Life Sciences Commercialisation in Singapore: Overview

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A Q&A guide to pharmaceutical IP and competition law in Singapore.

This Q&A provides a high-level overview of key practical issues, including the life sciences sector, pricing and state funding, distribution and sale, importing, advertising, patents, trade marks, competition law, and product liability.

Life Sciences Sector Overview

1. Give a brief overview of the life sciences sector in your jurisdiction.

Singapore is home to many generic pharmaceutical manufacturers and traders and is the manufacturing base for eight of the world's ten largest pharmaceutical firms. The pharmaceutical sector is a strong pillar of the Singapore economy, contributing to about 5% of Singapore's gross domestic product.

The life sciences industry in Singapore is regulated by the *Health Sciences Authority (HSA)*, operating under the oversight of the Singapore Ministry of Health (MOH). The regulation of health products, such as pharmaceuticals, cosmetics, medical devices, fall within the purview of the HSA.

The regulatory framework for medicinal and other health-related products in Singapore consists of the:

- Health Products Act 2007.
- Medicines Act 1975.
- Medicines (Advertisement and Sale) Act 1955.
- Poisons Act 1938.
- Sale of Drugs Act 1914.

Pharmaceutical products (also known as chemical or biologic drugs) previously regulated under the Medicines Act 1975 and the Poisons Act 1938 are regulated as "therapeutic products" under the Health Products Act 2007, along with other health products (medical devices and cosmetic products). This is part of the HSA's ongoing initiative to transfer regulatory control of all health products from the Medicines Act to the Health Products Act.

The Singapore Medical Council (SMC) regulates registered medical practitioners.

The SMC Ethical Code and Ethical Guidelines (ECEG 2016) sets ethical benchmarks for medical practitioners.

With regards to advertising, the pharmaceutical industry must comply with the general principles provided for in:

- The Medicines Act and Health Products Act (and any related subsidiary legislation).
- The Singapore Code of Advertising Practice (SCAP).
- Guidelines issued by the HSA in relation to the advertising of or supply of health or medicinal products.
- The SMA Ethical Code.
- The SMC Ethical Code.
- The SAPI Code of Conduct.

See *Question 9*.

2. Give a brief overview of key life sciences funding issues in your jurisdiction.

Private markets are the driving force behind healthcare innovation in relation to developing effective treatments for complex diseases. They are supported by government-owned SGInnovate, which provides funding, connections, and talent development initiatives.

The third quarter of 2021 saw the highest level on record, with more than 800 biotech M&A deals and over SGD50 billion in funding flows (source: CB Insights).

One challenge that many early-stage companies face in obtaining funding is some investors' preference to fund companies with products or treatments that are already clinically-approved, as

One challenge faced by many new life sciences companies in Singapore is the preference from certain investors to only fund companies with products or treatments that have already been clinically approved. These companies are often subject to the time-consuming regulator process for health care innovation matters. To counter this, SGInnovate has been working with corporates, incubators, and funds to support the growing number of early-stage emerging companies from Singapore's institutes of higher learning and research institutions.

Pricing, Government Funding, and Reimbursement

National Health Care System

3. What is the structure of the national health care system, and how is it funded? Briefly explain how pharmaceuticals are introduced into that system.

Structure and Funding

The national health care system in Singapore uses a mixed financing system. Broadly, there are four tiers of health care funding:

- Direct subsidies from the government.
- Medisave, a compulsory individual medical savings account scheme, where all working Singaporeans and their employers contribute part of the employee's monthly wages into the account, to save for the employee's future medical needs.
- MediShield Life, a low-cost basic health insurance plan for all Singapore citizens and permanent residents, which helps to pay for large hospital bills and selected costly outpatient treatments.
- Medifund, a medical endowment fund set up by the government for needy Singaporean patients, who cannot afford to pay their medical bills despite using the first three tiers of health care funding.

The government administers a number of other subsidy schemes, such as the:

- Community Health Assist Scheme.
- Interim Disability Assistance Programme for the Elderly.
- Medication Assistance Fund.

These three schemes subsidise primary health care, provide financial assistance to disabled elderly persons, and subsidise certain drugs.

For long-term disabilities, CareShield Life and ElderShield are long-term care insurance schemes provided by the government which offer Singapore citizens and Singapore permanent residents financial protection should they become severely disabled (that is, unable to perform at least three or more of the six activities of daily living), especially during old age.

Interaction of the Life Sciences Industry with the Health Care System

There is no specific legislation governing the collaboration of the pharmaceutical industry with health care professionals in the national health care system. However, the Singapore Medical Association (SMA) and the Singapore Association for Pharmaceutical Industries (SAPI) have prepared a joint paper (SMA-SAPI Joint Paper), which provides that:

- Health care professionals should place the health and welfare of patients above any financial or commercial gain.

- The pharmaceutical industry should invest in research and development, to develop of new and improved treatment options for the benefit of patients and should market these treatment options ethically.

The relationship between the pharmaceutical industry and health care professionals must always be seen to be impartial, honest and in compliance with the ethical codes promulgated by the SMA and the SMC, and the SAPI Code of Conduct.

The SMA-SAPI Joint Paper sets out recommendations in relation to:

- The marketing practices of the pharmaceutical industry (including in relation to promotions, gifts, symposiums or congresses, sponsorship and the supply of samples).
- Consultancy arrangements between the pharmaceutical industry and health care professionals.

While there are no specific rules and principles regarding the collaboration of the pharmaceutical industry with health care professionals, the SAPI Code of Conduct generally prescribes certain standards to be followed (for example, the substantiation of data, careful use of comparative statements, prohibition of false or misleading statements and so on).

The SMC Ethical Code states that doctors should only engage in promotion of food, vitamins, tonics and health and nutrition supplements where there is sufficient scientific basis or when generally accepted by the medical profession.

The SMC Ethical Code does not prohibit doctors from sponsoring, donating, participating or rendering services for any charitable endeavours. However, when participating in a medical event, conference, talk or publication, or educational website that is sponsored by a pharmaceutical company, or company marketing health or medical products, the doctor must ensure that their participation does not occur in such a way as to appear to endorse such products, or which persuades patients or the general public to use those products.

The doctor must also not permit the publication of any details of services provided by the doctor in relation to such participation. A doctor who is sponsored by a company to participate in an educational event, or who reports research sponsored by a company must declare their potential conflict of interest to the audience.

Price Regulation and Reimbursement

4. How are the prices of medicinal products regulated? When is the cost of a medicinal product funded by the government or reimbursed? How is a pharmacist compensated for dispensing services?

Price Regulation

The government does not generally regulate the prices of medicinal products. However, the government can manage drug costs through different mechanisms. These include:

- Integrating supply chain management across the public health care sector, to achieve better economies of scale and greater negotiating leverage.
- Adopting value-based pricing, to negotiate drug prices to levels commensurate with the benefits.
- Ensuring appropriate use of drugs (for example, encouraging the use of generic drugs where possible due to cost efficiency).

Separately, given that public hospitals in Singapore generally purchase medicinal products through centralised Group Procurement Offices (GPOs) by way of tender contracts, this operates in some way to regulate the prices of medicinal products.

Reimbursement

The national health care system in Singapore uses a mixed financing system that provides multiple tiers of financing for its citizens and residents. In addition to direct subsidies for services and drugs at public healthcare institutions, the Singapore government also administers a number of drug subsidy schemes to ensure that eligible patients have access to effective medications for medical conditions that are common in Singapore (see *Question 3, Structure and Funding*).

On the standard drugs list (SDL) the Drug Advisory Committee (DAC) is responsible for assessing whether a drug should be included. The DAC, with input from other clinicians and the Pharmacoeconomics and Drug Utilisation Unit (under the supervision of the HSA), reviews the SDL each year.

Pharmacist Reimbursement

Compensation for provision of dispensing services by pharmacists is not generally regulated.

Distribution and Sale

5. Who is authorised to prescribe and supply medicines to patients or consumers? Who is authorised to distribute prescription medicines and over-the-counter medicines?

Therapeutic Products

Therapeutic products are classified in Singapore as:

- **Prescription only medicines (POMs).** POMs can only be supplied by a doctor or dentist or a pharmacist at a retail pharmacy according to a prescription by a doctor or a dentist. The advertising or sales promotion of POMs to the general public is not allowed (Therapeutic Products Advertisement Guidance).
- **Pharmacy only medicines (P-medicines) or General Sales List (GSL).**P-medicines can be supplied by or under the supervision of a pharmacist without a prescription. GSL medicines can be purchased from any retailer. P-medicines must prominently display an advisory or warning statement (for example, statements advising consumers to read the information leaflet or product insert) and appropriate statements advising consumers to consult their healthcare

professionals on the use of the medicine or if symptoms persist, and specific advisories based on what is required of that specific drug. For both P-medicines and GSL medicines, recommendations relating to the use of the product must be consistent with the HSA's approved indications.

