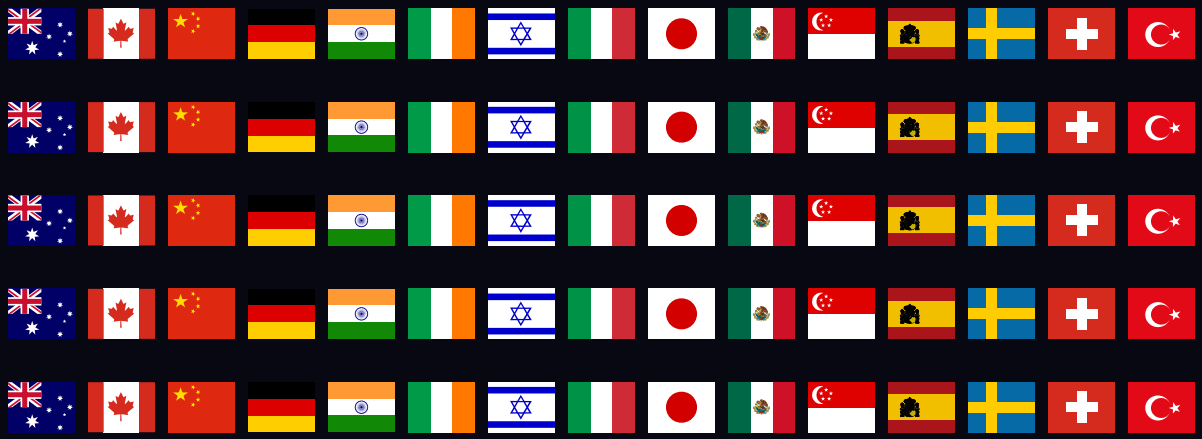
LIFE SCIENCES

Singapore



LEXOLOGY
Getting The Deal Through

Life Sciences

Quick reference guide enabling side-by-side comparison of local insights, including into organisation and financing; authorisation of providers; advertising; data protection, privacy and digitisation; collaboration with healthcare professionals and patient organisations; competition law; pricing and reimbursement; and recent trends.

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UPDATE AND TRENDS

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Singapore

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ORGANISATION AND FINANCING OF HEALTHCARE

Organisation

How is healthcare in your jurisdiction organised?

The Ministry of Health (MOH) oversees the regulation of healthcare in Singapore. There are various statutory boards established under the oversight of the MOH, including the Health Sciences Authority (HSA) (established by the Health Sciences Authority Act 2001) and the Health Promotion Board (established by the Health Promotion Board Act 2001).

The HSA was formed on 1 April 2001 and integrated five highly specialised agencies, namely the Centre for Drug Evaluation, Institute of Science and Forensic Medicine, National Pharmaceutical Administration, Product Regulation Department and Singapore Blood Transfusion Service. The HSA has been designated as the authority responsible for the administration of Singapore's health laws and regulations such as the Health Products Act 2007 , Medicines Act 1975 , Tobacco (Control of Advertisements and Sale) Act 1993 and Poisons Act 1938 .

Singapore promulgated the Health Products Act in 2007 with the intention that the Health Products Act (and all subsidiary legislation promulgated thereunder) would consolidate legislation regulating all health products (including medicinal products). Prior to 1 November 2016, the Health Products Act only regulated medical devices and cosmetics. The Medicines Act and other related legislation regulated the manufacturing, sale and distribution of medicinal products. There is also specific legislation regulating the use of radiation-emitting devices, contact lens substances and condoms. However, as part of the HSA's ongoing initiative to update and streamline the existing regulatory controls for health products and bring them under a single piece of legislation, namely the Health Products Act, so as to ensure that the controls remain relevant and adequate to different operational and business models, with effect from 1 November 2016, pharmaceutical products, conventionally termed as chemical and biologic drugs, have been introduced as a new category of health products in the First Schedule of the Health Products Act using the term 'therapeutic products'. Therefore, controls under the Medicines Act and the Poisons Act no longer apply to pharmaceutical products.

Medical practitioners in Singapore must be registered under the Medical Registration Act 1997 (MRA). The Singapore Medical Council (SMC), constituted under the MRA, governs all registered medical practitioners. In September 2016, the SMC issued the 2016 edition of the Ethical Code and Ethical Guidelines (SMC Ethical Code) together with the 2016 Handbook on Medical Ethics, which contains additional materials on the SMC Ethical Code and explains their applications and provides advice on best practices. The SMC Ethical Code came into effect on 1 January 2017 (except Guideline H3(7), which came into force on 1 July 2017). All registered medical practitioners are required to adhere to the SMC Ethical Code.

Singapore also established the Allied Health Professions Act 2011 (AHPA), which came into effect on 8 April 2013. The AHPA regulates the allied health professionals listed under Schedule 2 of the AHPA (such as occupational therapists, physiotherapists, speech therapists and radiographers). The Allied Health Professions Council, which is constituted under the AHPA, is the body that regulates all allied health professionals covered under the AHPA.

