered nurses and registered midwives; and/or
- persons undergoing training with a view to becoming qualified practitioners, registered pharmacists, registered nurses or registered midwives.

For all medical devices, advertisements must not contain any statement concerning the intended use and efficacy of the medical device unless such statement has been verified by objective evidence and such objective evidence has been furnished to the HSA at the time the application to register the medical device was made (if applicable), and must not contain any statement which expressly or implicitly suggests that the use of the medical device is promoted or endorsed by the HSA.

More generally in regard to advertising, the Singapore Code of Advertising Practice (SCAP) seeks to promote a high standard of ethics in advertising through self-regulation. The SCAP is a general code that applies to all advertisements for any goods or services appearing in any form or any media (eg, newspapers, television/radio commercials, mailing lists and digital communications, including via the internet). The SCAP sets out general principles and guidelines, as well as specific guidelines, which advertisements should adhere to. The SCAP also sets out specific guidelines in relation to medicinal and related products and advertisements containing health claims.

While the guidelines and principles under the SCAP are not legally binding, the Advertising Standards Authority of Singapore (ASAS) (which administers the SCAP) is empowered to require an advertiser or advertising agency to amend or withdraw any advertisement contrary to the SCAP, or to withhold such advertisement until it has been modified. ASAS may also, via the media owners in Singapore, withhold advertising space or time from advertisers, and withdraw the trading privileges of advertising agencies.

## IMPORT

### **6. What requirements are set as part of the import control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions and routine or risk-based border inspections)?**

A person must obtain an importer's licence to import therapeutic products or medical devices into Singapore. To obtain an importer's licence for the distribution of both therapeutic products and medical devices, the applicant must show that it is able to provide and maintain, or ensure the provision and maintenance of, the relevant staff, premises, equipment and facilities for the handling and storage of the therapeutic product/medical device as are necessary to prevent the deterioration of the therapeutic product/medical device, while it is in the applicant's ownership, possession or control.

For therapeutic products, the applicant must also show that it can comply with the requirements of the HSA's Guidance Notes on GDP for importers.

For medical devices, the applicant must also show that it can comply with the requirements of the Good Distribution Practice Standard for Medical Devices or ISO 13485.

In general, only registered therapeutic products and medical devices may be imported with an importer's licence. However, there are certain special access routes (SARs) that importers may rely on to import therapeutic products or medical devices without a licence, such as for personal use.

Specifically, unregistered therapeutic products can be imported without an importer's licence for patients' use on a named-patient basis with the prior approval of the HSA. To rely on this SAR, the therapeutic products may be imported only to: provide life-saving treatment when no registered alternatives exist in Singapore or supply a novel product that provides significant improvements compared to existing therapies.

Medical devices can also be imported without an importer's licence if the medical device is used for a clinical purpose in any type of clinical research, provided that notice is given to the HSA of the import.

The Harmonised System (HS) is an international six-digit nomenclature developed by the World Customs Organisation (WCO) for the classification of goods. Every good has a unique HS code, giving the customs authorities a common reference point. While WCO's HS code provides a harmonised international standard, certain regional blocs like the Association of Southeast Asian Nations (ASEAN) have their own extensions.

The ASEAN Harmonised Tariff Nomenclature (AHTN), used by all ASEAN member countries, including Singapore, is an eight-digit nomenclature developed based on the WCO's six-digit nomenclature. Pharmaceutical products, which include therapeutic products, fall under HS Chapter 30, with commonly used codes including 30.03 (medicaments consisting of two or more constituents, which have been mixed together for therapeutic uses, not put up in measured doses or in forms or packings for retail sale).

There are four main categories of goods which are subject to excise and/or customs duties in Singapore: intoxicating liquors, tobacco products, motor vehicles and petroleum products and biodiesel blends. Where the therapeutic products do not fall into any of the above categories, the importation of such products into Singapore will not be subject to excise and/or customs duties.