Medicinal Products

Traditional medicines, homoeopathic medicines, quasi-medicinal products, and medicated oil and balms are not currently subject to licensing. However, the sale and supply of Chinese proprietary medicines (CPM) requires an import licence for their local use and wholesale manufacture in Singapore. For CPMs, companies must therefore:

- Obtain an in-principle approval for the CPM product listing before making an application for a licence from the HAS.
- Comply with the HAS's Good Distribution Practice (GDP) standard.

In addition, prior to the manufacturing or assembly of CPMs, all Singapore facilities engaged in the process must also have a valid manufacturing licence and comply with the GDP standard.

All medicinal products are subject to the advertising controls in the Medicines Act and the Medicines (Advertisement and Sale) Act.

Under the Medicines (Medical Advertisements) Regulations, any advertisement or sales promotion that relates to, or is likely to cause any person to believe that it relates to, any medicinal product, requires prior approval from the HSA. Aside from certain advertisements relating to exempted medicinal products, an application must be made to the HSA for a Medical Advertisement and Sales Promotion Permit. This permit number must be printed legibly on the advertisement and promotional materials.

However, there are some exceptions for medical advertisements and sales promotion activities directed exclusively to a person in their business premises who can lawfully sell or supply any medicinal product in the course of their trade, business or profession.

Reference advertisements and trade advertisements, as well as medical advertisements published by a public authority or person authorised to issue or publish such an advertisement by the Minister for Health, are also exempted from the requirement to obtain an advertising permit.

Further, the HSA's Guide on Advertisements and Sales Promotion of Medicinal Products (Medical Advertisements Guidelines) prohibits certain specified types of sales promotions of medicinal products, including the:

- Offer of a gift or prize to promote sales of a medicinal product.
- Use of the word "free" or "complimentary".
- Use of a money-back guarantee.
- Offer of a medicinal product free-of-charge with the purchase of a non-medicinal product.
- Distribution of samples of Chinese proprietary medicines, traditional medicines, or homeopathic medicines.

Under section 3 of the Medicines (Prohibition of Sale, Supply and Importation) Order, a medicinal product cannot be sold or supplied to any person:

- After the expiry date stated on the label on the container or packaging of the medicinal product.
- If the medicinal product is harmful, unsafe or non-conforming in terms of strength, quality or purity with the medicinal product's specification registered with the HSA or with the manufacturer's specification (for a medicinal product not registered with the HSA).
- If the medicinal product contains the following toxic heavy metals exceeding the following amounts: arsenic (five parts per million (ppm)), cadmium (0.3 ppm), lead (10 ppm) and mercury (0.5 ppm).

The Prohibition of Sale Order also imposes limits on various microbes that can be found in Chinese proprietary medicines. Chinese proprietary medicines that contain any poisons are not permitted for sale, supply or import, unless those items:

- Are naturally present in the ingredients of the medicines.
- Fall within the exceptions set out in the Second Schedule to the Prohibition of Sale Order.

Internet, e-mail or Mail Order

Sales promotions of therapeutic or medicinal products on the internet, by e-mail or by mail order are generally governed by the same rules and guidelines set out above. The definitions of "advertisement" and "sales promotion" under the Health Products Act and the Medicines Act (and their subsidiary legislation) are broad and cover any form of advertising and promotion (including over the internet).

However, the sale of therapeutic or medicinal products through the internet is not well-regulated in Singapore. It seems that the sale through the internet of therapeutic products may need to be linked to a physical pharmacy location, and that physical location would need to be licensed by the HSA.

All advertisements in Singapore should also comply with the SCAP. The Advertising Standards Authority of Singapore (ASAS), a self-regulatory body which enforces SCAP, acknowledges that it may be difficult to ensure compliance with SCAP for advertisements received through the internet, and mail-order brochures from overseas. The SCAP Appendices contain further guidance, in particular Appendix D on interactive advertisements concerning commercial communications over the internet, and Appendix E on direct marketing of goods sold directly to consumers outside retail establishments.

6. How is the wholesale distribution of medicines regulated?

Wholesale distribution in relation to a health product can mean any of the following:

- Supply to a person for the purposes of them supplying it again to some other person.
- Supply to a person as a commercial sample in the normal course of a lawful trade.
- Supply to a government department or statutory body which requires the health product for the purposes of public service or use in connection with the exercise of statutory power.

- Supply to a person or institution concerned with scientific education or research which requires the health product for the purpose of education or research.
- Supply to a person who requires the health product for the purpose of enabling them to comply with any requirements made by, or pursuant to, any written law with respect to the medical treatment of individuals employed by that person in any business or trade carried out by that person.
- Supply to a person to use the health product, other than by way of administration to one or more individuals, for the purpose of the person's business or trade.
- Supply by export to a party outside of Singapore.

(Section 2, Health Products Act.)

Therapeutic Products

A person must obtain an importer's licence to import therapeutic products or medical devices into Singapore and a wholesaler's licence to export them (Health Products Act).

Importers and exporters of therapeutic products are required to appoint person responsible for ensuring compliance with the GDP standard. This person will be responsible implementing and maintaining an effective quality management system that meets the GDP standard. The person must be a registered pharmacist if the company deals in pharmacy-only medicines and POMs for local use and/or unregistered therapeutic products for patients' use.

For the import and wholesale of unregistered therapeutic products for patient's use, additional consignment approval from the HSA's Therapeutic Products Branch is required prior to import. However, if the import or wholesale of the unregistered therapeutic products are clinical research materials to be used only in clinical trials, neither an importer's licence nor a wholesaler's licence for therapeutic products will be necessary. The company will instead need to submit a Clinical Research Material (CRM) notification to the HSA's Innovation Office and Clinical Trials Branch beforehand. Separately, if a company holds a valid manufacturer's licence for therapeutic products, they will need neither an importer's licence nor a wholesaler's licence.

Medicinal Products

Imports and exports of medicinal products remain under the purview of the Medicines Act.

To import medicinal products into Singapore, a person must obtain either a product licence or an import licence. To export wholesale medicinal products, the person requires a product licence.

7. Which regulatory authority supervises the distribution of medicines? What are the consequences of non-compliance with the medicine distribution laws?

The HSA regulates health products in Singapore, including the distribution of medicines.

Non-compliance with the distribution laws in the Medicines Act may result in an offence and the accused may be liable for fines of up to SGS5,000, imprisonment of up to two years, or both.

Cross-Border Trade and Parallel Imports

8. What are the main requirements to import medicinal products into your jurisdiction? Are parallel imports of medicinal products into your jurisdiction allowed?

Import Requirements

To import medicinal products into Singapore, the importer must obtain an importer's licence.

An applicant for an import licence for medicinal products must be able to:

- Provide and maintain, or ensure the provision and maintenance of, staff, premises, equipment and facilities necessary for:
    - carrying out the stages of the manufacture of the therapeutic (medicinal) product; and
    - handling and storage of the therapeutic product, to prevent its deterioration while in the applicant's ownership, possession or control.
- Show that the therapeutic product is imported/intended for the purposes highlighted in section 5(1)(b) of the Health Products Regulations 2016.
- comply with the GDP for importers set out on the HAS's website.
- Make their application in the form and manner specified on the HSA's website.

(Health Products (Therapeutic Products) Regulations 2016.)

In addition, if the applicant intends to import a therapeutic product that is in all respects the same as a registered product, and the registrant of which has not authorised the applicant to import that registered therapeutic product, the applicant must obtain the HAS's approval for each consignment of the therapeutic product prior to import.

The following additional specific requirements apply when the therapeutic products contains psychotropic substances:

- The applicant must obtain the HSA's prior approval for each consignment of the therapeutic product.
- The amount of product must not exceed the approved quantity.
- An application for approval must be made in the form specified on the HSA's website.

The Singapore Accreditation Council has established several mutual recognition agreements with the following regional and international organisations:

- Asia Pacific Accreditation Cooperation for Testing, Calibration, Medical, Inspection, Proficiency Testing Providers, and Certification of Quality Management System, Environmental Management System, Energy Management System, Food Safety Management System and Product Certification.
- International Laboratory Accreditation Cooperation for Testing, Calibration and Inspection.
- International Accreditation Forum.

The objective of these agreements is to develop a global network of conformity assessment bodies in relation to, for example, certification, testing and calibration laboratories, and inspection. As a result, there is no need for duplicative re-testing, re-inspection or re-calibration of goods upon entry to importing countries.

Parallel Imports

Generally, parallel imports are allowed, provided that the importers of therapeutic or medicinal products hold the requisite product registrations/licences and/or import licences for the products imported.

Under Regulation 23 of the Health Products Regulation and section 12A of the Medicines Act, when the HSA is determining whether to approve a therapeutic product registration application or grant a product licence for a medicinal product, it considers:

- Whether a patent under the Patents Act 1994 is in force in respect of the product.
- If the applicant is the patent proprietor, or has obtained the patent proprietor's consent.
- If the patent is invalid, or will not be infringed by doing the act for which the licence is sought.

The patent proprietor (if not the applicant) can oppose the licence application, by applying for an order or declaration by a court or the Registrar of Patents.

