
CHAMBERS GLOBAL PRACTICE GUIDES

Life Sciences 2023

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Singapore: Law & Practice
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SINGAPORE



Law and Practice

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Drew & Napier LLC has been providing exceptional legal service since 1889 and is one of the largest full-service law firms in Singapore. The firm has three senior counsel. It is pre-eminent in dispute resolution, international arbitration, competition and antitrust, corporate insolvency and restructuring, IP (patents and trade marks), tax, and telecommunications, media and technology, and has market-leading practices in M&A, banking and finance, and capital markets. **Drew & Napier** has represented Singapore's

leaders, top government agencies and foreign governments in landmark, high-profile cases. It is also appointed by Fortune 500 companies, multinational corporations, and local organisations. The firm is experienced in international disputes before the Singapore International Commercial Court and covers the full range of commercial litigation matters, including building and construction, constitutional law, debt recovery, defamation, fraud and white-collar crime.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

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

The Health Sciences Authority (HSA), a statutory body under the Ministry of Health (MOH), is the main regulatory body which 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 That Enforce Pharmaceuticals and Medical Devices Regulation

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

- refusal of the HSA to register a health product;
- attachment of any condition to the registration of a health product;
- decision to re-categorise or reclassify a health product;
- decision to suspend or cancel the registration of a health product;
- refusal of the HSA 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 the aforementioned 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 Different 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 depends 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:

- 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. Where clinical trials of medical devices involve human biomedical research, such trials 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 which do not involve human biomedical research are currently unregulated in Singapore.

2.2 Procedure for 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 Clinical Trial Notification (CTN). CTAs are required for higher-risk clinical trials involving therapeutic products unregistered in Singapore or uses of registered therapeutic products which 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 Restriction on Using 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 International Council for Harmonisation (ICH) E6 (R2) Good Clinical Practice Guidelines.

2.5 Use of Data Resulting From the 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 Databases Containing Personal or Sensitive Data

The creation of a database containing personal or sensitive data would not be subject to requirements beyond that which is already required in the PDPA.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

The classification of the 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 has certain active ingredients as a constituent, 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,

has as a constituent any of the following active ingredients:

- 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,

and which exerts an inherent effect, either pharmacologically, chemically or by other physiologi-

cal means, leading to its use for a therapeutic, preventive, palliative or diagnostic purpose.

Medical Device

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 specific purposes of:

- 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,

and 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 intended function by such means.

Medical devices also include the following:

- 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 Granting a 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. Biosimilars 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 physicochemical characteristics, biological activity, safety and efficacy needs to be established.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

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 be 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 for Pharmaceutical and Medical Devices

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: submission of the application form online via the HSA's portal, PRISM, and submission of the technical dossier accompanying the application, within two working days of the PRISM application submission, must be made.

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 evaluation route applicable depends on whether the therapeutic product has received reference agency approvals.

Regulatory decision: the HSA will notify the applicant of one of the following outcomes after the application has been evaluated: approval, approvable, non-approvable or rejection.

Where the applicant receives an approvable regulatory decision, the applicant 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, the applicant will be informed of the deficiencies leading to the non-approvable 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 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 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 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 payment of the annual retention fee. To make a transfer application, the existing registrant first initiates the application via the HSA's portal, transfer@prism. 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 transfer@prism 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 which have not received prior reference agency

approvals will have to undergo the full evaluation route.

Medical device registration applications are submitted online via the HSA's portal, MEDICS. For applications under the full or abridged evaluation routes, the application will first be verified for eligibility and completeness before it is accepted for evaluation. In the event that 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 model(s) 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 MEDICS. 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 which are published on the public SMDR listing) may be implemented immediately upon the 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 Pharmaceutical and Medical Devices Without Marketing Authorisations

Unregistered therapeutic products may be imported and supplied for patient's 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 are 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, then 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 a clinical purpose in clinical research;
- for export or re-export; or
- for patients' use.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

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

Therapeutic Products

Ongoing obligations of 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 HAS 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 of 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 thereof.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

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.

The HSA makes publicly available, on an online database, information submitted to the HSA 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 the disclosure is to a government body.