Subject to certain exceptions, all goods imported into Singapore are subject to goods and services tax (GST) at the prevailing rate of nine per cent. Exceptions include where (1) the goods (other than intoxicating liquors and tobacco) are imported by post or air with the total cost, insurance and freight (CIF) value not exceeding SGD 400, (2) the director general or any senior officer of customs has at their discretion granted relief to the importer from the payment of GST, and (3) where the goods are subject to customs or excise duty, such duty payable does not exceed SGD 20 and is waived under Section 11 of the Customs Act 1960. Where the importer of the therapeutic goods has been granted relief from payment of GST by the director general or any senior officer of customs and the CIF value of such therapeutic goods imported by post or air is less than SGD 400, a GST of nine per cent is not likely to apply.

Singapore conducts a combination of risk-based and routine custom inspections. Singapore Customs will analyse information collected, such as previous shipment data and modus operandi, to identify irregularities and target suspicious shipments for inspections. In addition, Singapore Customs also conducts routine inspections on activities carried out by traders in, for example, free trade zones.

Within ASEAN, Singapore has entered into an agreement between the customs administration of the member states of the Association of Southeast Asian Nations regarding the mutual recognition of their respective authorised economic operator programmes (the ‘Agreement’) to facilitate trade and promote economic growth among ASEAN member states. Under the Agreement, Singapore endeavours to reduce the physical cargo inspections and expedite the clearance process for members of the Agreement. Priority checks will also be granted where such cargoes are subject to physical inspection.

**7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by post), and what quantitative limits, prescription requirements, customs declarations, duties or other restrictions apply?**

Individuals may bring in medication for their own or their family members’ personal use (personal import) when travelling into Singapore. Depending on the medication, an approval from the HSA may be required.

Generally, therapeutic products that do not contain controlled drugs, psychotropic substances, or codeine and dextromethorphan greater than the amount specified by the HSA can be brought into Singapore for personal use without a licence or prior approval from the HSA. However, the amount of therapeutic products to be imported for personal use must not exceed a total dosage of three months’ supply per individual.

For other therapeutic products or therapeutic products that exceed the abovementioned dosage, an application for approval should be submitted to the HSA at least two weeks before arrival.

In relation to medical devices, individuals importing a medical device for personal use will require HSA approval, except those that are already in use upon arrival, such as implanted devices or those already in contact with the individual’s skin or eyes. Each approval will allow the applicant to import a maximum quantity of three months’ supply, and imports exceeding three months’ supply of such devices will be rejected.

**8. Are foreign suppliers allowed to ship therapeutic products directly to consumers via e-commerce or mail order, and what local presence, platform registration, verification or labelling obligations – if any – must they satisfy?**

The same rules and restrictions for the importation of therapeutic products and medical devices, in general, apply to foreign suppliers that ship directly to consumers.

Such foreign suppliers will need a valid import licence or must engage a licensed Singapore importer.

Companies wishing to sell their therapeutic products directly to consumers via e-commerce will have to abide by the same rules as local e-pharmacy rules (see Question 4). Retail pharmacies will have to be licensed by the HSA and seek approval to begin offering e-pharmacy services.

For completeness, we highlight that for the registration of therapeutic products or medical devices prior to such import, the registrant must typically be a local company or local business entity.

**9. How is the parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual property rights, product re-labelling or re-packaging and requirements to maintain the product’s original quality, safety and traceability?**

Generally, the importers of therapeutic products and medical devices must hold the requisite product registrations and/or import licences for any products imported into Singapore, regardless of whether they are part of a parallel import.

For completeness, we highlight that for the registration of therapeutic products or medical devices prior to such import, the HSA may have regard to whether a product is registered in other jurisdictions when evaluating whether to approve a product’s registration in Singapore. For example, therapeutic products that have been approved by the HSA’s reference drug regulatory agencies (ie, the European Medicines Agency, the US Food and Drug Administration, Health Canada, the UK Medicines and Healthcare Products Regulatory Agency, Swissmedic, Australia’s Therapeutic Goods Administration) may choose the verification evaluation route, which is a simpler route than the full evaluation route. There are also similar simplified evaluation routes applicable to the registration of medical devices.

