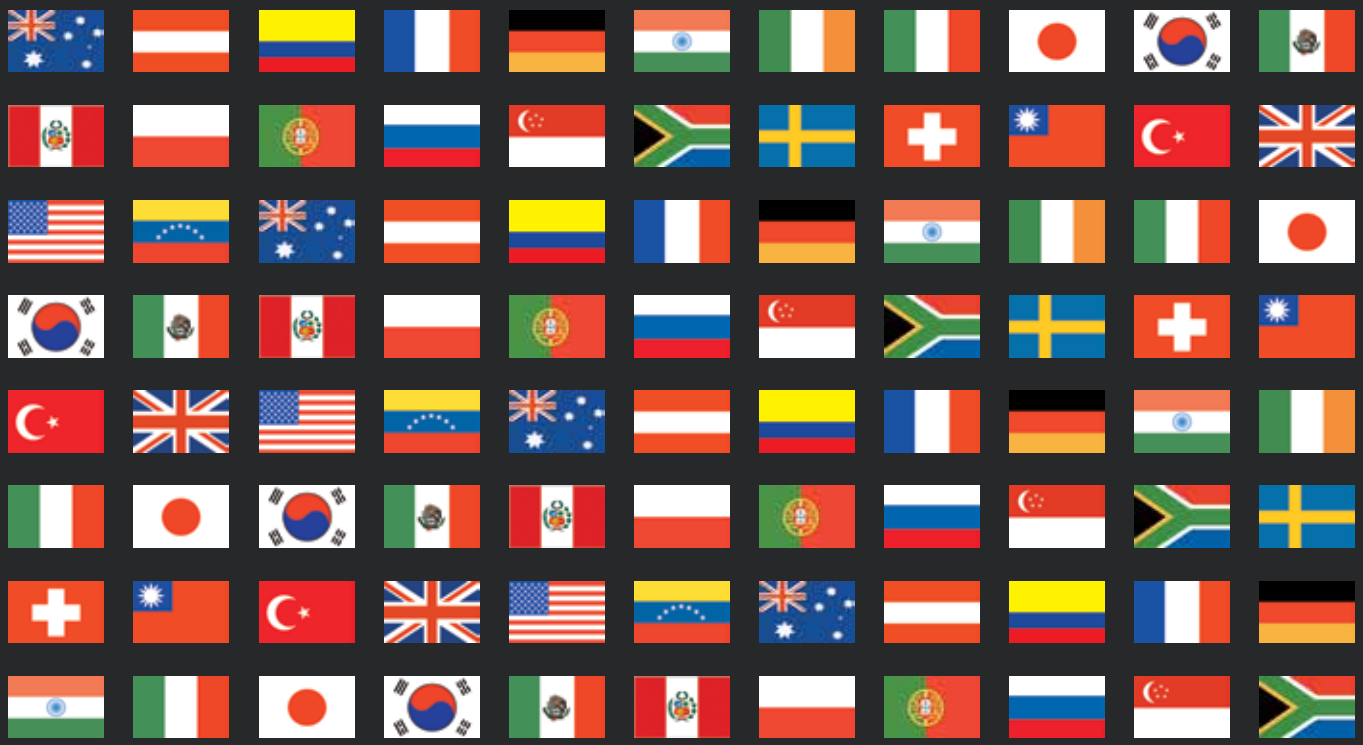
Life Sciences

Contributing editor
Alexander Ehlers



2016

GETTING THE DEAL THROUGH

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Life Sciences 2016

Contributing editor

Alexander Ehlers

Ehlers, Ehlers & Partner Rechtsanwaltsgesellschaft mbB

Publisher
Gideon Roberton
gideon.roberton@lbresearch.com

Subscriptions
Sophie Pallier
subscriptions@gettingthedealthrough.com

Business development managers
Alan Lee
alan.lee@gettingthedealthrough.com

Adam Sargent
adam.sargent@gettingthedealthrough.com

Dan White
dan.white@gettingthedealthrough.com

Law Business Research

THE QUEEN'S AWARDS FOR ENTERPRISE: 2012

Published by
Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
Tel: +44 20 3708 4199
Fax: +44 20 7229 6910

First published 2010
Seventh edition
ISSN 2042-4329

Printed and distributed by
Encompass Print Solutions
Tel: 0844 2480 112

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Singapore

Benjamin Gaw and Tony Yeo
Drew & Napier LLC

Organisation and financing of health care

1 How is health care in your jurisdiction organised?

The Ministry of Health (MOH) oversees the regulation of health care 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 and the Health Promotion Board (established by the Health Promotion Board Act).

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, Medicines Act, Medicines (Advertisement and Sale) Act, Tobacco (Control of Advertisements and Sale) Act, Sale of Drugs Act and Poisons Act.