In addition, importers of therapeutic and medicinal products (or any other person involved in the storage, transport, and distribution of such products) should comply with the HSA's Guidance Notes on Good Distribution Practice (GDP Guidelines), which seek to ensure the quality of the products during storage, transport and distribution. For example, the GDP Guidelines require storage conditions for products to comply with instructions on the label. On receipt, each incoming delivery should also be checked for tampering and damage. Further, the GDP Guidelines require a distribution system to be in place, to ensure that products due to expire first are sold and/or distributed first.

For information on pharmaceutical patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports, see *Question 24*.

Advertising

9. What is the main legislation and what are the regulatory authorities that control pharmaceutical advertising? Does the industry have a system of self-regulation based on industry codes of conduct? What are the main elements of that system?

The advertising of therapeutic products is mainly governed by Part V of the Health Products Act and the Therapeutic Products Advertisements Regulations. Under the Health Products Act, advertisements include:

- Publication in a newspaper, magazine, journal or other periodical.
- Display of posters or notices.
- Circulars, handbills, brochures, pamphlets, books or other documents.
- Letters addressed to individuals or business entities.
- Photographs or cinematograph films.
- Sound broadcasting, television, the internet or other media.
- Public demonstration of the use of the product.
- Offer of trials of the product to the public.

The Therapeutic Products Advertisement Guidance also sets out further guidance on the advertising control principles for therapeutic products.

The advertising of medicinal products (which include Chinese proprietary medicines, traditional medicines, homoeopathic medicines, quasi-medicinal products, and medicated oil and balms) is governed by Part VI of the Medicines Act, the Medicines (Advertisement and Sale) Act and their subsidiary legislation, particularly the Medicines (Medical Advertisements) Regulations (Medical Advertisements Regulations). The HSA's Medical Advertisements Guidelines sets out guidelines relating to the advertising of medicinal products to the general public.

These statutes and guidelines on advertising therapeutic and medicinal products are enforced by the HSA.

The SCAP is a guidance code promulgated by the ASAS, a self-regulatory body for the advertising industry under the Consumer Association of Singapore (CASE). The Medical Advertisements Guidelines require compliance with the SCAP.

The SAPI prescribes a Code of Marketing Practices and an OTC Medicine Code of Advertising and Promotion Practices as advertising guidelines for the pharmaceutical industry.

10. Is there a definition of advertising or advertisement in relation to pharmaceuticals? What kinds of activities, channels and communications meet those definitions (and are therefore subject to restrictions), and what falls outside (and is therefore permitted)?

The definition of advertisement in relation to pharmaceuticals can be found in the Health Products Act, all of which are subject to the same restrictions as those provided for under the Medical Advertisements Regulations (see *Question 9*).

Certain types of advertisements may be exempt from the regulations, such as:

- Reference advertisements or trade advertisements (see *Question 12*).
- A medical advertisement issued or published by a public authority or person authorised to issue a communication to the public, such as an advertisement by the Minster of Health. This would include, for example, public health programmes such as vaccination efforts since they are initiated by the MOH and other public authorities.

11. Do companies have to set up internal procedures for managing and approving their advertising of pharmaceuticals?

Advertising violations published by companies would fall within an "offence by a body corporate" (section 59, Health Products Act). It is not a legal requirement to have designated staff to manage and approve advertising, but it is recommended for pharmaceuticals companies to have both specific staff and mechanisms in place to ensure thorough checks and management in relation to its advertising are carried out, to prevent the company from being subject to such liabilities.

For details of sanctions for non-compliance with the rules on advertising pharmaceuticals, see *Question 16*.

12. Does pharmaceutical advertising have to be approved by a regulator?

Natural Health Products

A valid permit from HSA is required prior to the publication of any medical advertisement or sales promotion activities directed to the general public in relation to any of the following products:

- Chinese proprietary medicines.
- Traditional medicines.
- Homoeopathic medicines.
- Quasi-medicinal products, such as medicated soaps, medicated plasters, medicated beverages, medicated toothpastes, lozenges, and vitamin and mineral preparations.

- Medicated oils and balms.
- Medicinal products not subject to licensing requirements, such as topical antiseptics.

However, a permit is not required for the following types of advertisements and sales promotion activities:

- Medical advertisements or sales promotion activities directed exclusively to persons who lawfully sell or supply medicinal products in the course of their trade, business or profession (such as healthcare professionals) which are not accessible to the general public.
- Reference advertisements (containing a brief description of the product, its use, any contraindications and warnings appearing without charge) in a publication sent or delivered to practitioners or pharmacists by a person involved in the sale or dealings of the medicinal product (that is, not a manufacturer, supplier, retailer, importer or exporter).
- Trade advertisements (in a catalogue, price list or other document for the wholesale supply) that do not contain recommendations on the product's use indicating a therapeutic classification other than as part of the product's name, or as part of any heading or sub-heading.

Therapeutic Products

Prior approval from the HSA is not required for advertisements relating to therapeutic products. Advertisements of therapeutic products are governed by the Health Products Act and the Health Products (Advertisement of Therapeutic Products) Regulations 2016. The advertiser must therefore ensure compliance with these regulations, with the HSA undertaking a monitoring role to ensure due compliance.

Medical Devices

Advertisements and promotions of medical devices also do not require prior approval from the HSA.

13. Are there rules on comparative advertising that apply to pharmaceutical advertising?

Advertisements of pharmaceutical products made to the public must not compare or contrast the product with other named health products or related brands. However, it is permissible to make comparisons among products within the same brand by the same company to highlight differences.

Any comparative claims must not mislead the public in relation to product being advertised, or in relation to any product which it is compared with.

However, certain advertisements which are not directed at the general public can make comparative claims. These include:

- Advertisements distributed to relevant healthcare professionals.

- Advertisements distributed at pharmaceutical trade fairs, exhibitions and scientific conferences, or forums which are restricted in attendance to medical or scientific professionals, and which are not open to the general public.

14. Is it possible to share information about pharmaceuticals or indications that are unlicensed and is there a risk that this could be caught by advertising rules?

Advertisements of unregistered therapeutic products can only be presented to health care professionals in the following scenarios:

- In articles for medical or scientific journals, reviews or publications.
- When providing or exchanging scientific or medical information at a (private) scientific conference or forum, in accordance with its published programme or agenda.
- At a (private) pharmaceutical trade fair, pharmaceutical trade exhibition, scientific conference or scientific forum. The therapeutic product must, however, be approved, licensed or registered in at least one country outside of Singapore and the advertisement must contain a statement that the product is not registered in Singapore.

In addition, advertisements of unregistered therapeutic products can contain representations concerning their intended purpose or efficacy, which must be substantiated by objective scientific evidence.

15. Are there particular rules or issues with the use of the internet and social media for advertising pharmaceuticals?

In general, pharmaceutical advertisements can use any form or type of media. This includes e-advertisements on the internet and social media. However, these cannot:

- Be directed, or contain any material that is directed, principally at any person below the age of 14 years.
- Contain or give the impression of any endorsement or recommendation by:
    - health care professionals;
    - anyone who, because of their celebrity, social or professional status, would be likely to encourage the use of the specified health product.
- Use the HAS's names or logos or those of any of its professional groups or associations.

It is likely that the corporate websites of the product registrants and licensees will include factual information about their products (including information on POMs and the list of specified diseases and conditions). However, when presenting this information on a corporate website:

- The information must be non-promotional, consistent with its registration or supported by evidence.
- The information must not contain promotional elements for the purpose of inducing sales or use of the product.
- Discussion boards or forums relating to the product are not permitted.

16.What are the consequences of non-compliance with the rules on advertising pharmaceuticals? How are the rules enforced and by which authorities or organisations?

If the HSA finds that an advertiser has failed to comply with the rules concerning the advertising of pharmaceuticals, the HAS can order the advertiser to:

- Stop the advertisement with immediate effect.
- Take reasonable and necessary measures to remove advertisements already published.
- Publish a corrective advertisement in such a manner and/or containing information as specified by the HSA.

The advertiser in violation of the rules will also bear the costs and expenses from them taking any required measures stipulated by the HSA.

If the advertiser fails comply with an order from the HSA:

- The responsible person may be guilty of an offence and liable on conviction to fines of up to SGD20,000, imprisonment of up to 12 months, or both.
- The HSA will be authorised to take such steps as it thinks reasonable and necessary to implement the requirements of the order and can recover any costs and expenses reasonably incurred by it from the individual in so doing.

If the offence is committed by a corporation, enhanced penalties may apply: the court can impose fines of up to two times the amount imposed on individuals.

Third parties can report breaches of the advertising rules or can notify the HSA by emailing the *Medical Advertisements and Compliance Monitoring Unit*.

Advertising to the Public

17. Which pharmaceuticals can and cannot be advertised to the public? What information must and must not be included in advertising of pharmaceuticals to the public?

Therapeutic Products

Advertisements for therapeutic products do not require prior approval by the HAS but must comply with the principles and requirements of the Health Products Act and the Therapeutic Products Advertisements Regulations.

Generally, if a product is not a therapeutic product within the meaning of the Health Products Act, it cannot be advertised as a therapeutic product and cannot be presented as functioning as a therapeutic product. Advertisements of therapeutic products must be aligned with the intended uses (indications) registered with the HSA.