**EXPORT**

**10. Are there quantitative quotas, permits or other measures that restrict or condition the export of therapeutic products (for example, to mitigate shortages or address public health emergencies), and how are such measures administered and enforced?**

For therapeutic products, the import of therapeutic products solely for export only typically requires an importer’s licence. A wholesaler’s licence is not required. For therapeutic products manufactured in Singapore, a manufacturer’s licence is required regardless of whether the therapeutic products will be exported.

In addition, exporters of therapeutic products that contain a psychotropic substance or codeine cough preparations must obtain prior approval from the HAS for each consignment of such therapeutic product to be exported.

For medical devices, exporters must hold a valid wholesaler’s licence.

Singapore does not impose any export restrictions to mitigate supply shortages or in order to address public health emergencies.

**11. Is there any form of ‘export-only’ or ‘dual-labelling’ authorisation that permits the manufacture and export of therapeutic products not approved for domestic marketing and, if so, what standards, labelling or record-keeping obligations apply?**

As mentioned in Question 10 above, an importer may import therapeutic products solely for export purposes as long as it has an importer’s licence. It does not need a wholesaler’s licence. However, regardless of whether the therapeutic product will be sold or marketed domestically, a manufacturer’s licence is required for therapeutic products manufactured in Singapore.

In terms of registration, therapeutic products need not be registered if they do not contain a psychotropic substance, they are not a controlled drug and they are imported solely for re-export or manufactured solely for export.

For medical devices, importers without existing importer or wholesaler licences can apply to import unregistered medical devices for the purposes of re-export under a special access route. However, dealers are required to maintain documentary evidence of their import and supply activities (eg, traceability records), as part of their mandatory device distribution records.

In terms of labelling, medical devices must be labelled with a unique device identifier (UDI). However, medical devices intended for export only from Singapore and strictly not for supply in Singapore are not required to comply with the UDI requirement.

**LABELLING, TRACEABILITY AND PRODUCT INFORMATION**

**12. What local-language labelling, patient information, unique device identification, serialisation, anti-counterfeiting or traceability requirements must be met before imported therapeutic products may circulate domestically or before therapeutic products may be exported?**

The labelling requirements for therapeutic products and medical devices apply to all such products, regardless of whether they are imported. We set out certain key requirements that we consider are more likely to apply to imported products.

For both medical devices and therapeutic products, all characters on the labelling must be in English. For therapeutic products, if non-English text is included on the labelling, applicants must declare that the non-English text is complete, accurate, unbiased and consistent with the English text.

For therapeutic products, patient information leaflets (PILs) are required for Ps and GSL medicines. The PIL must be easily understood and consistent with the product labels and/or package insert. Package inserts (PIs) are required for POMs. Electronic package inserts and PILs may be used for the labelling of POMs once the product registrants notify the HSA.

For medical devices, each medical device must be accompanied by the information necessary to identify the device and its product owner and in order to communicate safety and performance-related information to users.

The device packaging must also indicate either the batch code/lot number (eg, on single-use disposable devices or reagents) or the serial number (eg, on electrically powered medical devices),

to allow appropriate action to be taken in order to trace and recall such devices. The device packaging must also include the name and contact details of the product owner, the trade or brand name of the medical device and sufficient details for the user to identify the device.

Singapore has also recently adopted the UDI system, which is being rolled out in phases. Currently, only Class D medical devices and all coronary stents, orthopaedic joint replacement implants and intraocular lens need to be labelled. Class C devices and Class B devices will need to be labelled with UDI from 1 November 2026 and 1 November 2028, respectively. Under the UDI system, medical devices must be labelled with a UDI on the device package labels and/or directly marked on the devices. The UDI should be presented on the medical device labels according to the compliance dates applicable to the medical device, based on the relevant risk class.