Singapore promulgated the Health Products Act in 2008 with the intention that the Health Products Act (and all subsidiary legislation promulgated thereunder) will be consolidated legislation regulating all health products (including medicinal products). At present, the Health Products Act only regulates medical devices and cosmetics. The Medicines Act and other related legislation regulate the manufacturing, sale and distribution of medicinal products and pharmaceutical products. There is also specific legislation regulating the use of radiation-emitting devices, contact lens substances and condoms. 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 legislation, namely the Health Products Act, so as to ensure that the controls remain relevant and adequate to different operational and business models, the HSA is also considering proposed amendments to the Health Products Act to import the regulatory control of Western medicines (or medicinal products) under the Health Products Act by way of a new category of regulatory products known as 'therapeutic products' with the intent that the Health Products Act will serve as the consolidated legislation regulating such medicines. As of November 2014, the HSA has concluded public consultations on the proposed subsidiary legislation to transfer the regulatory controls of pharmaceutical products under existing laws to the Health Products Act.

Medical practitioners in Singapore must be registered under the Medical Registration Act (MRA). The Singapore Medical Council (SMC), constituted under the MRA, governs all registered medical practitioners. The SMC has promulgated the Singapore Medical Council Ethical Code and Ethical Guidelines (SMC Ethical Code). All registered medical practitioners are required to adhere to the SMC Ethical Code. In addition, the Singapore Medical Association (SMA), which is the national medical organisation representing the majority of medical practitioners in both the public and private sectors in Singapore, has published the SMA Code of Ethics (SMA Ethics 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). 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, hospitals and private medical clinics are regulated under the Private Hospitals and Medical Clinics Act.

2 How is the health-care system financed in the outpatient and in-patient sectors?

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

There are four tiers of health-care 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 qualifying Singaporeans.

The second tier is the Medisave scheme, which is a compulsory individual medical savings account 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, is a basic, low-cost catastrophic medical insurance scheme that allows Singaporeans to effectively pool the financial risks of major illnesses. MediShield is administered by the Central Provident Fund (CPF) Board. Singaporeans may also supplement their basic MediShield coverage by applying for a Medisave-approved Integrated Shield Plan directly from one of the private insurers under the Private Medical Insurance Scheme. These integrated private insurance policies are made up of the MediShield plan and an enhancement plan for treatment in the private sector. From the end of 2015, the MediShield scheme will be replaced by the MediShield Life scheme, which will offer better protection and higher payouts to Singapore citizens and permanent residents for life, regardless of changes in their health or life circumstances (see the 'Update and trends' section for more details).

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.

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 15 chronic diseases and medical conditions, namely, diabetes mellitus, hypertension (high blood pressure), lipid disorders (eg, high cholesterol), stroke, asthma, chronic obstructive pulmonary disease (COPD), schizophrenia, major depression, dementia, bipolar disorder, osteoarthritis, benign prostate hyperplasia (enlargement of prostate gland), anxiety, Parkinson's disease and nephritis/nephrosis (chronic kidney disease). From 1 June 2015, the CHAS will cover four more chronic conditions, which are epilepsy, osteoporosis, psoriasis and rheumatoid arthritis. The eligibility criteria for the scheme has been enhanced with effect from 1 January 2014, with the removal of the qualifying age for the CHAS (which was previously stipulated at 40 years old), raising of the qualifying property annual value criteria for economically active households (from S$13,000 to S$21,000) and raising of the income criteria from S$1,500 to S$1,800 per capita monthly household income.

In addition, the IDAPE scheme provides financial help to elderly Singapore citizens who become disabled but who are not eligible for Eldershield when it was launched in 2002 because they had exceeded the maximum entry age or have pre-existing disabilities.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertising of medicinal products to the general public and health-care professionals?

The advertisement of medicinal products is governed by the Medicines Act and the Medicines (Advertisement and Sale) Act and their subsidiary legislation, including the Medicines (Medical Advertisements) Regulations. The HSA Guide on Advertisements and Sales Promotion of Medicinal Products (HSA A&S Guide) and the Singapore Code of Advertising Practice (third edition, 2008) (SCAP) also set out guidelines pertaining to the advertisement of medicinal products to the general public. The Singapore Association of Pharmaceutical Industries' (SAPI) Code of Marketing Practices and OTC Medicine Code of Advertising and Promotion Practices (SAPI OTC Code) further prescribe standards of advertising or promotion that should be adhered to (see question 9).

4 What are the main rules and principles applying to advertising aimed at health-care professionals?

In Singapore, advertising directed at health-care professionals must abide by the same rules and principles as those directed at the general public (see question 5).