Further, private hospitals and medical clinics were previously regulated under the Private Hospitals and Medical Clinics Act 1980 (PHMCA). However, the PHMCA will gradually be replaced by the Healthcare Services Act 2020 (HCSA). The HCSA adopts a services-based regulatory framework rather than the current premises-based regulatory framework. The HCSA's regulatory scope is broader than that of the PHMCA, and includes healthcare services, nursing and allied health services, traditional medicine, and complementary and alternative medicine. Phased implementation of the HCSA has commenced. Phase 1 of the implementation, which encompasses clinical support services (with the exception of human tissue banking service, nuclear medicine services and preventive health service), commenced on 3 January 2022. Phases 2 and 3 of the implementation, which encompass inpatient, outpatient and the remaining clinical support services, will commence in June 2023 and the end of 2023 respectively. The MOH has also announced proposed amendments to the HCSA which will make the following licensable: specified services and non-premises-

based modes of service delivery (eg, virtual medical consultations, home medical care). These amendments are expected to be effective in June 2023.

Law stated - 30 October 2022

Financing

How is the healthcare system financed in the outpatient and inpatient sectors?

Singapore adopts a mixed financing system that provides multiple tiers of financing for its citizens' healthcare expenditure.

There are four main tiers of healthcare financing.

The first tier consists of subsidies from the government, which provides a subsidy of up to 80 per cent of the total bill in acute public hospital wards to all Singaporeans.

The second tier is the MediSave scheme. It is a compulsory individual medical savings scheme where all working Singaporeans and their employers contribute a part of the employee's monthly wages into the account to save for the employee's future medical needs.

The third tier, MediShield Life (which replaced MediShield from 1 November 2015), is a basic, low-cost catastrophic medical insurance scheme that allows Singaporeans to effectively pool the financial risks of major illnesses. MediShield Life is administered by the Central Provident Fund Board. Singaporeans may also supplement their basic MediShield Life coverage by applying for a MediSave-approved Integrated Shield Plan directly from one of the private insurers under the Private Medical Insurance Scheme. The Integrated Shield Plans are made up of two components – MediShield Life and additional private insurance coverage providing additional benefits and coverage (eg, to cover the cost of private hospitals or Class A/B1 wards in the public hospitals).

The fourth tier, MediFund, is a medical endowment fund set up by the government to further assist needy Singaporean patients who cannot afford to pay their medical bills despite utilising the first three tiers.

In addition, ElderShield is a severe disability insurance scheme administered by private insurers that aims to provide basic financial protection to Singaporeans who need long-term care, especially in old age, and is designed to help supplement Singaporeans' savings in the event of severe disability. An enhanced severe disability scheme, CareShield Life, which offers higher initial cash payouts, has been launched, with Singapore Citizens or Permanent Residents born in 1980 or later being automatically covered on 1 October 2020 or when they turn 30 (whichever is later). The government has also taken over the administration of ElderShield from the end of 2021.

Separately, the government also administers other subsidy schemes, such as the Community Health Assist Scheme (CHAS) (formerly known as the Primary Care Partnership Scheme), Interim Disability Assistance Programme for the Elderly (IDAPE) and the Medication Assistance Fund.

Under the CHAS, general practitioners and dental clinics that have agreed to partner with the MOH will provide common outpatient medical treatment and basic dental services to needy elderly or disabled patients at subsidised charges. The CHAS covers 23 chronic diseases and medical conditions, namely, diabetes mellitus, hypertension (high blood pressure), lipid disorders (eg, high cholesterol), stroke, asthma, chronic obstructive pulmonary disease, schizophrenia, major depression, dementia, bipolar disorder, osteoarthritis, benign prostate hyperplasia (enlargement of prostate gland), anxiety, Parkinson's disease and nephritis/nephrosis (chronic kidney disease), epilepsy, osteoporosis, psoriasis, ischaemic heart disease, psoriasis, gout and chronic hepatitis B, and rheumatoid arthritis. To better protect Singaporeans from vaccine-preventable diseases and to reduce the risk of outbreaks in the community, the MOH has announced enhanced subsidies for vaccinations recommended under the National Childhood Immunisation Schedule and National Adult Immunisation Schedule at all polyclinics and CHAS general practitioners from 1 November 2020. All Singapore citizens are eligible to receive subsidies under the CHAS, although enrolment is on an application basis, and

subsidies are tiered according to household monthly income per person or, for households with no income, the Annual Value of the home.

In addition, the IDAPE scheme, launched in 2002, provides financial help to elderly Singapore citizens who become disabled but who are not eligible for ElderShield due to exceeding the maximum entry age or having pre-existing disabilities.

ElderFund, officially launched at the end of January 2020, is a new discretionary assistance scheme aimed to assist severely disabled lower-income Singaporeans aged 30 and above, who are not able to benefit from CareShield Life, ElderShield and IDAPE, and have low MediSave balances and personal savings that are insufficient to meet their care needs in the long run.

Law stated - 30 October 2022

Basic structures

What are the basic structures of the provision of care to patients in statutory and private care?

Under Singapore's hybrid delivery healthcare model, healthcare providers in both the public and private sectors offer primary healthcare services, acute hospital services and step-down care services. Private sector providers account for around 80 per cent of the market in the primary care sector, while public sector providers account for around 80 per cent of the market in the acute care sector. Voluntary welfare organisations, which are mostly funded by the government for services provided, account for a majority of the market in the step-down care sector.

Law stated - 30 October 2022

HEALTHCARE SERVICES

Authorisation

What steps are necessary to authorise the provision of health services, and what law governs this?

Currently, physical premises that are used as a private hospital, medical clinic, clinical laboratory or healthcare establishment are subject to licensing controls under the Private Hospitals and Medical Clinics Act (PHMCA). That said, licensing under the PHMCA is transitioning to the Healthcare Services Act 2020 (HCSA), which will instead adopt a services-based regulatory framework and be implemented in phases. Under the HCSA, the healthcare services to be licensed fall within six broad categories: clinical support services, special services, non-premises-based services, ambulatory care services, hospital services and long-term care services.