Advertisements of unregistered therapeutic products or unapproved uses of a registered therapeutic product (unregistered indications) are not allowed. False or misleading advertisements of therapeutic products are also prohibited.

Under the Therapeutic Products Advertisements Regulations, advertisements of therapeutic products must (without limitation):

- Substantiate all assertions of uniqueness and prominence with facts or objective evidence.
- Not discourage the reader from medical or professional advice.
- Not encourage inappropriate or excessive use.
- State the nature, quality and properties of the product truthfully.
- Not directly or indirectly cause fear, alarm or distress to consumers.
- Not abuse the trust or exploit the lack of knowledge of consumers.
- Not contain any claim or statement of guaranteed results, or that the product is free from side effects.
- Not offer to refund money to users.
- Not falsely indicate or suggest that the use of the product is promoted, supported, or endorsed by the government or any public authority.
- Not contain material directed exclusively or principally at children under the age of 14 years.
- Not include any recommendation by any health care professional, or any person with a celebrity, social or professional status that is likely to encourage the use of the product.
- Not compare or contrast the therapeutic product with other named products or their brands (if the advertisement is directed at the public).

Advertisements that directly or indirectly claim, indicate or suggest that a therapeutic product will prevent, alleviate or cure any of the 19 diseases or conditions set out in the Second Schedule to the Therapeutic Products Advertisements Regulations are prohibited.

Advertisements of POMs directed to the general public are prohibited. The prescribed advisories must be prominently displayed on direct-to-consumer advertisements of P-Medicines. The HSA can also, by notice or direction to individual product registrants at the time of registration, require specific advisories or warning statements for advertisements of specific P-Medicines.

Breach of any of the above advertising restrictions can be an offence, punishable by a fine up to SGD20,000 and/or imprisonment for a term up to 12 months.

Medicinal Products

An advertising permit from the HSA is necessary to issue any medical advertisement or conduct any sales promotion of a medicinal product (Regulation 3, Medical Advertisements Regulations) (see *Question 5, Medicinal products*).

Advertising or promoting medicinal products without a valid permit is an offence, punishable by a fine up to SGD5,000 and/or imprisonment up to 12 months.

Issuing (or causing another to issue) a false or misleading advertisement relating to a medicinal product is an offence (section 50, Medicines Act). It is also an offence to make a false or misleading representation relating to either:

- A medicinal product, in connection with the sale of that product.
- Medicinal products of a particular description to a person, to induce that person to purchase them from a retailer.

Advertisements that directly or indirectly claim, indicate or suggest that a medicinal product will prevent, alleviate or cure any of the 19 diseases or conditions specified in the First Schedule to the Medicines Act are also prohibited.

Section 3 of the Medical Advertisements Guidelines covers general and specific principles applicable to medical advertisements and sales promotions, which are largely similar to those in the Therapeutic Products Advertisements Regulations (see above, *Therapeutic products*).

18. Is it permitted to provide free samples to the public? Are there restrictions on special offers and other types of inducements?

Sales promotion activities directed to the public are prohibited from:

- Offering prizes through activities such as lucky draws, dips and contests as an inducement to purchase the therapeutic product.
- Offering medicinal or health products with a therapeutic product.
- Offering samples of the therapeutic product.

A person is also prohibited from distributing, giving, causing to be distributed or given, or assisting in the distribution/giving of free samples of a specified health product to the public or any section of the public.

However, a qualified medical practitioner, or person acting in accordance with the instructions of a qualified practitioner, can provide, or cause another to be provided with, a sample of a specified health product to a patient of that practitioner.

Engagement with Patient Organisations

19. What activities are permitted (or required) in relation to engagement with patient organisations? What restrictions apply?

Engagement with patient organisations requires contact with the respective organisations that form the patient groups (generally hospitals and specialised disease societies in Singapore). Engagement is generally carried out by the:

- **Agency for Care Effectiveness (ACE).** This is the national health technology assessment (HTA) agency in Singapore within the MOH. ACE reviews clinical and economic evidence to determine how well health technologies (such as drugs, vaccines and medical devices) work in relation to how much they cost. The information is then used by MOH to make funding recommendations for public hospitals.
- **Consumer Engagement and Education (CEE).** This was set up in 2021 to help patients, caregivers and the public become involved in ACE's work. Moving forward, the CEE will be inviting patient and volunteer organisations to provide input on ACE's HTA evaluations to ensure its recommendations are relevant to those affected by them.

The process of patient input would be a two-way conversation:

- After patients provide their input, they receive early feedback from ACE on the usefulness of their input along with suggestions for specific information to close gaps if necessary.
- After a decision on funding is made, ACE shares details with the patients on how their input was used in its deliberation and the types of input it found most useful. This is then shared with other organisations providing input in the future.

ACE will be appointing a Consumer Panel to help guide ACE towards meaningful patient involvement. The panel will consist of senior members of patient and volunteer organisations with lived experience of the Singapore health care system.

Advertising to Health Care Professionals and Organisations

20. What are the definitions of a health care professional and a health care organisation? What information must be included in advertising to them?

The term "health care professional" includes:

- Qualified practitioners.
- Registered pharmacists.
- Enrolled nurses, registered nurses and registered midwives.
- Persons undergoing training with a view to becoming qualified practitioners, registered pharmacists, enrolled nurses, registered nurses or registered midwives.

There is no specific definition of a healthcare organisation in relation to advertising. The applicable limitations or restrictions therefore relate to advertisements directed towards healthcare professionals/qualified practitioners.

Advertisements for POMs or advertisements referencing specified diseases and conditions can only be distributed to health care professionals. For details of the general principles, see *Question 17*.

Advertisements concerning unregistered therapeutic products made to health care professionals can contain representations concerning their intended purpose or efficacy, which must be substantiated by objective scientific evidence. For the rules concerning the advertising of unregistered therapeutic products to health care professionals and/or for trade, see *Question 14*.

Gifts and Incentives

21. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for health care establishments or individual medical practitioners?

The general principles of the following must be adhered to:

- The Health Products Act and the Medicines Act, and their subsidiary legislation, including the Health Products (Advertisement of Therapeutic Products) Regulations 2016 (Therapeutic Products Advertisements Regulations) and the Medicines (Medical Advertisements) Regulations.
- The HSA Explanatory Guidance to the Therapeutic Products Advertisements Regulations (Therapeutic Products Advertisement Guidance).
- The HSA Guide on Advertisements and Sales Promotion of Medicinal Products.

- The SMC Ethical Code and Ethical Guidelines (2016 edition), and the accompanying SMC Handbook on Medical Ethics.

Statutory offences under the Health Products Act and the Medicines Act and their subsidiary legislation include:

- The offer of a prize as an inducement to purchase a therapeutic product.
- Issuance of any false or misleading advertisements, and making false or misleading representations to practitioners, to induce them to prescribe or supply medicinal products.

Members of the SAPI must also comply with the SAPI Code of Marketing Practices.

The SMC and the SAPI strictly regulate the relationship between doctors and the pharmaceutical industry, particularly in relation to:

- Acceptance of gifts, promotional items and educational materials by doctors.
- Invitations from pharmaceutical companies for doctors to travel overseas to attend medical conferences and associated travel grants.

It is an offence for a person to corruptly solicit or receive, or agree to receive for themself or for another person (or corruptly give, promise or offer to a person, for the benefit of that person or another person), any gratification as an inducement to or reward for a person doing or not doing anything in respect of any matter or transaction, actual or proposed (Prevention of Corruption Act 1960). This also applies to acts of Singapore citizens outside Singapore.

Transparency and Disclosure

22. Do pharmaceutical companies have to disclose details of transfers of value to health care professionals or health care organisations?

[Consider: are there any actual or proposed US Sunshine Act style registration or mandatory reporting disclosure requirements? Is there a distinction between public and private providers? How can a person find out about transfers of value?]

There are no specific Singapore laws or regulations on transfers of value to health care professionals or health care organisations. However, the SMC has published advisory guidance on the payment of fees to third parties (for example, managed care companies, third-party administrators, insurance entities or patient referral services). The advisory guidance provides that:

- A patient referral to a doctor should be in the patient's best interests, based on the doctor's expertise and reputation and not because the doctor has paid for the referral.
- Any referral fees must reflect the fair work done by third party in handling and processing patients.

- Any referral fees payable to third parties must be communicated and transparent to the patient.

See *www.healthprofessionals.gov.sg/docs/librariesprovider2/guidelines/smc-advisory-on-the-payment-of-fees-to-third-parties-(13dec2016).pdf*.

Guideline H3(7) also prohibits doctors from paying fees to third parties if they:

- Are based primarily on the services the doctors provide or the fees doctors collect.
- Are so high as to constitute "fee splitting" or "fee sharing."
- Render doctors unable to provide the required standard of care.

Guideline H3(7) reflects the SMC's concerns that the payment of fees by doctors to third parties will lead to rising medical costs for patients and/or would compromise their medical treatment. Therefore, prior to entering into any arrangement that requires them to pay a fee to a third party, doctors should consider whether the arrangement would result in the profiteering of the third party at the expense of a patient or other person paying for the medical treatment.