Subject to certain exceptions, any person intending to issue any medical advertisement or conduct any sales promotion in relation to medicinal products must first obtain an advertising permit under section 3 of the Medicines (Medical Advertisements) Regulations. Sales promotion includes any sales campaign (including door-to-door sales), exhibition, competition or any other activity for the purpose of introducing, publicising or promoting the sale or use of any medicinal product or any device, instrument, apparatus or contrivance used or represented to be used for a medicinal purpose.

There is an exception for 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, health-care professionals).

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 health-care 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 to imprisonment of up to two years, or both.

5 What are the main rules and principles applying to advertising aimed at the general public?

Medicinal products in Singapore are classified into three categories to reflect the different levels of access control to these products, namely:

- prescription-only medicines, which are medicinal products that can only be sold with a doctor's prescription;
- pharmacy-only medicines, which are medicines that can be purchased from a licensed pharmacist without a prescription; and
- general sales list (or over-the-counter (OTC)) medicines, which are medicines that can be purchased without a prescription or supervision of a pharmacist.

Only OTC medicines can be marketed and advertised to the public. An advertising permit must be obtained under section 3 of the Medicines (Medical Advertisements) Regulations for a person to issue any medical advertisement or conduct any sales promotion in relation to OTC medicinal products.

Such advertisements must comply with the Medicines Act (for medicinal products) and the Health Products Act (for health products). Both Acts prescribe that advertisements must not be false or misleading.

Medicinal products

Under section 50 of the Medicines Act, an advertisement may be false or misleading if it:

- is made to a patient or client of a practitioner for the purpose of inducing him or her to request the practitioner to prescribe medicinal products of that description;
- is made to a person for the purpose of inducing him or her to purchase medicinal products of that description from a person selling them by retail;
- makes a representation relating to the product, which consists of or includes unauthorised recommendations;
- falsely describes the description of the medicinal products to which it relates; or
- is likely to mislead as to the nature or quality of medicinal products of that description or as to their uses or effects.

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 to imprisonment of up to two years, or both.

In addition, advertisements to the public relating to medicinal products must comply with the HSA A&S Guide, as well as the SCAP.

The HSA A&S Guide states that the advertisements should, among other things:

- truthfully state the nature, quality and properties of the medicinal product, and not mislead in any way by ambiguity, exaggeration, omission or otherwise;
- make only substantiated claims (ie, the supporting literature should be of established sources);
- not inaccurately state recommendations relating to the use of medicinal products in moderate terms;
- not contain comparisons with other medicinal or related products unless scientifically proven; and
- not directly or indirectly encourage indiscriminate use of medicinal products.

The SCAP prescribes that, generally, advertisements of medicinal products should not, among other things:

- claim or imply the cure of any ailment, illness or disease;
- offer to diagnose, advise, prescribe or treat any ailment, illness or disease;
- claim to provide rejuvenation to prevent, retard or reverse the physiological changes and degenerative conditions brought about by, or associated with, increasing age;
- cause the advertisement audience unwanted anxiety lest they are suffering from any disease or condition of ill health, or falsely suggest that any product is necessary for the maintenance of health or the retention of physical or mental capacities;
- offer any product for any condition that requires the attention of a registered medical or other qualified practitioner;
- encourage the indiscriminate, unnecessary or excessive use of health or medicinal products;
- make exaggerated claims;
- contain any offer to refund money to dissatisfied users; or
- rest on claims that a product does not contain a given ingredient that is in common use in competitive products in any way that may give the impression that the ingredient is generally unsafe or harmful.

Health products

Pursuant to section 20 of the Health Products Act, advertisements relating to health products may be false or misleading if they falsely describe the

health product or give false information or if it is likely to create an erroneous impression regarding the formulation, composition, design specification, quality, safety, efficacy or uses of the health product.

In addition, pursuant to section 19 of the Health Products Act, an advertisement must not procure to advertise a product to be advertised as a health product if that product is not a health product, and advertisements in relation to registered health products must not represent the registered health product as being usable for any purpose other than that for which it has been registered. Section 21 of the Health Products Act also prescribes that advertisements should comply with such requirements as may be prescribed by the HSA.

6 What are the most common infringements committed by manufacturers with regard to the advertising rules?

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

7 Under what circumstances is the provision of information regarding off-label use to health-care professionals allowed?

There is no legislation in Singapore specifically prohibiting the use of medicinal products in off-label indications. However, section 4.1.4 of the SMC Ethical Code provides that:

> *A doctor shall treat patients according to generally accepted methods and use only licensed drugs for appropriate indications. A doctor shall not offer to patients, management plans or remedies that are not generally accepted by the profession, except in the context of a formal and approved clinical trial.*

Section 50(2) of the Medicines Act prohibits the making of any advertisements that consists of or includes unauthorised recommendations in relation to medicinal products that have been licensed. Any person guilty of an offence shall be liable on conviction to a fine not exceeding S$5,000 or to imprisonment of a term not exceeding two years, or both.