Additionally, 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 is a therapeutic product registration application of 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.

3.8 Rules Against Illegal Medicines and/or Medical Devices

It is an offence under the HPA to manufacture, supply or import:

- an adulterated health product;
- a counterfeit health product;
- a health product that has been tampered with; or
- an unwholesome health product.

If found dealing with any adulterated, counterfeit or tampered health products, offenders may be subject to a fine not exceeding SGD100,000 and/or imprisonment for up to three years.

If found dealing with any unwholesome health products, offenders may be subject to a fine not exceeding SGD50,000 and/or imprisonment for up to two years.

The HSA has also compiled a non-exhaustive public database of detected and tested illegal health products in Singapore.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

Border measures are available under intellectual property law for proprietors or licensees of registered trade marks. See **10.1 Counterfeit Pharmaceuticals and Medical Devices** for more information.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

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 obtain 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 Audit and Licensing of Pharmaceutical Manufacturers in December 2017.

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, 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 health-care 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 used 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.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical 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 March 2021.

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 apply.

Wholesale of Medical Devices

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

- 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;
- 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.

The period of validity of a wholesaler's licence depends on the respective terms and conditions of the licence.

5.2 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.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices 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. Additionally, 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 and thereafter, the regulations are applied and enforced by the HSA.

6.2 Importer of Record of Pharmaceutical and Medical Devices

Only a qualified pharmacist or a person approved by the HSA may act as the importer of record of therapeutic products. There are no specific requirements regarding the importer of record of medical devices.

6.3 Prior Authorisations for the Importation 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.

Some exemptions from holding an importer's licence include 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;
- 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; and
- in light of the COVID-19 situation, the HSA announced that surgical masks, particulate respirators, thermometers and protective gear for medical professionals may be imported

without a licence (see **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**).

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

Harmonised System (HS) codes are required in Singapore in the permit declaration of goods. They 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.

6.5 Trade Blocs and Free Trade Agreements

Singapore is part of the ASEAN trade bloc and is a party to Free Trade Agreements with numerous jurisdictions containing provisions on trade/regulatory facilitation, including the European Union, China and New Zealand.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 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.

7.2 Price Levels of Pharmaceutical 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.

7.3 Pharmaceuticals and Medical Devices: 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.

Additionally, the government 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.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The Agency for Care Effectiveness (ACE), under the purview of the MOH, is the national health technology assessment agency in Singapore. The ACE works to lower 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.

7.5 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.

8. Digital Healthcare

8.1 Rules for Medical Apps

There is currently no specific legislation governing mobile medical applications in Singapore. Mobile medical applications may be classified as telehealth products, which includes any equipment (eg, instruments, apparatus, machines or software, including mobile phone applications) that is involved in the provision of healthcare services over physically separate environments via info-communication technologies (including mobile technology). The HSA has clarified under the Regulatory Guideline for Telehealth Products that, generally, telehealth products may be considered medical devices if they are intended to be used for medical purposes such as investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process.

Telehealth products that are medical devices are subject to the following medical device regulatory controls:

- product registration;
- dealer's licence requirements; and
- post-market obligations.

Separately, there is an immediate registration pathway for Standalone Medical Mobile Applications (SaMD). SaMD refers to a software and/or mobile application that is intended to function by itself and is not intended to be used to control or affect the operation of other hardware medical devices. Where the SaMD has been approved by at least one of the HSA's reference agencies for the same intended use, the submission of a product registration application with the HSA grants it immediate market access.

On the other hand, where the application is for general wellness purposes, such as for fitness tracking, then it is not regulated as a medical device. However, owners of such applications should clearly state that the application is intended for use only for general wellbeing purposes or to encourage or maintain a healthy lifestyle, and is not intended to be used for any medical purpose.

8.2 Rules for Telemedicine

While there is no legislation governing telemedicine, the policy stance taken in Singapore is reflected in the National Telemedicine Guidelines issued by the MOH in January 2015 and the HSA Regulatory Guidelines for Telehealth Products, which were revised in April 2019.