Any fees paid to third parties by doctors must be disclosed if these fees are passed on to the patients or other person paying for the medical treatment.

23. What are the consequences of non-compliance with the rules on marketing to health care professionals?

Any person who advertises a health product to health care professionals in a manner that does not comply with the Health Products Act and its subsidiary legislation may be guilty of an offence and liable on conviction to fines of up to SGD20,000, imprisonment of up to months, or both. The HPA may also order the advertiser to take corrective measures in relation to advertisements already published.

Any person who advertises a medicinal product to health care professionals in a manner that does not comply with the Medicines Act and its subsidiary legislation may be guilty of an offence and liable on conviction to fines of up to SGD5,000, imprisonment of up to two years, or both.

Patents

Conditions for Patentability

24. Provide a brief definition of a patent, the key legal requirements to obtain it and the law that applies.

Conditions and Legislation

The patents regime in Singapore, including the registration, grant, revocation and infringement of patents, is governed by the Patents Act 1994 and its subsidiary legislation, including the Patents Rules.

To obtain a patent for an invention, the invention must:

- Be new.
- Involve an inventive step.
- Be capable of industrial application.

(Section 13, Patents Act.)

An invention is considered new when it does not form part of the state of the art (section 14(1), Patents Act). It involves an inventive step when it is not obvious to a person skilled in the art (section 15, Patents Act). It is capable of industrial application if it can be made or used in any kind of industry (section 16(1), Patents Act).

Generally, patent protection lasts for 20 years from the date of the filing of the patent (section 36(1), Patents Act), subject to payment of renewal fees annually. There are certain limited circumstances prescribed under section 36A of the Patents Act where a patent term may be extended.

Since patent protection is territorial in nature, if a patent is filed in Singapore only, protection is limited to Singapore.

Types of Patent Available

In Singapore, there are generally product and process patents.

Main Categories Excluded from Patent Protection

Certain types of inventions are not patentable in Singapore. For example:

- A method of treatment of the human or animal body by surgery, therapy or of diagnosis practised on the human or animal body, as it is not considered to be capable of industrial application (section 16(2), Patents Act).
- An invention, the publication or exploitation of which would be generally expected to encourage offensive, immoral or anti-social behaviour (section 13(2), Patents Act).

According to the Examination Guidelines for Patent Applications at the Intellectual Property Office of Singapore (IPOS), inventions relating to transgenic plants and transgenic non-human animals do not generally raise any ethical issues. This also appears to be the case even if the genome of such transgenic non-human animals contains human genes. Since creating such transgenic plants and non-human animals is not expressly prohibited by law, and given the scientific and medical benefits arising from such related research, section 13(2) of the Patents Act would not apply to such inventions. However, the position on germline genetic modification of non-human animals is less clear.

Generally, an invention relating to genetic manipulations that can cause public safety concerns or serious environmental hazards may attract objections under section 13(2) of the Patents Act, and may therefore not be patentable.

Specific Provisions for the Life Sciences Industry

Inventions relating to organisms, genetic sequences and biological material may be patentable provided they are not mere discoveries (which cannot be patented under section 13(1) of the Patents Act). According to the Examination Guidelines for Patent Applications at IPOS, an "isolated or purified material or micro-organism from nature" would represent a discovery. However, a specific use of the isolated or purified material or micro-organism may be considered an invention. If contributions have been made beyond isolating or purifying the material or micro-organism, such that the isolated or purified material or micro-organism can be adapted for a specific use, the modified material or micro-organism and the specific related uses can be considered inventions.

Known substances or compositions not been previously used for medical purposes may be claimed in the form of a first and/or second medical use (section 16(3) and section 14(10), Patents Act). A claim to the first medical use of a new or known substance or composition could broadly claim any therapeutic use, or be drafted in the form of a specific medical use claim.

Second or subsequent use of a substance or composition can only be claimed in the form of "Swiss-type" claim. Second medical use claims can only derive novelty from their intended use where the use is a method of treatment excluded under section 16(2) of the Patents Act. It should be noted that the IPOS' practice for using the Swiss-type claim format differs to the UK and Europe, which are contracting members of the European Patent Convention 2000.

Registering a Patent

25. Which authority registers patents? Briefly outline the key stages and timing in obtaining a patent.

Patent Registration Authority

An application for a patent must be made to the *Registry of Patents at IPOS*. The IPOS website provides guidance on the application procedure, prescribed forms and fees.

Process and Timing

A preliminary examination (where the application is checked for compliance with all formal requirements) is conducted on a patent application when it is filed (section 28, Patents Act). If all formal requirements have been complied with, the Registrar notifies the applicant (section 28(11), Patents Act).

The applicant can then file a request in the prescribed form for a search and/or examination report, within 36 months from the earliest declared priority date or the filing date (if no priority is claimed) (section 29, Patents Act together with Rule 43, Patents Rules).

Once the search and/or examination report has been issued, the Patent Registry will issue either a:

- **Notice of eligibility to proceed to the grant of a patent.** The applicant can file a request for grant of the patent with the necessary fees within two months from the date of issue of the notice (section 30, Patents Act read with Rule 47, Patents Rules). The Registrar will then grant the patent by issuing to the patent proprietor a certificate of grant and publishing a notice of grant in the journal (section 35, Patents Act).
- **Notice of intention to refuse the application, based on objections disclosed in the examination report.** The applicant can file a request for a review of the examination report within two months from the date of issue of the notice (section 29B, Patents Act read with Rule 46A, Patents Rules). An examination review report will then be issued. If there are still unresolved objections, the Registrar will issue a notice of refusal of the application. The application is deemed refused when two months have passed from the time the notice of refusal is forwarded to the applicant. If there are no remaining objections, a notice of eligibility is issued to require the applicant to file a request for grant (with payment of the grant fees) within two months from the date of the notice.

(Section 29A, Patents Act.)

To accelerate grants of patent applications in all technology fields, IPOS has launched the SG Patent Fast Track. Patent applications in all technology fields which are first filed in Singapore can use the SG Patent Fast Track, under which a patent may be granted in six months. Examples of technologies benefiting from it include those with a health care impact, such as digital health solutions, tracing applications, ventilators and diagnostics kits. The programme was expanded on 1 September 2020 to include related trade mark and registered design applications. The expanded programme, SG IP FAST pilot programme, will run until 30 April 2024.

Length of Patent Protection

26. When does patent protection start and how long does it last? Can monopoly rights be extended by other means?

Duration

Patent protection typically lasts for 20 years, beginning from the application filing date, subject to payment of annual renewal fees (section 36, Patents Act) from the end of the fourth year from the filing date until the patent expires (Rule 51, Patents Rules).

Extending Protection

The patent proprietor can apply to the Registrar of Patents to extend the patent term on any of the following grounds:

- There was an unreasonable delay by the Registrar of Patents in granting the patent.

- The patent was granted on the basis of prescribed documents relating to a corresponding patent application, there was an unreasonable delay in issuing the corresponding patent, and the patent office that granted the corresponding patent has extended the term of the corresponding patent because of that delay.
- The subject of the patent includes an active ingredient of a pharmaceutical product, and there has been an unreasonable curtailment of the opportunity to exploit the patent because of the need to obtain marketing approval for the first pharmaceutical product using that substance as an active ingredient, and the patent term has not been previously extended on this ground.

(Section 36A, Patents Act.)

Patent Infringement

27. What rights does a patent grant to its owner? On what grounds can a patent infringement action be brought? What are the main defences to a patent infringement action? How is a claim for patent infringement made and what remedies are available?

Rights Granted by a Patent

A patent confers the owner of the patent the right to prevent others from exploiting the invention without their consent during the term of the patent, subject to the payment of annual renewal fees.

Grounds for Patent Infringement

A patent is infringed when a person does any of the following acts in Singapore in relation to the invention, without the proprietor's consent:

- Makes, disposes of, offers to dispose of, uses or imports the invention product, or keeps it for disposal or otherwise.
- Uses the invention process or offers it for use in Singapore when they know, or it is obvious to a reasonable person in the circumstances, that such use without the proprietor's consent will infringe the patent.
- Disposes of, offers to dispose of, uses or imports any product obtained directly by means of the invention process, or keeps any such product for disposal or otherwise.

(Section 66(1), Patents Act.)

There are certain defences to infringement (section 66(2), Patents Act). The most relevant are when an act:

- Is done privately and for non-commercial purposes.
- 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 by a registered medical or dental practitioner, or consists of dealing with a medicine so prepared.
- Is done in relation to the subject-matter of the patent to support an application for marketing approval for a pharmaceutical product, provided anything used to support the application is not made, used or sold in Singapore, or exported outside Singapore.
- Consists of the import, disposal or offer to dispose of a patented pharmaceutical product for use by or on a specific patient in Singapore, if certain conditions are met.

Claim and Remedies

A patent proprietor can bring civil infringement proceedings in the Singapore High Court in relation to any act alleged to infringe its patent.