Phased implementation of the HCSA has commenced. Phase 1 of the implementation, which encompasses clinical support services (with the exception of human tissue banking service, nuclear medicine services and preventive health service), commenced on 3 January 2022. Phases 2 and 3 of the implementation, which encompass inpatient, outpatient and the remaining clinical support services, will commence in June 2023 and the end of 2023 respectively. The Ministry of Health (MOH) has also announced proposed amendments to the HCSA that will introduce specified services and non-premises-based modes of service delivery (eg, virtual medical consultations, home medical care) for various licensable healthcare services. These amendments are expected to be effective in June 2023.

During the transition period, PHMCA licensees must continue abiding by the prevailing regulations under the PHMCA, and HCSA licensees must abide by the general HCSA requirements and respective service regulations. Service providers who hold both PHMCA and HCSA licences will need to abide by the requirements from each statute that pertains to the services provided.

An application for an HCSA licence together with the requisite licence fee must be made to the MOH through the new Healthcare Application & Licensing Portal (HALP) no later than two months before the intended practice commencement date. When all licensing requirements are met, the MOH will issue an e-licence on HALP.

Licences must be renewed no later than two months before their current licence expires.

Law stated - 30 October 2022

Structure

Which types of legal entities can offer healthcare services?

PHMCA licensees may be companies, sole proprietors or charitable organisations.

HCSA licensees may be the corporate entity itself (including companies and sole proprietors) or natural persons (eg, the CEO of a licensable healthcare service).

Law stated - 30 October 2022

Services of foreign companies

What further steps are necessary for foreign companies to offer health services?

Typically, foreign companies offering healthcare services in Singapore will incorporate a Singapore entity, which will apply for the requisite PHMCA licence.

From 3 January 2022, foreign companies intending to offer healthcare services will have to apply for an HCSA licence.

Law stated - 30 October 2022

ADVERTISING

Legislation

Which legislation governs advertising of medicinal products to healthcare professionals?

As of 1 November 2016, the advertising of medicinal products and therapeutic products is governed by the Medicines Act and the Health Products Act and their subsidiary legislation, including the Medicines (Medical Advertisements) Regulations and the Health Products (Advertisement of Therapeutic Products) Regulations 2016 . Since section 76(1) of the Medicines Act has come into operation, the Medicines (Advertisement and Sale) Act and the Sale of Drugs Act have been repealed, and any subsidiary legislation made under those Acts revoked. This does not affect the regulatory requirements of advertisement control for other product groups that continue to remain under the Medicines Act, for example, complementary health products, which include Chinese proprietary medicines, traditional medicines, homoeopathic medicines and quasi-medicines (vitamin and mineral preparation, medicated plasters, etc). The Singapore Association of Pharmaceutical Industries' (SAPI) Code of Conduct 2022 (SAPI Code of Conduct) further prescribes standards of advertising or promotion that should be adhered to. The Singapore Manufacturing Federation's Medical Technology Industry Group's (MTIG) Code of Ethical Conduct for Interactions with Healthcare Professionals (MTIG Code) in turn sets out principles for ethical collaboration between organisations that develop, manufacture, sell, market or distribute medical technologies (ie, products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities) in Singapore. The Advertising Standards Authority of Singapore's Singapore Code of Advertising Practice provides guidelines for ethical advertising through industry self-regulation, and includes advertising guidelines related to medicinal and related products and advertisements containing health claims.

Law stated - 30 October 2022

Main principles

What are the main rules and principles applying to advertising of medicinal products aimed at healthcare professionals?

In Singapore, advertising of medicinal products directed at healthcare professionals must generally abide by the same rules and principles as those directed at the general public.

That said, medical advertisements, sales promotions and representations directed exclusively to a person in his or her business premises who may lawfully sell or supply any medicinal product in the course of his or her trade, business or profession (eg, healthcare professionals) are exempted from the requirement to obtain an advertising permit.

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

Reference advertisements are advertisements containing a brief description of a medicinal product, its use, any contraindications and warnings relating thereto or of any device, instrument, apparatus or contrivance used or represented to be used for a medicinal purpose appearing without charge in a publication consisting mainly of such advertisements, and where the publication is sent or delivered to practitioners and pharmacists by a person not commercially interested in the product.

Trade advertisements are advertisements relating to a medicinal product or any device, instrument, apparatus or contrivance used or represented to be used for a medicinal purpose that is issued by means of a catalogue, price list or other document for the purpose of a sale by way of wholesale dealing, but that does not contain any recommendation relating to the use of the same other than as part of the name of the medicinal product or device, or as part of any heading or sub-heading indicating a therapeutic classification.

Advertisements made to healthcare professionals must not be false or misleading. Section 50 of the Medicines Act states that an advertisement may be false or misleading if it is made to a practitioner for the purpose of inducing him or her to prescribe or supply medicinal products of that description. A person who makes a false or misleading advertisement is guilty of an offence and may be liable to a fine of up to S$5,000 or imprisonment of up to two years, or both.

Law stated - 30 October 2022

Advertising of medical devices

Is the advertising of medical devices to healthcare professionals regulated as rigorously as advertising in the pharmaceuticals sector? What are the main differences?

The advertising of medical devices is regulated under the Health Products (Medical Devices) Regulations 2010 .