Registered medical practitioners may provide medical attention through a mobile device in Singapore. Such services were previously regulated under the Licensing Experimentation and Adaptation Programme (LEAP), a regulatory sandbox initiative launched by the MOH in April 2018. The MOH has since closed the sandbox for telemedicine, in February 2021.

Under the new Healthcare Services Act 2020 (HCSA), independent doctors/dentists offering teleconsultations themselves or organisations which have set up clinical and operational governance for their doctors and/or dentists to provide teleconsultation will need to be licensed. As part of the transition to the licensing framework under the HCSA, the MOH has also introduced a voluntary listing of direct telemedicine service providers. It is expected that the HCSA will take effect fully by the end of 2023.

8.3 Promoting and/or Advertising on an Online Platform

There are no special rules governing the promotion and advertisement of therapeutic products and medical devices online. The general rules regarding the advertisement of therapeutic products and medical devices apply.

8.4 Electronic Prescriptions

Electronic prescriptions are allowed and used in Singapore by both public and private healthcare providers. Electronic prescriptions are not specifically regulated and are subject to the general legislation governing the collection of personal data and medical records under the PDPA and various healthcare-related legislation.

8.5 Online Sales of Medicines and Medical Devices

General Sale List Medicines may be sold online, subject to certain regulatory requirements. They are set out in the Medicines (General Sale List) Order 2016.

On 5 May 2020, the HSA introduced the roll-out of the e-pharmacy service. HSA-licensed retail pharmacies and wholesalers in Singapore with a good track record in handling Prescription Only Medicines and Pharmacy Only Medicines may apply for a retail pharmacy licence, or include

such services in their existing retail pharmacy licence if they intend to carry out e-pharmacy operations.

In general, Class A medical devices and selected categories of unregistered Class B, C and D medical devices may be sold online.

8.6 Electronic Health Records

Electronic health records are currently not specifically regulated in Singapore and are subject to the general legislation governing the collection of personal data and medical records under the PDPA and various healthcare-related legislations.

Health-related information is not regulated as sensitive data, although the PDPC, which administers the PDPA, has taken the position in several enforcement decisions that medical data is more sensitive in nature and require a higher standard of protection.

Cloud Platforms

While there are no specific requirements for the storage of information on cloud platforms, the PDPC has published the Guide to Data Protection Practices for ICT Systems, to provide guidance for organisations using cloud platforms. Sensitive data of patients may be transferred and stored on cloud platforms. Where the cloud platforms are based outside Singapore, the PDPA requires organisations to ensure that the transferred personal data is accorded a standard of protection that is comparable with that of the PDPA.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

In Singapore, patents are regulated under the Patents Act 1994 (Patents Act) and its various subsidiary legislations, which include the Patents Rules. Therapeutic products are commonly patented in Singapore and there are generally no patentability requirements specific to therapeutic products or medical devices.

Issues

The Court of Appeal in *Warner-Lambert Company LLC v Novartis (Singapore) Pte Ltd* [2017] SGCA 45 has recently raised the issue of whether Swiss-type claims are necessary in Singapore to frame second and subsequent medical-use claims, given that purpose-limited product claims may be sufficient to protect such claims. While the Intellectual Property Office of Singapore continues to take the approach that Swiss-type claims are valid, it is not certain if this approach will change in the future to reflect the Court of Appeal's views.

As software is not patentable under the Singapore patent regime, medical devices consisting exclusively of software may not receive patent protection.

9.2 Second and Subsequent Medical Uses

Second and subsequent medical uses of a known product are patentable in so far as they are claimed in the form of "Swiss-type" claims. Additionally, second medical-use claims can only derive novelty from their intended use where the use is a method of treatment of the human or animal body by surgery or therapy or a method

of diagnosis practised on the human or animal body. It should be noted that the Singapore patents' registry practice for using the Swiss-type claim format differs from that of the United Kingdom and Europe, which are contracting members of the Europe Patent Convention 2000.

Patentability of Claims

Second medical-use claims are typically used to protect the use of a substance or composition in the treatment of a different disease.

They are also allowable for new dosage regimes, on the condition that the claimed dosage regime is novel and inventive. However, the patents' registry recognises that, in most cases, it is generally presumed that new dosage regimes lack inventiveness, unless there is a clear technical prejudice pointing away from the claimed dosage regime.