Various remedies are available, such as:

- An injunction (including an interim injunction).
- A court order for the infringer to deliver up or destroy infringing products.
- Damages or an account of profits (a court will not award both for the same infringing act (section 67(2), Patents Act)).
- A declaration that the patent is valid and was infringed by the infringing party.

(Section 67, Patents Act.)

Defences to a Patent Infringement Action

Research exemption. The following research exemptions are available as defences to a patent infringement action:

- Acts that done for experimental purposes relating to the subject matter of an invention would not constitute patent infringement (section 66(2)(b)).
- Bolar exemption. This is a legal exemption from infringement that can be used when a third party "infringer" can prove that the acts (which otherwise would have been infringing) were done for the purposes of meeting the marketing approval requirements for the pharmaceutical product. The primary purpose of the bolar exemption is to protect parties that would be infringing, so that they can conduct research and/or trials to prove that their generic version of the product is the bioequivalent of the patented drug, or when they may, in the course of obtaining marketing approval for the release of a drug in Singapore, inadvertently infringe a patent.

IP exhaustion. With the exception of certain provisions related to pharmaceutical products, the use, disposal or offer to dispose of or importation of any patent-protected product which was produced by or with the consent of the patent owner either in Singapore or abroad would not constitute patent infringement. Therefore, parallel importation into Singapore of patented products that were legally brought on the market in another country where the products are protected by a patent of the same owner is in principle allowed (section 66(2)(g) Patents Act).

Other exemptions. These include:

- Acts done privately and for non-commercial purposes (section 66(2)(a), Patents Act).
- Acts involving the extemporaneous preparation of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner, or when such a person deals with a medicine so prepared (section 66(2)(c), Patents Act).
- Acts that involve the use of a product or process in the body or operation of a relevant aircraft, hovercraft or vehicle which has temporarily or accidentally entered or is crossing Singapore (including the airspace above it and its territorial waters) or the use of accessories for such a relevant aircraft, hovercraft or vehicle (section 66(2)(d), Patents Act).
- Acts involving the use, exclusively for the needs of a relevant ship, of a product or process in the body of the ship or in its machinery, tackle, apparatus or other accessories, when the ship has temporarily or accidentally entered Singapore's territorial waters of (section 66(2)(e), Patents Act).
- Acts involving the use of an exempted aircraft that has lawfully entered or is lawfully crossing Singapore as mentioned in section 66(2)(d) of the Patents Act, or in relation to the importation into Singapore, or the use or storage, of any part or accessory for that aircraft (section 66(2)(f), Patents Act).

International IP Treaties

28. Is your jurisdiction party to international treaties that facilitate the recognition of foreign IPRs in your jurisdiction?

General

Singapore is party to the *WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*.

Patents

Singapore is party to the Patent Cooperation Treaty 1970 (PCT) and the Paris Convention for the Protection of Industrial Property 1883

Trade Marks

Singapore is party to the *WIPO Madrid Agreement Concerning the International Registration of Marks 1891*, the *Paris Convention for the Protection of Industrial Property 1883*.

Trade Marks

Legal Requirements to Obtain a Trade Mark

29. Provide a brief definition of a trade mark, the key legal requirements to obtain it, and the law that applies.

The registration, cancellation, revocation, invalidation and infringement of trade marks in Singapore are governed by the Trade Marks Act (Chapter 332) and its subsidiary legislation, including the Trade Marks Rules.

An owner of unregistered marks can rely on common law causes of action such as the tort of passing off to protect their mark against unauthorised use.

Alternatively, if the mark is well-known within the meaning of section 2(1) of the Trade Marks Act, the owner is entitled to restrain by injunction unauthorised use of the mark in Singapore, even if the mark has not been registered in Singapore (section 55(3), Trade Marks Act).

A trade mark is registered for a period of ten years from the date of registration. At the request of the proprietor, the mark can be renewed for further periods of ten years (section 18 read with section 19, Trade Marks Act).

Since trade mark protection is territorial in nature, if a trade mark is registered in Singapore only, protection is limited to Singapore.

General Conditions and Specific Rules for Naming Medicines

For a trade mark to be registered under the Trade Marks Act, the mark must be:

- A sign (as defined in section 2(1), Trade Marks Act).
- Capable of being represented graphically.
- Distinctive (capable of distinguishing goods or services dealt with or provided in the course of trade).

(Section 2(1), Trade Marks Act.)

Medicinal brands can generally be registered as trade marks, provided they meet the general legal requirements of registrability.

Certain signs cannot be registered as a trade mark (sections 7 and 8, Trade Marks Act). Examples include signs which:

- Do not satisfy the legal criteria (see above).
- Are contrary to public policy or morality.

As far as the authors are aware, there are no specific prohibitions in relation to the images, symbols or words used in pharmaceutical trade marks under the Trade Marks Act. That said, the Registry of Trade Marks will check whether the trade mark consists of a protected International Non-Proprietary Name, which are generic names for specific pharmaceutical substances.

Registering a Trade Mark

30. Which authority registers trade marks? Briefly outline the key stages and timing to obtain a registered trade mark.

Trade Mark Registration Authority

An application to register a trade mark is made by filing Form TM4 with IPOS. The *IPOS website* provides guidance on the application procedure, prescribed forms and fees.

Singapore applies the International Classification of Goods and Services, which divides goods and services into 45 classes. An application for trade mark registration must list the classes of goods or services for which the applicant seeks to register the trade mark (section 5, Trade Marks Act).

Process and Timing

The application is filed in the manner prescribed in section 5 of the Trade Marks Act, together with the prescribed fees.

If the applicant has filed an earlier claim for the same mark in another Paris Convention country or a World Trade Organisation member country, and wishes to claim priority for that mark, the application in Singapore must be filed within six months from the date of first filing (section 10, Trade Marks Act).

The IPOS checks the application for completeness and compliance with the minimum filing requirements, about 15 days after the filing of the application. If the minimum filing requirements are met, the application undergoes examination to ensure that the application satisfies the registration requirements (section 12, Trade Marks Act).

If the requirements for registration are not met, the IPOS will issue an examination report providing its grounds for refusal. The applicant is given four months (extendable on filing the requisite form and payment of fees) to respond to the examination report.

If the examination is successful, the IPOS accepts and publishes the application (section 13(1), Trade Marks Act).

Any interested party can oppose the registration of the trade mark within two months of publication (section 13(2), Trade Marks Act read with Rule 29(1), Trade Marks Rules).

If the mark is not opposed or if opposition proceedings are withdrawn or decided in favour of the applicant, the IPOS will register the trade mark and issue a registration certificate to the applicant (section 15, Trade Marks Act). Registration takes effect from the application filing date (section 15(2), Trade Marks Act).

Registration takes about four to six months if the examination is successful and registration is not opposed. If not, registration takes about six to 18 months.

Competition Law Issues

Competition Authorities and Legislation

31. Briefly outline the competition law framework in your jurisdiction and how it impacts on the pharmaceutical sector.

Competition Law and Main Provisions

Competition law issues that arise in the pharmaceutical sector are subject to the Competition Act 2004. The Competition Act prohibits, among other things:

- Agreements between undertakings, decisions by associations of undertakings or concerted practices which have as their object or effect the prevention, restriction or distortion of competition within Singapore (Section 34 Prohibition).
- Undertakings from abusing their dominant positions in any market in Singapore (Section 47 Prohibition).
- Mergers that have resulted, or may be expected to result, in a substantial lessening of competition within any market in Singapore for any goods or services (Section 54 Prohibition).

Competition Authority

The *Competition and Consumer Commission of Singapore (CCCS)* is responsible for enforcing the Competition Act.

If the CCCS has reasonable grounds to suspect the above prohibitions have been breached, it can conduct an investigation. During an investigation, the CCCS has the power, among others, to require production of relevant documents or information, interview individuals to obtain relevant information, take copies or extracts of documents, and enter premises (with or without a warrant).

If an undertaking is found to have infringed the Competition Act intentionally or negligently, the CCCS can:

- Impose a fine up to 10% of the undertaking's annual turnover in Singapore for each year of infringement, up to a maximum of three years.
- Issue directions to modify or cease behaviour, and/or require other necessary activity to end the infringement.

Criminal liability can arise if undertakings or individuals obstruct the CCCS in the performance of its duties or refuse to provide information requested pursuant to the CCCS's statutory powers.

If the CCCS has issued an infringement decision and the appeal process has been exhausted, any party who suffers loss or damage due to an infringement of any of the Section 34, 47 or 54 Prohibitions can bring a civil claim against the infringing undertaking for damages and compensation.

There have been no reported infringement decisions involving pharmaceutical/medical companies in relation to the Section 34 Prohibition or the Section 47 Prohibition.