### **PRICING, REIMBURSEMENT AND MARKET ACCESS**

#### **13. Are there any price control, reimbursement, public procurement or stock/supply-related obligations that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?**

The market price of therapeutic products is not generally governed by law or regulation in Singapore. However, public healthcare institutions in Singapore generally procure medicinal products in bulk by way of tender contracts through group procurement offices to achieve economies of scale.

The MOH publishes fee benchmarks for hospital fees that serve as a guideline as to what constitutes reasonable fees in the private sector. The hospital fee benchmarks include fee components such as medication and surgical facilities.

Drug subsidy schemes administered by the MOH include the standard drug list (SDL) subsidy framework and the Medication Assistance Fund (MAF).

Under the SDL subsidy framework, the Singapore government provides up to 75 per cent subsidies for drugs on the SDL used to treat common medical conditions at public healthcare institutions for Singapore citizens. The SDL subsidy framework, which is modelled on the World Health Organization's essential drug lists, consists of drugs assessed to be cost effective and essential to the provision of medical care.

The MAF on the other hand provides financial assistance in respect of non-standard, high-cost drugs, and is available to patients who face difficulties affording their medical bills. Eligible patients are able to receive government subsidies of up to 70 per cent for moderate- to high-cost drugs that are not on the SDL but are clinically effective.

The MOH's Drug Advisory Committee also makes recommendations to the MOH as to whether a drug should be subsidised through its listing on the SDL or MAF.

In relation to medical devices, the Singapore government has also implemented the Seniors' Mobility and Enabling Fund, which provides subsidies for seniors to offset the costs of certain assistive and mobility devices (some of which are considered to be medical devices) and home healthcare items. Patients at public healthcare institutions also receive subsidies for all implants

featured on the Implant Subsidy List, which are implants assessed to be safe, clinically and cost effective.

## **ENFORCEMENT, COMPLIANCE AND RECENT DEVELOPMENTS**

### **14. What investigative powers, sanctions and remedial measures (administrative, civil or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?**

The HSA is granted broad powers of investigation and enforcement under the HPA. These include the right of entry into premises and powers to inspect, search, take samples and seize goods and documents, among others, to ascertain whether there is, or has been, a breach of the relevant laws regulating therapeutic products.

The HSA also has the power to suspend or revoke a licence or cancel any approval granted if it has reasonable grounds to believe that, among others:

- the registration has been obtained by fraud or misrepresentation;
- the registration has contravened any provision in the HPA or any condition attached to the licence or approval; or
- the formulation, composition, design specification, quality, safety or presentation of the product has changed, so that it is unsuitable to continue to be registered.

Under the HPA, persons must typically hold a valid licence for the manufacture, import or wholesale of health products, which must typically be registered. The manufacturing, supplying or importing of adulterated, counterfeit, tampered with or unwholesome health products is also illegal. The HSA also maintains a public database of detected illegal health products in Singapore.

For all offences, offenders can face fines and/or jail terms upon conviction.

For example, in 2024, a woman was fined SGD 19,000 and sentenced to two weeks' jail for supplying unregistered health products during her home-based aesthetic services. The HSA seized 51 types of health products, including dermal fillers and vials of lidocaine carbonate injections, from the woman's home.

### **15. Is there any recent case law, legislative or policy developments, noteworthy enforcement trends or anticipated reforms that may significantly alter the regulation of trade, distribution or cross-border movement of therapeutic products in the future?**

In August 2024, the HPTPR was amended. In particular, Regulation 23(11) HPTPR now provides that the patent linkage regime in Singapore does not apply to the following types of patents:

- a process patent, other than a process patent that contains a claim for the use of an active ingredient in the manufacture of a therapeutic product for a specific therapeutic, preventive, palliative or diagnostic use;
- a patent that contains only claims relating to packaging;
- a patent that contains only claims to metabolites; and
- a patent that contains only claims relating to intermediates.

This amendment appears to have narrowed the scope of the patent linkage regime in Singapore in favour of generics that may be suitable to enter the market.