Depending on the factual scenario, second medical-use claims may rely solely on the patient population to be treated to fulfil the requirements of novelty and inventive step, despite known associations of the claimed product and the disease to be treated. For such claims to be patentable, the new patient group must consist of a distinctly different patient population from those treated in the prior art.

Infringement

It is uncertain how the Singapore courts will apply the legislation on infringement to second and subsequent patents as, at the time of writing, there are no cases in Singapore on the infringement of second and subsequent patents of pharmaceutical products.

9.3 Patent Term Extension for Pharmaceuticals

Under the Patents Act, the proprietor of a patent can make an application to the patents' registry to extend the terms of the patent on any of the following grounds:

- where there was an unreasonable delay by the patents' registry in granting the patent;
- where the patent was granted on the basis of any prescribed documents relating to a corresponding application or related national phase application, and there was an unreasonable delay in the issue of the corresponding patent or related national phase patent, and the patent office that granted the corresponding patent or related national phase patent has extended the term of the corresponding patent or related national phase patent on the basis of that delay; or
- where the subject of the patent includes any substance which is an active ingredient of any pharmaceutical product, and there was an unreasonable curtailment of the opportunity to exploit the patent, due to the process of obtaining marketing approval for the first pharmaceutical product, which uses the substance as an active ingredient, and the patent term has not previously been extended on this ground.

Further guidance on how the aforementioned grounds are applied is set out in the Patent Rules.

Patent-term extensions may not be challenged by third parties.

9.4 Pharmaceutical or Medical Device Patent Infringement

When a person carries out any of the following acts in Singapore in relation to the invention of

a patent without the consent of the proprietor's consent, it will constitute a patent infringement:

- where the invention is a product, the person makes, disposes of, offers to dispose of, uses or imports the product, or keeps it, whether for disposal or otherwise;
- where the invention is a process, he or she uses the process or offers it for use in Singapore when he or she knows, or it is obvious to a reasonable person in the circumstances, that its use without the consent of the proprietor would be an infringement of the patent; and
- where the invention is a process, he or she disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product, whether for disposal or otherwise.

An application for marketing authorisation, in itself, will not infringe a patent. However, the HSA may refuse the application if the doing of the act for which the marketing authorisation is sought will infringe on an existing patent.

Only actual infringement is actionable under the Patents Act and a person aggrieved by groundless threats of infringement proceedings may bring an action against the person making the threats.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Relevant to pharmaceuticals and medical devices, it is a defence to patent infringement if the act:

- is done for experimental purposes relating to the subject-matter of the invention;

- consists of the extemporaneous preparation of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared;
- consists of the doing of any infringing act in relation to the subject-matter of the patent to support any application for marketing approval for a pharmaceutical product, provided that anything produced to support the application is not made, used or sold in Singapore or exported outside Singapore, other than for purposes related to meeting the requirements for marketing approval for that pharmaceutical product; or
- consists of the import, disposal or offer to dispose of a patented pharmaceutical product for use by or on a specific patient in Singapore, or the use of that product by or on that patient, where that product is required for use by or on that patient, the relevant authority has granted approval specifically for the import of that product for use by or on that patient, and that product was produced by or with the consent (conditional or otherwise) of the proprietor of the patent or any person licensed by him or her.

Compulsory Licence

An interested person may apply to the court for the grant of a licence under a patent on the ground that the grant of the licence is necessary to remedy an anti-competitive practice. The court may grant the licence if:

- there is a market for the patented invention in Singapore;
- that market is not being supplied on reasonable terms; and
- the court is of the view that the proprietor of the patent has no valid reason for failing to supply that market with the patented inven-

tion, whether directly or through a licensee, on reasonable terms.

9.6 Proceedings for Patent Infringement

The proprietor of the patent may bring proceedings for patent infringement in court and make a claim for any of the following remedies:

- an injunction restraining the defendant from any apprehended act of infringement;
- an order for the defendant to deliver up or destroy any patented product in relation to which the patent is infringed, or any article in which that product is inextricably comprised, or any material, and implement, the predominant use of which has been in the creation of the infringing product;
- damages in respect of the infringement;
- an account of the profits derived by the defendant from the infringement; and/or
- a declaration that the patent is valid and has been infringed by the defendant.