A ‘medical device’ includes any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of any disease;
- diagnosis, monitoring, treatment or alleviation of or compensation for an injury;
- investigation, replacement, modification or support of the anatomy or of a physiological process;

- supporting or sustaining life;
- control of conception;
- disinfection of medical devices; or
- providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body, and that does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means.

A 'medical device' also includes the following articles:

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

Under Regulation 19 of the Health Products (Medical Devices) Regulations 2010, advertisements of medical devices must not contain any statement that expressly or implicitly suggests that the use of the medical device is promoted or endorsed by the Health Sciences Authority (HSA). Advertisements for medical devices that are intended for direct delivery to the general public or for direct use by the general public must not contain any statement concerning the intended use and efficacy of the medical device unless such statement has been verified by objective evidence, and where the medical device is a registered medical device, such objective evidence has been furnished to the HSA at the time the application to register the medical device was made.

Where the advertisement of a medical device contains any statement, assertion, certification, award or feature of uniqueness or prominence differentiating the medical device from any other competing or similar medical device, the statement, assertion, certification, award or feature must be substantiated by facts or evidence (Regulation 20 of the Health Products (Medical Devices) Regulations 2010). For example, the identity of the certifying or awarding body and the date the certification or award was granted should be stated. Where the advertisement makes any claim of historical precedence in the use or administration of the medical device for the purpose of medical treatment, information on the outcome of that use or administration of the medical device should also be stated.

Regulation 21 of the Health Products (Medical Devices) Regulations 2010 states that no person shall advertise any registered 'professional use only' medical device or any unregistered 'professional use only' medical device that is supplied in accordance with the Regulations, unless the advertisement is distributed only to, or is contained in a publication intended for circulation mainly among, qualified practitioners.

Contravention of any of the above provisions is an offence for which an offender may be liable to a fine of up to S $20,000 or imprisonment of up to 12 months, or both. In contrast to the penalties prescribed under the Medicines Act, the penalties prescribed under the Health Products Act (under which the Health Products (Advertisement of Therapeutic Products) Regulations 2016 and Health Products (Medical Devices) Regulations 2010 are promulgated) are more stringent.

Law stated - 30 October 2022

DATA PROTECTION, PRIVACY AND DIGITISATION IN HEALTHCARE

Digitisation

What are the legal developments regarding digitisation in the healthcare sector and industrial networks or sales channels?

The Private Hospitals and Medical Clinics Act (PHMCA), which adopts a premises-based regulatory framework, is transitioning to a new services-based regulatory framework under the Healthcare Services Act (HCSA). This was partly prompted by the increasing use of digital healthcare solutions, which may not involve physical premises. Under the HCSA, telemedicine services will be licensable healthcare services. The Ministry of Health (MOH) has also announced proposed amendments to the HCSA which will introduce specified services and non-premises-based modes of service delivery (eg, virtual medical consultations, home medical care) for various licensable healthcare services. These amendments are expected to be effective in June 2023.

In this connection, the MOH launched the Licensing Experimentation and Adaptation Programme on 18 April 2018, a regulatory sandbox initiative for telemedicine and mobile medicine to facilitate the development of innovative healthcare models in a controlled environment. As of February 2021, the MOH has closed the sandbox for telemedicine and mobile medicine after successfully achieving the objectives it had set out. As a transition approach prior to licensing under the HCSA at the end of 2023 and due to the increasing number of telemedicine providers, the MOH has started to list direct telemedicine service providers online. Under the HCSA, direct doctor and dentist-led teleconsultations will be licensable from the end of 2023.

Law stated - 30 October 2022

Provision of digital health services

Which law regulates the provision of digital health services, and to what extent can such services be provided?

Currently, telemedicine services are not licensable per se under the PHMCA, which adopts a premises-based regulatory framework, and all registered medical practitioners may provide telemedicine services. However, telemedicine services are regulated under the MOH's 2015 National Telemedicine Guidelines (NTG), as well as the SMC Ethical Code and 2016 Handbook on Medical Ethics. The NTG provides guidance to healthcare providers on clinical standards and outcomes, human resources, organisational issues, and technology and equipment. The SMC Ethical Code, to which all registered medical practitioners are required to adhere, sets out how such services are to be provided responsibly. For instance, it provides that doctors engaging in telemedicine must endeavour to provide the same quality and standard of care as in-person medical care, otherwise they must state the limitations of their opinion.

However, the PHMCA is gradually being replaced by the HCSA. Under the HCSA, telemedicine services will be licensable healthcare services from the end of 2023. That said, the MOH has stated that it will adopt a risk-based approach in regulating telemedicine, and that only direct doctor and dentist-led tele-consultation will be licensable for a start. At the time of writing, the MOH will not be licensing indirect telemedicine providers, which refers to those who do not provide direct medical care and only offer technology support for telemedicine, such as platforms offering software-as-a-service for teleconsultation, directory listings and payment solutions.)

Law stated - 30 October 2022

Authorities

Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation? Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

The Personal Data Protection Act 2012 (PDPA) is Singapore's main personal data protection legislation and is administered and enforced by the Personal Data Protection Commission (PDPC). The PDPA prescribes baseline standards relating to the collection, use, disclosure, access, protection, retention and transfer of personal data to which all organisations must adhere.