The CCCS has cleared the following merger notifications involving pharmaceutical/medical companies:

- GSK Trading Services Limited's acquisition of distribution and marketing rights in Singapore from UCB Singapore Pte Limited (2009).
- Novartis AG's acquisition of shares in Alcon Inc (2010).
- Fresenius Medical Care Beteiligungsgesellschaft mbH and Fresenius Medical Care AG & Co KGaA's acquisition of Asia Renal Care Limited (2010).
- The proposed Acquisition by Johnson and Johnson of Synthes Inc (2012).
- Asia Renal Care (SEA) Pte Limited's acquisition of shares in Orthe Group (2012).
- Fresenius Medical Care Singapore Pte Limited's acquisition of shares in RenalTeam Pte Limited (2020).
- The proposed acquisition by Thermo Fisher Scientific Inc of PPD Inc (2021).

In March 2015, the then-CCS announced a provisional decision to block Parkway Holdings Ltd's proposed acquisition of RadLink-Asia Pte Limited, since it would infringe the Section 54 Prohibition. The merger was subsequently abandoned. According to the CCS, post-merger:

- Parkway would have become the only commercial supplier of radiopharmaceuticals in Singapore.
- In relation to providing radiology and imaging services, the merged entity would have had a very substantial market share, the merger companies were each other's closest competitors, entry barriers are moderate to high and the bargaining power of customers is weak.
- A substantial lessening of competition would have been likely due to vertical integration of the merger parties' operations. The merged entity would have been able to restrict competition in the market for radiology and imaging services by controlling supply, prices and/or a range of radiopharmaceuticals available to its downstream competitors.

In October 2019, the CCCS granted conditional approval for Pathology Asia Holdings Pte Limited to acquire Innovative Diagnostics Private Limited and Quest Laboratories Pte Limited after accepting various commitments from the parties. These included commitments to:

- Supply tests at fair, reasonable and non-discriminatory rates to certain customers .
- Remove exclusivity obligations in new and renewed agreements.
- Allow for early termination without cause.
- Not increase its prices.
- Maintain the same terms and conditions as those set out in its existing agreements with certain customers.

32. Has pharmaceutical competition case law in your jurisdiction focused on any key areas?

There have been no reported CCCS decisions on competition issues with the generic entry of pharmaceuticals into Singapore.

However, the CCCS has recognised potential anti-competitive effects of pay-for-delay arrangements and anti-competitive settlement agreements in its guidelines. It has also conducted public seminars, including with IPOS, discussing potential concerns when a patent holding company enters into settlement agreements, or otherwise pays generic drug manufacturing companies to delay market entry.

There have been no reported CCCS decisions relating to an abuse of dominance in the pharmaceutical sector.

There have been no reported CCCS decisions relating to the parallel import of pharmaceuticals into Singapore.

Generally, the importation of a pharmaceutical product is not allowed if the product has not been sold or distributed in Singapore by or with the consent of the patent proprietor. Once the patent proprietor has introduced the product into Singapore, the proprietor is in competition with parallel importers.

In particular, an import of a patented product produced by or with the patent proprietor's consent or any person licensed by them is not an infringement (section 66(2)(g), Patents Act). However, this does not apply if both:

- The product has not previously been sold or distributed in Singapore by or with the consent of the patent proprietor or any person licensed by them.
- The import will result in the product being distributed in breach of a contract between the patent proprietor and a person licensed by the patent proprietor to distribute the product outside Singapore, and the importer has actual or constructive knowledge of the breach.

Importing 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, will not be an infringement if certain conditions are met (section 66(2)(i), Patents Act).

Commercial Contracts and Competition Law

33. Briefly outline the competition issues that can arise in relation to commercial contracts and other business arrangements relating to medicinal products.

The CCCS Guidelines on the Treatment of Intellectual Property Rights in Competition Cases (IP Guidelines) provide some guidance on competitive issues that can arise in relation to the licensing of technology and patents in a pharmaceutical context:

- **Grantbacks.** The licensee agrees to assign to the licensor rights to any improvements it may make to the licensed technology. This may have pro-competitive effects, for example, if it increases the licensor's incentive to license or

promote dissemination of the improvements. However, anti-competitive concerns may arise if it significantly reduces the licensee's incentive to conduct research and development (R&D) and thereby restrict innovation.

- **Technology pools.** At least two parties create a pool of technology which they cross-license as a package to each other and third parties. This is generally pro-competitive if the technologies in the pool are essential and complementary to each other. However, if the pool is largely made up of technologies that are solely or mainly substitutable with each other, the pooling may be an anti-competitive agreement in breach of the Section 34 Prohibition. In assessing if anti-competitive effects arise, the CCCS will consider the risk of foreclosing alternative technologies that are not in the pool. Furthermore, competition concerns may also arise if pool members discriminate against non-member licensees, restrict the independent licensing of the patents, or use the pool to share confidential business information so as to reduce competition in a downstream market.
- **Non-challenge clauses.** The licensee agrees not to challenge the validity of the licensor's IP right. This includes clauses stipulating the licensor's right to terminate a licensing agreement if the licensee were to challenge the validity of any IP right of the licensor. These types of clauses may be anti-competitive, but the CCCS will consider various factors such as:
    - whether the clause operates as part of an exclusive licensing agreement;
    - the respective market positions of the licensor and the licensee.
- **Refusal to supply a licence.** An IP right owner can generally decide who to license its technology to. However, in certain circumstances a refusal to license by a dominant licensor may give rise to anti-competitive effects in breach of the Section 47 Prohibition, for instance if it refuses to license access to technology that is an essential facility. A facility may be seen as essential if there are no potential substitutes (through duplication or otherwise) and it is indispensable to the exercise of the activity in question.
- **Tying.** If a dominant licensor, as a condition of granting a licence, requires licensees to buy additional products unrelated to the technology being licensed, this may result in anti-competitive effects in breach of the Section 47 Prohibition. It is open to the dominant licensor to objectively justify its conduct by showing, for example, that buying the additional products is necessary for the satisfactory exploitation of the licensed technology.
- **R&D.** Licensing agreements which, directly or indirectly, restrict the ability or incentive of any of the parties to carry out independent R&D, including independent R&D with third parties, may have anti-competitive effects. In determining whether such agreements are likely to be in breach of the Section 34 Prohibition, the CCCS will consider whether the restriction is indispensable to prevent the disclosure of licensed know-how to third parties. To be covered by the exception, the restrictions imposed to protect the licensor's know-how against disclosure must be necessary and proportionate to ensure such protection. For instance, where the agreement designates particular employees of the licensee to be trained in and responsible for the use of the licensed know-how, it may be sufficient to oblige the licensee not to allow those employees to be involved in R&D with third parties. Licensing Approvals and Formalities

34. Does a patent or trade mark licence and payment of royalties under it to a foreign licensor have to be approved by a government or regulatory body? Are there any formalities or other requirements to make the licence enforceable?

As far as the authors are aware, the Patents Act or the Patents Rules do not expressly impose any restrictions on the licensing or transferring of patents to foreign parties.

According to the WIPO report on IP Management by the Government of Singapore dated 19 September 2018, the management, ownership and commercialisation of IP arising from R&D by the government depends on the internal policies and terms and conditions of collaborative projects, which typically include provisions on apportioning IP rights.

There is an indication that government agencies may not prefer to hold the IP rights, and instead allow funded private entities to commercialise the patented product if they are better placed to do so.

Depending on the terms and conditions of the project, private or collaborating entities can retain the use of IP rights, while the government agency obtains a non-exclusive perpetual irrevocable and worldwide licence and right to use the IP rights for non-commercial purposes. Restrictions on IP transfer therefore depend on the agreement between the private entity and the government agency.

There are no express provisions requiring patent or trade mark licences and payment of royalties under them to a foreign licensor to be approved or accepted by IPOS.

However, it is advisable for any transaction affecting the rights in a patent or registered trade mark (including a licence and assignment) to be registered as soon as possible after its execution.

An entry of a transaction, instrument or event on the register is prima facie evidence of it if there is a dispute about who owns the rights to the patent or trade mark:

- For patents, registration allows a person who acquires rights under the registered transaction to be entitled against a person claiming rights under an earlier transaction, provided that at the time of the later transaction, the earlier transaction was not registered, and the person claiming under the later transaction did not know of the earlier transaction (section 43, Patents Act).
- For trade marks, a similar rule applies to certain transactions (for example, an assignment of a registered trade mark) but not to a grant of a licence (sections 39(3) and 39(5), Trade Marks Act).

(Section 101, Trade Marks Act; section 45, Patents Act.)

An entry of a transaction, instrument or event in the register also affects the right of the proprietor or licensee to claim certain infringement remedies:

- For patents, a patent proprietor or licensee will not be awarded damages or an account of profits in a patent infringement action occurring before a registrable transaction is registered, unless the transaction is registered within six months of its occurrence (or the court or IPOS Registrar is satisfied that it was not practicable to register the transaction in this period and it was registered as soon as practicable thereafter) (section 75, Patents Act).
- For trade marks, there is a similar restriction on claiming damages, an account of profits or statutory damages for infringement occurring before registration of certain transactions (for example, an assignment), but this does not apply to a grant of a licence (sections 39(4) and 39(5), Trade Marks Act).

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, see *Country Q&A: Life Sciences Regulation in Singapore*.