The proprietor of a patent and any other person may choose to refer to the Registrar of Patents to determine whether the other person has infringed the patent, upon mutual agreement.

The procedure for regular court proceedings apply to a patent infringement action in court. Typically, the plaintiff commences an action by filing an originating claim and serving it on the defendant. Parties will then file their respective pleadings and exchange their affidavits before setting down for trial. Patent infringement actions are heard in the General Division of the High Court and any appeals are made directly to the Court of Appeal. Separate procedures apply for references to the Registrar of Patents.

Invalidity is an available defence to patent infringement and can be invoked during the infringement proceedings at the pleadings stage.

9.7 Procedures Available to a Generic Entrant

In general, when processing applications for therapeutic product registration, the HSA will take into account patent protection.

Before making an application for a generic market entry, the applicant must first declare the existence of any patent in force in respect of the therapeutic product, and whether the applicant is the proprietor of the patent. Where a patent is in force in respect of the therapeutic product and the potential applicant is not the proprietor, the potential applicant should first obtain the consent of the patent proprietor to make the application.

Where an applicant takes the position that the patent is invalid or will not be infringed by the generic market entry, the HSA may require the applicant to serve on the proprietor a notice in the form specified by the HSA, declaring that the applicant has made an application in respect of the proprietor's patent. If the proprietor does not make a court application to restrain the generic market entry or seek a declaration that the patent is valid or will be infringed by the generic market entry within 45 days of receiving the notice, the HSA may proceed with the generic market entry application. If the proprietor is successful in its court application, a 30-month moratorium will be granted, during which the HSA will not grant marketing approval for the generic market entry.

Where the patent proprietor misses the deadline to make a court application and the applicant successfully registers the therapeutic product, the proprietor may still make an application to

the HSA to cancel the registration if the proprietor has obtained a determination that:

- the doing of an act authorised by the registration infringes a patent; or
- the initial declaration made by the applicant contains a statement that is false or misleading in a material particular or omits to disclose any matter that is material to the application.

This was confirmed in the recent Court of Appeal case *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2019] SGCA 31.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

It is an offence under the Trade Marks Act 1998 to counterfeit a trade mark, falsely apply a registered trade mark to goods or services, or do any of the following in relation to goods to which a registered trade mark is falsely applied:

- import into Singapore for the purpose of trade or manufacture;
- sell or offer or expose for sale; or
- possess for the purposes of trade or manufacture.

Seizure of Infringing Goods

The proprietor or licensee of a registered trade mark in Singapore who expects infringing goods to be imported or exported may request the Singapore Customs to seize the goods by giving written notice and sufficient information to identify the goods, enable the Singapore Customs to ascertain when and where the goods are expected to be imported or exported, and satisfy the Singapore Customs that the goods are infringing goods. The requestor may also be required to

provide security for the liability or expense of seizing the goods, and their subsequent storage and disposal.

At any time after the goods have been seized, the Singapore Customs may give the requestor the name and contact details of any person connected with the import or proposed export of the seized goods and permit the requestor to inspect the seized goods. The seized goods will be released to the importer or exporter if the requestor has not instituted an infringement action in relation to the goods before the expiry of the retention period.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Trade marks used for therapeutic products and medical devices will not be registered if they contain or consist of their international non-proprietary name without being accompanied by any other distinctive matter due to their descriptiveness and lack of distinctive character. There are no restrictions under trade mark law to import and distribute non-counterfeit, genuine pharmaceutical or medical device products.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

While the concept of trade dress is not expressly recognised in Singapore, it is possible to register the design of therapeutic products and medical devices and their packaging, and any such registered designs can receive protection for up to 15 years. Registrable designs generally refer to the features of shape, configuration, colours, pattern or ornament applied to any article or non-physical product that give that article or non-physical product its appearance, but do not include methods or principles of construction and designs that are solely functional.