The Personal Data Protection (Amendment) Act 2020 , which introduces amendments to the PDPA aimed at strengthening public trust, enhancing business competitiveness, and providing greater organisational accountability and assurance to consumers, in support of Singapore's digital economy, was passed by Parliament on 2 November 2020. The first phase of the Personal Data Protection (Amendment) Act came into effect on 1 February 2021 and permits disclosure of personal data about an individual who is a current or former patient of a licensee under the PHMCA, a licensee under the HCSA, and a prescribed healthcare body to a public agency for the purposes of policy formulation or review.

The PDPC has also issued the Advisory Guidelines for the Healthcare Sector, which aim to address the unique circumstances facing the healthcare sector in complying with the PDPA.

Other regulatory instruments relating to data protection and privacy in the healthcare sector include the following:

- the Medicines Act and the Health Products Act which contain regulations relating to pharmacovigilance, adverse event reporting and the conduct of clinical trials;
- the PHMCA and the HCSA, which contains provisions relating to the protection of confidential information such as patients' medical records, diagnosis or treatment; the Specific Licensing Terms and Conditions on Medical Records for Healthcare Institutions, to which all healthcare institutions licensed under the PHMCA must adhere;
- the 2015 Guidelines for the Retention Periods of Medical Records issued by the MOH;
- the SMC Ethical Code and the Allied Health Professions Council's Code of Professional Conduct, which set out standards of conduct expected of medical practitioners and allied health professionals respectively, such as those relating to patient confidentiality; and
- the Healthcare Cybersecurity Essentials, which were developed by the MOH and meant as a guidance document for licensees under the PHMCA and HCSA, as well as entities providing intermediate and long-term care services, in adopting basic safeguards for their IT assets and data.

Law stated - 30 October 2022

Requirements

What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

The PDPA prescribes baseline standards relating to the collection, use, disclosure, access, protection, retention and transfer of personal data to which all organisations must adhere.

Under the PDPA, organisations are required to protect personal data in their possession or under their control by making reasonable security arrangements to prevent unauthorised access, collection, use, disclosure, copying, modification, disposal or similar risks, as well as prevent the loss of any storage medium or device on which personal data is stored.

Additionally, the PDPA generally requires organisations to seek consent from an individual before collecting, using or disclosing his or her personal data. In seeking such consent, the organisation is required to notify the individual of the purposes for such collection, use or disclosure, which must be what a reasonable person would consider appropriate in the circumstances. The organisation may not, as a condition of providing a product or service, require an individual to consent to the collection, use or disclosure of personal data about the individual beyond what is reasonably required

for the provision of the service.

The PDPA also requires organisations to designate one or more individuals to be responsible for ensuring the organisation's compliance with the PDPA. These individuals are typically known as Data Protection Officers (DPOs). Key responsibilities of a DPO include the following:

- ensuring compliance with the PDPA when developing and implementing policies and processes for handling personal data;
- fostering a personal data protection culture among employees;
- communicating personal data protection policies to stakeholders;
- handling access and correction requests to personal data;
- managing personal data protection-related queries and complaints;
- alerting management to any risks that might arise with regard to the personal data handled by the organisation; and
- where necessary, liaising with the PDPC on personal data protection matters.

Law stated - 30 October 2022

Common infringements

What are the most common data protection and privacy infringements committed by healthcare providers?

Organisations are required to protect personal data in their possession or under their control by making reasonable security arrangements to prevent unauthorised access, collection, use, disclosure, copying, modification, disposal or similar risks, pursuant to the PDPA.

The PDPC has stated that among the various data protection obligations under the PDPA, breaches of the above protection obligation are the most common in its reported decisions. Notably, in January 2019, the PDPC fined Integrated Health Information Systems, the central national IT agency for Singapore's public healthcare sector, and Singapore Health Services Pte Ltd, one of Singapore's three public healthcare clusters, S$750,000 and S$250,000 respectively for failing to comply with that obligation, in respect of a data breach in which the non-medical personal data of around 1.5 million patients and the outpatient prescription records of around 160,000 patients were exfiltrated in a major cyberattack.

Law stated - 30 October 2022

COLLABORATION

Legislation

Which legislation governs the collaboration of the pharmaceutical industry with healthcare professionals? Do different rules apply regarding physicians in the outpatient and inpatient sectors?

There is no specific legislation governing the collaboration of the pharmaceutical industry with healthcare professionals. However, the Singapore Medical Association (SMA) and the Singapore Association of Pharmaceutical Industries (SAPI) have prepared a joint paper (SMA-SAPI Joint Paper), which states that healthcare professionals are expected to place patients' health and welfare above any financial or commercial gains, whereas the pharmaceutical industry is expected to invest in research and development to develop new and improved treatment options for the benefit of patients and market them ethically. The relationship between the pharmaceutical industry and healthcare

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.

Further, any advertisements or promotions offered by the pharmaceutical industry to healthcare professionals must comply with the Medicines Act and Health Products Act (and any subsidiary legislation thereunder), the Singapore Code of Advertising Practice (SCAP) and any other guidelines issued by the Health Sciences Authority (HSA) pertaining to the advertising of or supply of health or medicinal products.

The same rules generally apply to physicians in the outpatient and inpatient sectors.

Law stated - 30 October 2022

Collaboration with healthcare professionals

What are the main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals?

The pharmaceutical industry must comply with the general principles of advertising as provided for in the Medicines Act and Health Products Act (and any subsidiary legislation thereunder), the SCAP and any other guidelines issued by the HSA pertaining to the advertising of or supply of health or medicinal products, as well as the SMA Ethical Code, SMC Ethical Code and SAPI Code of Conduct.