Product Liability

Regulators

35. Outline the key regulators and their powers in relation to medicinal product safety.

The main regulator of medicinal product liability is the HSA.

The key provisions on medicinal product liability for therapeutic products are in the Health Products Act. However, the Medicines Act continues to regulate other medicinal products, including Chinese proprietary medicines.

The HSA administers the legal requirements for medicinal products. The HSA also constantly monitors the product market to ensure the safety, efficacy and quality of the import, distribution and use of medicinal products.

Specifically, the HSA's Health Products Regulation Group (HPRG) is responsible for ensuring that drugs, innovative therapeutics, medical devices and health-related products in Singapore are properly regulated to meet appropriate standards of safety, quality and efficacy. The HPRG consists of the:

- Pre-Market Cluster (Therapeutic Products, Medical Devices, Complementary Health Products, Clinical Trials and Advanced Therapy Products branches).
- Post-Market Cluster (Vigilance and Compliance, Enforcement, Tobacco Regulation, Audit and Licensing and Certification branches).
- Group Director's Office and Stakeholder Engagement Office.

The HSA has wide-ranging powers to enforce these regulations. Most significantly, the HSA can order a recall of a particular batch of a product, or recall a product entirely from the market, if it is defective or non-compliant. A recall can be a permanent removal of a product from the market, or a temporary removal for product correction.

The HSA also has power to enter premises and to inspect, take samples of, and seize non-compliant therapeutic or medicinal products (such as products manufactured, imported or supplied without a valid licence, and illegal products). This can include taking samples of a therapeutic or medicinal product, or any substance or article used or intended to be used in its manufacture, for testing, examination or analysis. A court can order forfeiture of any goods seized by the HSA.

Under the Health Products Act, obstructing, hindering or impeding the HSA in performing or executing its duties under the Health Products Act is an offence. It is punishable on conviction by a fine of up to SGD20,000 and/or imprisonment for a term of up to 12 months.

Under the Medicines Act, wilful obstruction of the HSA, or any failure to render assistance or information it may reasonably require, is an offence, punishable by a fine up to SGD2,000.

A person who knowingly gives any false information or statements to the HSA commits an offence, and can be liable to a fine up to SGD5,000 and/or imprisonment for up to two years.

Singapore Customs and the Singapore Police Force can seize and detain therapeutic or medicinal products imported contrary to a prohibition or restriction under the Health Products Act or the Medicines Act. A court can order the forfeiture of seized therapeutic or medicinal products if it is satisfied that the goods are the subject matter of or were used in committing an offence under the Health Products Act or the Medicines Act. The HSA can then dispose of the forfeited goods in such manner as it thinks fit.

Medicinal Product Liability Law

36. Outline the key areas of law applicable to medicinal product liability, including key legislation and recent case law.

Legal Provisions

Medicinal product liability can arise under an action in tort, contract and/or breach of relevant statutory provisions.

An action in tort can arise where the manufacturer, importer and/or distributor has breached its duty of care, such as its duty to ensure adequate quality control measures for medicinal products, or to exercise reasonable care in the marketing and advertisement of products.

An action for a breach of contract can arise from a breach of express or implied contractual terms, most commonly of an implied term that goods supplied are of satisfactory quality (section 14, Sale of Goods Act 1979).

Criminal liability can also arise under the Health Products Act. For example, a person who sells therapeutic products that can only be dispensed on prescription, without a prescription given by an appropriate practitioner, commits an offence (section 17, Health Products Act, together with Regulations 11 and 12, Health Products (Therapeutic Products) Regulations). The issue of a false or misleading advertisement relating to therapeutic products is also an offence (section 20, Health Products Act).

Substantive Test

To establish the tort of negligence, it must be shown that:

- There was a duty of care owed by the person committing the tort to the consumer.
- The person committing the tort did not meet a reasonable standard of care, as determined by the court.
- The injury to the consumer is causally linked to the person committing the tort's act and the injury was reasonably foreseeable, as determined by the court.

To establish a breach of contract, certain elements must be proved, such as the existence of a contract and a breach of its terms.

Liability for statutory offences differs, depending on the conditions in the relevant statute.

Parties may settle disputes privately through mediation or bring a claim in court.

Liable Parties

37. Who is potentially liable for defective medicinal products?

All parties involved in a chain of distribution of a defective therapeutic or medicinal product (that is, the product registrant/ licence holder, manufacturer, importer and supplier) are responsible for the safety, quality and efficacy of their product. They can therefore be potentially liable for defects in the product.

In addition, officers of such companies can also be personally liable if they authorised, directed, or procured the commission of the tort.

A Singapore Court of Appeal case illustrates how an importer and a sole distributor were both found negligent (for trading in defective slimming pills). The director and principal shareholder of the importer was also found liable for his involvement in procuring, directing and authorising his company's negligence (*TV Media Pte Ltd v De Cruz Andrea Heidi and another [2004] 3 SLR(R) 543*).

In relation to therapeutic products, where the presentation requirements in Part 4 of the Health Products Regulations have been breached by a manufacturer, importer, supplier or registrant of a therapeutic product, the HSA can order them to initiate a product recall.

Similarly, product licence holders of medicinal products are generally responsible for ensuring that the statutory packaging and labelling requirements are complied with. In the event of a medicinal product labelling error, the HSA can initiate a product recall.

In such a case, the manufacturer, importer, supplier or registrant of a therapeutic product (as the case may be) may also have committed an offence under the Sale of Drugs Act 1914. This prohibits the sale of any drug in any package that contains any false or misleading statement, word, brand, label or mark purporting to indicate the nature, quality, strength, purity, composition, weight, origin, age or proportion of the article contained in the package or of any ingredient. This offence carries a penalty on conviction of up to SGD1,000 for first-time offenders and up to SGD4,000 for subsequent offenders. If an offence is committed by the personal act, default or culpable negligence of the offender, the offender can be liable for a fine up to SGD4,000 or up to three months of imprisonment, even if it is the first offence.

Similarly, any person making an advertisement that consists of or includes unauthorised recommendations (such as off-label use) in relation to a registered medicinal product can also be liable to an offence under the Medicines Act. The penalty is a fine of up to SGD5,000 and/or imprisonment of a term of up to two years.

While there is currently no specific legislation in Singapore that prohibits the off-label use of therapeutic or medicinal products, medical practitioners (doctors) are generally required, under the SMC's Ethical Code and Ethical Guidelines, to treat their

patients according to generally accepted methods and use only licensed drugs for appropriate indications (that is, generally, no treatment of patients using off-label indications). A medical practitioner who fails to comply with these guidelines can be subject to disciplinary proceedings.

Businesses manage the risk of product liability by having insurance coverage and negotiating necessary indemnity clauses.

Defences

38. What defences are available to product liability claims? Is it possible to limit liability for defective medicinal products?

Possible defences include:

- The elements of the tort of negligence are not made out (for example, that the duty of care was not owed, or the standard of care was not breached).
- Contributory negligence or voluntary assumption of risk.
- For breach of contract cases, certain vitiating factors such as frustration, mistake, misrepresentation, illegality and unfairness.
- Statutory defences for offences under the Medicines Act and the Health Products Act.

Product Liability Claims

39. How can a product liability claim be brought?

Limitation Periods

The limitation period for bringing a product liability claim in contract or tort is six years from the date on which the cause of action accrued (section 6, Limitation Act 1959).

Class Actions

Class action suits can be brought under Order 15, Rule 12 of the Rules of Court. This is a form of group litigation where proceedings are brought by or against one or more of a group of numerous persons with the same interest in the proceedings. However, class action suits are generally uncommon in Singapore. To the best of the authors' knowledge, the authors have not come across a class action suit for product liability claims in Singapore for medicinal products.

Remedies

40. What remedies are available to the claimant? Are punitive or exemplary damages allowed for product liability claims?

A claimant can obtain damages and/or an injunction for a successful negligence claim.

In a claim for breach of contract, the claimant can be awarded damages or specific performance, and may be entitled to terminate the contract in certain circumstances.

The authors have not come across a case involving a product liability claim where punitive damages have been awarded.

The Singapore High Court has not decided whether it is possible for aggravated damages to be awarded for negligence in general. The closest it came to deciding this issue was a case concerning professional negligence of an anaesthetist (not product liability) (*Tan Harry and another v Teo Chee Yeow Aloysius and another [2004] 1 SLR(R) 513*). It was suggested that aggravated damages could be awarded if there was exceptional or contumelious conduct or motive by the wrongdoer. However, the court did not decide this issue conclusively. In *AYW v AYX [2015] SGHC 312*, the High Court also declined to determine whether aggravated damages could be awarded for negligence.

Where negligence is found, the Singapore courts have in general awarded two types of compensatory damages:

- General damages for:
    - pain and suffering, loss of amenities, and loss of expectation of life; and
    - post-trial monetary loss such as future earnings.
- Special damages for pre-trial pecuniary loss, including:
    - out-of-pocket expenses such as medical, nursing and supportive care, transportation and household expenses, loss of or damage to property, and reimbursement of third-party expenses; and
    - pre-trial loss of earnings or profits.

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