The design and packaging of therapeutic products and medical devices, including their three-dimensional shape, may also potentially be registered as trade marks or receive protection under the common law tort of passing off.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Safety and efficacy data generated in support of an innovative therapeutic product registration cannot be relied on by a subsequent similar therapeutic product to obtain registration for a period of five years after the date of the registration of the first therapeutic product. Chemical drugs and biologics are not treated differently.

There is no such registration exclusivity period for medical devices.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices Waiver of Import Licence Requirements for Masks, Thermometers, etc

On 31 January 2020, an exemption order was effected, following which the HSA waived the requirement for import licences for surgical masks, particulate respirators (eg, N95 masks), thermometers and protective gear for medical professionals such as gloves. Commercial importers were still required to file online notifications. However, the 2020 exemption order has been revoked from 1 September 2022 and all standard regulatory controls are now back in force.

Provisional Authorisations for COVID-19 Diagnostic Tests

As a temporary measure for the timely detection of COVID-19, the HSA had previously set up an expedited provisional authorisation process for COVID-19 diagnostic tests. However, the HSA is no longer accepting any such applications. With effect from 1 January 2022, COVID-19 test kits must undergo a fully fledged registration with the HSA, or be authorised under the Pandemic Special Access Route (PSAR), in order to be supplied in Singapore. It is also noted that from 15 March 2022, applicants who wish to supply COVID-19 antigen rapid self-test kits which use nasal swab samples only will no longer be eligible for PSAR submission and will have to apply for the full-fledged registration with HSA.

Regulatory Flexibility in Relation to Respiratory Devices

On 1 April 2020, the HSA announced a position of regulatory flexibility towards respiratory devices in view of the COVID-19 pandemic. The regulatory measures had:

- allowed the safe use of HSA-registered anaesthesia machines and positive airway pressure devices as emergency ventilators without approval;
- allowed upgrades or modifications to HSA-registered ventilators without approval as long as the changes do not affect registered performance specifications, the devices continue to meet the safety and performance requirements and the changes are notified on a six-monthly basis; and
- advised companies seeking to supply unregistered ventilators to meet local clinical needs.

However, these regulatory measures have since been discontinued. All standard regulatory controls are now back in force.

Provisional Authorisations for Respirator Decontamination Devices

On 11 June 2020, the HSA announced a provisional authorisation pathway for medical devices intended for decontaminating used respirators, in view of the increasing demand for respirators and the global supply constraints during the COVID-19 situation. However, this regulatory measure has since been discontinued. All standard regulatory controls are now back in force.

11.2 Special Measures Relating to Clinical Trials

As of February 2022, the HSA has not issued any special regulations in relation to clinical trials of COVID-19 treatments and vaccines specifically.

HSA Guidance on the Conduct of Clinical Trials

On 27 March 2020, the HSA issued a guidance on the conduct of clinical trials in relation to the COVID-19 situation, which was subsequently revised on 29 July 2020. The potential contingency measures discussed include:

- remote study visits;
- direct-to-patient services for investigational product supply;
- obtaining informed consent remotely; and
- sponsor site-monitoring visits.

Recommendations include:

- ensuring proper documentation of reasons for implementing any contingency measure and performing an impact assessment of the implemented measures on trial-participant safety, data credibility and trial integrity;
- engaging in early consultations with sponsors, investigators, IRBs and the HSA; and
- including in the Clinical Study Report the impact of COVID-19 and contingency meas-

ures on the safety and efficacy data for the clinical trial.

The guidance was revised again on 26 August 2022. A notable change from this latest revision is that the HSA will now prioritise clinical trial applications that are made to address the needs of public health emergencies such as COVID-19. The HSA may also allow for a shortened review time where appropriate. In a similar vein, the HSA will also prioritise requests made by sponsors and investigators for rapid scientific and regulatory advice on the regulatory requirements for the development of novel vaccines and therapeutics to address the public health emergency.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices New Pandemic Special Access Route (PSAR)
In 2020, the HSA introduced the PSAR, which facilitates early access to novel vaccines, medicines and medical devices which the government designates as being required for a pandemic by granting such products an interim authorisation, exempting them from the registration and licensing requirements.