The SMA-SAPI Joint Paper sets out recommendations in relation to the marketing practices of the pharmaceutical industry including promotions, gifts, symposiums or congresses, sponsorship and the supply of samples, as well as consultancy arrangements between the pharmaceutical industry and healthcare professionals. The SMA and the SAPI maintain strict oversight of the relationship between individual doctors and the pharmaceutical industry, particularly in relation to the acceptance of gifts, promotional items and educational materials by doctors, and invitations from pharmaceutical companies for doctors to travel overseas to attend medical conferences and travel grants associated therewith. The SMA-SAPI Joint Paper also recommends that continuing medical education programmes provided by pharmaceutical companies must be organised through a registered and recognised academic or professional medical society or institution. Where pharmaceutical companies organise marketing talks about their new products, doctors are encouraged to analyse the information presented at such talks critically.

Further, section 50 of the Medicines Act prohibits advertisements to practitioners that have the purpose of inducing such practitioners to prescribe or supply medicinal products of that description. Contravention of section 50 of the Medicines Act is an offence for which an offender may be liable to a fine of up to S$5,000 or imprisonment of up to two years, or both.

Section 19 of the Health Products Act prohibits the advertisement of any product as a health product (which includes therapeutic products) if it is not a health product within the meaning of section 2 of the Health Products Act. Similarly, advertisements of registered health products that portray that they are usable for any other purpose other than that for which they have been registered are prohibited. In addition, advertisements must not be false or misleading, and must comply with any requirements that may be prescribed by the HSA prior to its approval of the advertisement. A contravention of the above provisions under the Health Products Act is an offence for which an offender may be liable to a fine of up to S$20,000 or imprisonment of up to 12 months, or both. While there are no rules and principles specific to the collaboration of the pharmaceutical industry with healthcare professionals under the SAPI Code of Conduct, it nonetheless prescribes that, generally, the following standards of promotion should be adhered to:

- data is substantiated;
- false or misleading claims are not allowed;
- unapproved products and indications are not promoted;
- material and data are presented in good taste;

- unqualified superlatives are not allowed;
- new products are clearly identified;
- comparative statements must be used carefully;
- imitation that may give rise to confusion is not allowed;
- medical ethics are adhered to;
- distinction of promotional material is clearly defined;
- products, activities or representatives of other pharmaceutical companies must not be disparaged; and
- medical and scientific opinions of opinion leaders and healthcare professionals must not be disparaged.

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 if they are generally accepted by the medical profession.

In addition, the SMC Ethical Code does not prohibit doctors from sponsoring, donating, participating or rendering services for any charitable endeavours. However, where a doctor participates in a medical event, conference, talk or publication, or on an educational website sponsored by pharmaceutical companies or any company marketing health or medical products, such doctor must ensure that his or her participation does not occur in such a way as to appear to endorse such products, or to persuade patients or the general public to use those products. Additionally, the doctor must 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 all such potential conflicts of interest to the audience.

Law stated - 30 October 2022

Collaboration with patient organisations

What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

There is no specific legislation governing the collaboration of the pharmaceutical industry with patient organisations. However, the collaboration of the pharmaceutical industry with patient organisations is indirectly regulated by the Medicines Act and Health Products Act (and the subsidiary legislation thereunder), the SCAP and any other guidelines issued by the HSA pertaining to the advertising of or supply of health or medicinal products, as well as the SAPI Code of Conduct.

The SAPI Code of Conduct prescribes general advertising or promotion principles that the pharmaceutical industry must comply with.

Law stated - 30 October 2022

Common infringements

What are the most common infringements committed by pharmaceutical manufacturers regarding collaboration with healthcare professionals?

The HSA and government authorities do not make this information publicly available.

Law stated - 30 October 2022

Collaboration on medical devices

Is the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as collaboration in the pharmaceuticals sector? What are the main differences?

There is no specific legislation governing the collaboration of manufacturers of medical devices with healthcare professionals. However, manufacturers of medical devices must comply with the general principles of advertising as provided for in the Health Products Act (and any subsidiary legislation thereunder), the SCAP and any other guidelines issued by the HSA pertaining to the advertising of or supply of medical devices, the SMA Ethical Code and SMC Ethical Code, as well as the Medical Technology Industry Group's (MTIG) Code of Ethical Conduct for Interactions with Healthcare Professionals (MTIG Code).

The MTIG Code sets out the following general principles to ensure that the medical device industry's collaborations with healthcare professionals are made in the best interest of consumers and patients:

- advancement: the company's relationship with healthcare professionals must be for the purpose of advancing medical technology, innovation and patient care;
- integrity: the company must interact with healthcare professionals in an honest, truthful and fair manner;
- independence: the company may not provide anything of value to improperly influence a healthcare professional from making medical decisions that are based on the best interests of patients;
- appropriateness: interactions must be modest or reflect fair market value, and be for legitimate purposes; and
- transparency: the company must be open regarding significant financial relationships with healthcare professionals.

There is no specific legislation governing the collaboration of the medical device industry with patient organisations. However, the collaboration of the medical device industry with patient organisations is indirectly regulated by the Health Products Act (and the subsidiary legislation thereunder), the SCAP and any other guidelines issued by the HSA pertaining to the advertising of or supply of health or medicinal products, as well as the MTIG Code.

Law stated - 30 October 2022

COMPETITION LAW

Authority enforcement

Are infringements of competition law by healthcare providers pursued by national authorities?

Singapore's generic competition laws are contained in the Competition Act 2004 (Competition Act) . A person who believes that an entity is in breach of competition law may make a complaint to the Competition and Consumer Commission of Singapore (CCCS), which administers and enforces the Competition Act. The CCCS may also choose to initiate its own investigation into alleged anticompetitive behaviour. The CCCS can take action against healthcare providers that: enter into anticompetitive agreements, engage in an abuse of their dominant position or enter into mergers that substantially lessen competition (or are expected to substantially lessen competition) within any market in Singapore. Where the CCCS, upon completion of an investigation, decides that there has been an infringement of competition law, it may, inter alia, impose financial penalties, issue directions or take other appropriate measures to remedy, mitigate or prevent the harmful effect of the infringement, and to prevent recurrence of the same.

Law stated - 30 October 2022

Private enforcement

Is follow-on private antitrust litigation against healthcare providers possible?

Only after the CCCS has found a party to be in breach of competition law in Singapore, and after the expiry of the applicable appeal period, can third parties bring actions under section 86 of the Competition Act for loss or damage suffered directly as a result of a healthcare provider's infringement of competition law. There is a two-year time limit for the commencement of such private actions from the expiry of the applicable appeal period. To date, there have been no published instances where a party has brought a follow-on private action against a manufacturer.

Law stated - 30 October 2022

Anti-corruption and transparency

What are the main anti-corruption and transparency rules applicable to healthcare providers?

There is no specific legislation in Singapore on the anti-corruption and transparency rules applicable to healthcare providers. However, the Prevention of Corruption Act 1960 (PCA) is the primary statute dealing with corruption offences in Singapore. The PCA criminalises corruption in both the public and private sectors and is enforced by the Corrupt Practices Investigation Bureau.

Sections 5 and 6 of the PCA prohibit bribery in general. Under section 5 of the PCA, it is an offence for a person (whether by him or herself or in conjunction with any other person) to:

- corruptly solicit, receive, or agree to receive for him or herself or for any other person; or
- corruptly give, promise or offer to any person, whether for the benefit of that person or of another person, any gratification as an inducement to or reward for or otherwise on account of:
  - any person doing or forbearing to do anything in respect of any matter or transaction whatsoever, actual or proposed; or
  - any member, officer or servant of a public body doing or forbearing to do anything in respect of any matter or transaction whatsoever, actual or proposed, in which such public body is concerned.

Any person convicted of an offence under section 5 of the PCA may be liable to a fine not exceeding S$100,000 or imprisonment for a term not exceeding five years, or both.

Section 6 of the PCA sets out the offence of corrupt transactions with agents. It is an offence under section 6 of the PCA for:

- any agent to corruptly accept or obtain any gratification as an inducement or reward for doing or forbearing to do, or for having done or forborne to do, any act in relation to his or her principal's affairs or business;
- a person to corruptly give or agree to give or offer any gratification to any agent as an inducement or reward for doing or forbearing to do, or for having done or forborne to do any act in relation to his or her principal's affairs or business; or
- a person to knowingly give to an agent a false or erroneous or defective statement, or an agent to knowingly use such statement, to deceive his or her principal.

Any person who is convicted of an offence under section 6 of the PCA may be liable to a fine not exceeding S$100,000 or imprisonment for a term not exceeding five years, or both.

In addition, the ethical codes of the Singapore Medical Association, the Singapore Medical Council, the Singapore Association of Pharmaceutical Industries and the Singapore Manufacturing Federation's Medical Technology Industry Group promulgate the principle that the relationship between the pharmaceutical industry and healthcare professionals must always be seen to be impartial and honest.

Law stated - 30 October 2022

PRICING AND REIMBURSEMENT

Price regulation

To what extent is the market price of a medicinal product or medical device governed by law or regulation?

The market price of a medicinal product or a medical device is not generally governed by law or regulation in Singapore. However, the Ministry of Health (MOH) administers several drug subsidy schemes, including the Standard Drug List (SDL) Subsidy Framework and the Medication Assistance Fund (MAF).

The SDL Subsidy Framework, which is modelled on the World Health Organization's essential drug lists, consists of drugs assessed to be cost-effective and essential to the provision of medical care to all Singaporeans. Certain revisions to the SDL Subsidy Framework will take effect from 1 November 2022. The MAF was set up in August 2010 to provide financial assistance in respect of non-standard, high-cost drugs.

The Drug Advisory Committee (DAC) is responsible for making recommendations to the MOH as to whether a drug should be subsidised through listing on the SDL or MAF. The DAC's recommendations are informed by drug evaluations conducted by the Agency for Care Effectiveness, the national health technology assessment agency in Singapore residing within the MOH. Drugs on the SDL or MAF may be reviewed periodically, and the MOH may at its discretion revoke, extend or vary the conditions of listing. The DAC considers four core decision-making criteria in making its subsidy recommendations:

- the clinical need of patients and the nature of the condition;
- the clinical effectiveness and safety of the technology;
- the cost-effectiveness; and
- the estimated annual drug cost and the number of patients likely to benefit from treatment.

Law stated - 30 October 2022

Negotiations between manufacturers and providers

Must pharmaceutical and medical device manufacturers negotiate the prices of their products with public healthcare providers?

Public healthcare providers generally purchase drugs through a tender process, and it may be possible that the terms of the supply (including the prices) would be negotiated between the public healthcare providers and the pharmaceutical and medical device manufacturers. In August 2021, an additional 55 cancer drugs were included in the SDL pursuant to negotiations with various pharmaceutical companies.