The HSA will consider interim authorisation if there is reasonable quality, safety and efficacy (QSE) data suggesting that the potential benefits outweigh the known risks and there is continuing QSE data generated from ongoing studies to support the eventual transition of the interim authorisation to full registration. The HSA may cancel an interim authorisation if the evolving data suggests that the benefits no longer outweigh the risks, or if the emergency ceases.

The PSAR allows vaccines, medicines and medical devices to be evaluated based on data submitted on a rolling basis instead of full data sets, giving the HSA more time to review sub-

mitted data while companies to continue with clinical trials and development. Companies will be required to file an application to transition the status of the health product from PSAR interim authorisation to full registration, once sufficient data is available for full registration.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

Other than the measures targeted at medical devices (such as diagnostic tests) for addressing COVID-19 specifically (discussed in **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**), no other simplifications or flexibilities in certification requirements were formally introduced by the HSA as a result of COVID-19.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

Waivers were granted for import licences on masks, respirators, thermometers and protective gear, although they are now discontinued (discussed in **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**).

The PSAR (discussed in **11.3 Emergency Approvals of Pharmaceuticals and Medical Devices**) allows, subject to conditions, the interim authorisation of vaccines, medicines and medical devices designated by the government to be exempt from the prohibition against importation without the required importer's licences and product registrations.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Financial Support for Telemedicine

On 3 April 2020, to support the safe-distancing measures to minimise activities and to reduce the risk of local transmission of COVID-19, the

Ministry of Health introduced a time-limited initiative to allow the tapping of funds from the Community Health Assist Scheme (a government scheme which provides subsidies for medical care at general practitioner clinics) and Medisave accounts (the national savings scheme which sets aside part of a person's income for medical expenses) for follow-up video consultations by approved healthcare institutions for certain chronic conditions. The list of eligible chronic conditions was subsequently expanded from seven to 20.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Power to Issue Compulsory Licences

There have been no announcements by the government regarding the compulsory licensing of COVID-19 treatments or vaccines. To the best of the available knowledge, the government has never exercised these powers.

Under the Patents Act, the government (and any authorised party) may do anything in relation to a patented invention for a public non-commercial purpose or, for or during a national emergency or other circumstances of extreme urgency, without amounting to an infringement of the patent.

In particular, the government may import any health product and do anything in relation to any imported health product that is patented, upon giving the Council for the Agreement on Trade-Related Aspects of Intellectual Property Rights the required notification.

Restrictions and Obligations of the Power to Issue a Compulsory Licence

The government can only issue licences which are non-exclusive and non-assignable (except where the assignment is in connection with the

goodwill of the business in which the patented invention is used).

The government's right to use a patented invention is similarly non-exclusive, non-assignable and limited to the supply of the patented invention, predominantly in Singapore.

The government must inform the patentee promptly of its use of the patented invention and must pay the remuneration that has been agreed, or in default of agreement, remuneration as determined by the Singapore courts. There is no requirement to pay remuneration if the patentee has already received or will receive some other remuneration.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

As far as is known, no information is publicly available as to whether liability exemptions or indemnities are applicable for COVID-19 vaccines or treatments.

Notably, the government has introduced the Vaccine Injury Financial Assistance Programme to provide a one-time goodwill financial assistance to persons who experience serious side effects from the COVID-19 vaccines. To be eligible, the individual must have received his or her COVID-19 vaccine under the National Vaccination Programme and the side effect experienced must be assessed by a doctor to be related to the individual's COVID-19 vaccination.

11.9 Requisition or Conversion of Manufacturing Sites

As far as is known, no manufacturing sites were requisitioned or converted due to COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

No systemic changes were made to the system of public procurement of medicines and medical devices due to COVID-19. However, according to a statement released by the Second Minister for Finance, emergency procurement procedures were invoked at the early stages of the pandemic to allow the government to source and secure essential medical supplies quickly. Instead of open sourcing, the government contracted directly with suppliers with the necessary expertise and resources and who were best able to meet the requirements within the shortest timeframe possible.

The Minister signalled that, as the situation improves and the urgency to secure supplies abates, a larger proportion of procurement will be done through the default process of open sourcing.

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