Law stated - 30 October 2022

Reimbursement

In which circumstances will the national health insurance system reimburse the cost of medicines?

The national health insurance system in Singapore comprises multiple tiers. In general, there is heavy subsidy of services and medicinal products provided by the national healthcare institutions to qualifying Singaporeans. In addition, generally all Singaporeans must maintain an individual medical savings account under the MediSave scheme. A secondary level of medical insurance scheme, MediShield Life (which replaced MediShield from 1 November 2015), allows Singaporeans to pool against the financial risks of major illnesses, whereas ElderShield and CareShield Life allow Singaporeans to pool against the financial risks of suffering a severe disability. Integrated Shield Plans are also available as an additional level of insurance for Singaporeans. Further, MediFund is available as a safety net for those who cannot afford the subsidised bill charges, despite coverage under schemes such as MediSave and MediShield Life. The MAF (which was implemented in August 2010) also assists patients who require costly medication. Through the Community Health Assist Scheme (CHAS), the government has also engaged private general practitioners to provide common outpatient medical services to needy Singapore citizens at subsidised charges. Finally, the government has also introduced the Pioneer Generation Package, whereby Singapore citizens who were aged 16 and above in 1965 and who obtained Singapore citizenship on or before 31 December 1986 are eligible for additional subsidies for their healthcare costs for life.

It should be noted that MediSave, MediShield Life, ElderShield, CareShield Life and any Integrated Shield Plans do not only reimburse the cost of medicines, but also hospitalisation and certain outpatient expenses.

Claims under MediShield Life can be made through the hospital where the patient is being treated. The hospital will inform the Central Provident Fund (CPF) Board that the patient is insured under the MediShield Life scheme and submit the claim to the CPF Board. After determining the amount payable from MediShield Life, the CPF Board will make payment directly to the hospital, and the outstanding amount may be settled with the patient's MediSave or by cash payment, or by a combination of the two. The withdrawal limits for MediSave depend on the type of treatment required by the patient.

MediFund assistance is available to Singapore citizens who are subsidised patients receiving treatment from a MediFund-approved institution. A patient who wishes to apply for MediFund assistance must demonstrate that the patient and family have difficulty affording the medical bill despite the available government subsidies and contributions from MediShield Life and MediSave. These patients (or their family members) may approach a medical social worker at a MediFund-approved institution for assistance. Every MediFund-approved institution has a MediFund committee to consider and approve applications, and decide on the appropriate quantum of assistance to provide. The MediFund committee comprises independent volunteers, most of whom are actively involved in community social work and are familiar with the needs and problems faced by lower-income Singaporeans. The actual amount of assistance provided will depend on the patient's financial and social circumstances, as well as the size of the medical bill incurred.

The MAF is available to patients who face difficulties affording their medical bills after MediShield Life or MediSave claims or deductions. Patients who are prescribed MAF-listed drugs can apply for the MAF by approaching a medical social worker in the restructured hospitals and institutions or polyclinics.

Under the CHAS, low to middle-low-income or disabled Singaporeans with any of the following 23 chronic diseases or medical conditions – diabetes mellitus, hypertension (high blood pressure), lipid disorders (eg, high cholesterol), stroke, asthma, chronic obstructive pulmonary disease, schizophrenia, major depression, dementia, bipolar disorder, osteoarthritis, benign prostate hyperplasia (enlargement of prostate gland), anxiety, Parkinson's disease, nephritis/ nephrosis (chronic kidney disease), epilepsy, osteoporosis, psoriasis, ischaemic heart disease, psoriasis, gout, chronic hepatitis B and rheumatoid arthritis – enjoy subsidised charges when seeking common outpatient medical treatment

or basic dental charges at participating clinics.

In addition, the government introduced the Pioneer Generation Package in February 2014 to help over 450,000 eligible senior citizens with their healthcare costs for life, including the provision of financial subsidies for outpatient treatment (in terms of both services and medications) at polyclinics and specialist outpatient clinics, MediSave top-ups (amount dependent on date of birth) and further subsidies for MediShield Life premiums.

Law stated - 30 October 2022

Price adjudication

If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

The Ministry of Health is the competent body for decisions regarding subsidising certain medicinal products under the SDL and the MAF.

Law stated - 30 October 2022

Discount

Are manufacturers or distributors of medicinal products statutorily obliged to give a discount to health insurance schemes or third parties?

No, there are no statutory obligations on manufacturers or distributors of medicinal products to give a discount.

Law stated - 30 October 2022

UPDATE AND TRENDS

Key developments of the past year

Is there any legislation expected in the near future that will have a major impact on the current legal environment for medicines or medical devices?

To our knowledge, there are none at the time of writing.

Law stated - 30 October 2022

Jurisdictions

Australia	Clayton Utz
Canada	Stikeman Elliott LLP
China	East & Concord Partners
Germany	Ehlers Ehlers & Partner
India	LexOrbis
Ireland	Matheson
Israel	S Horowitz & Co
Italy	CMS Cameron McKenna Nabarro Olswang LLP
Japan	Anderson Mōri & Tomotsune
Mexico	OLIVARES
Singapore	Drew & Napier LLC
Spain	Roca Junyent
Sweden	Cirio Advokatbyrå AB
Switzerland	Wenger Vieli Ltd
Turkey	Gün + Partners