8 Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals? Do different rules apply regarding physicians in the outpatient and in-patient sectors?

There is no specific legislation governing the collaboration of the pharmaceutical industry with health-care professionals. However, the SMA and the SAPI have prepared a joint paper (SMA-SAPI Joint Paper), which states that health-care 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 health-care professionals must always be seen to be impartial, honest and in compliance with the ethical codes promulgated by the SMA, the SMC and the SAPI.

Further, any advertisements or promotions offered by the pharmaceutical industry to health-care professionals must comply with 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.

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

9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with health-care professionals?

The pharmaceutical industry must comply with the general principles of advertising as provided for in 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 SMA Ethics Code, SMC Ethical Code, SAPI Code of Marketing Practices and SAPI OTC Code.

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 health-care professionals. The SMA and the SAPI maintain a 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, the 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 to imprisonment of up to two years, or both. It should also be noted that the pharmaceutical industry is prohibited from offering any gift or prize in connection with its promotion of or sale of any medicinal product to health-care professionals under the Medicines (Medical Advertisements) Regulations. An offence under the Medicines (Medical Advertisements) Regulations will attract a financial penalty of up to S$5,000 or imprisonment of up to 12 months, or both.

Section 19 of the Health Products Act prohibits the advertisement of any product as a health product 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 to imprisonment of up to 12 months, or both.

While there are no rules and principles specific to the collaboration of the pharmaceutical industry with health-care professionals under the SAPI Code of Marketing Practices, 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;
- medical and scientific opinions of opinion leaders and health-care professionals must not be disparaged;
- pre-printed prescription pads that carry product-specific advertisements are prohibited; and
- doctors' names or photographs must not be used in any way that is contrary to medical ethics.

The SMC Ethical Code states that doctors should only engage in promotion of vitamins, tonics and health and nutrition supplements where the content of such promotions (ie, what they say, write or broadcast) is supportable by good-quality scientific evidence.

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.

10 What are the most common infringements committed by manufacturers with regard to collaboration with health-care professionals?

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

11 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 Marketing Practices.

The SAPI Code of Marketing Practices prescribes general advertising or promotion principles that the pharmaceutical industry must comply with (see question 9).

In addition, the offering of any gift or prize in connection with a promotion or sale of any medicinal product is prohibited under the Medicines (Medical Advertisements) Regulations.

12 Are manufacturers' infringements of competition law pursued by national authorities?

Pursuant to the Competition Act, a person who believes that an entity is in breach of competition law may make a complaint to the Competition Commission of Singapore (CCS). The CCS may also choose to initiate its own investigation into alleged anti-competitive behaviour. The CCS can take action against pharmaceutical manufacturers that enter into anti-competitive agreements, engage in an abuse of their dominant position or enter into mergers that substantially lessen competition (or is expected to substantially lessen competition) within any market in Singapore. Where the CCS, 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.

13 Is follow-on private antitrust litigation against manufacturers possible?

Only after the CCS has found a party to be in breach of competition law in Singapore, and after the expiry of any 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 manufacturer's infringement of competition law. There is a two-year time limit for the commencement of such private actions from the time the CCS issues the infringement decision or from the determination of the appeal, whichever is later. To date, there have been no instances where a party has brought a follow-on private action against a manufacturer.

Compliance – medical device manufacturers

14 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

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, 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;
- providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and
- such item 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.

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 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 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, 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 (Medical Devices) Regulations 2010 are more stringent.

Pharmaceuticals regulation

15 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

The Medicines Act states that all medicinal products imported into or sold in Singapore are required to be licensed by the Health Products Regulation Group of the HSA. A person who imports or sells medicinal products in Singapore without a valid product licence commits an offence and may be liable to a fine of up to S$5,000 or to imprisonment of up to two years, or both. A medicinal product is defined in the Medicines Act as 'any substance which is to be used for administration to human beings and animals for the diagnosis, prevention or treatment of ailments including preparations intended for the promotion of health, for anaesthesia or for contraception'. The onus of applying for a product licence rests with the licence holder, which is a locally registered company responsible for the safety, quality and efficacy of the product. The HSA may impose licence conditions requiring the medicines to be marketed in accordance with specific requirements.

Under the Medicines (Traditional Medicines, Homeopathic Medicines and Other Substances) (Exemption) Order, traditional medicines, homeopathic medicines, quasi-medicinal products, raw materials used as ingredients in the preparation or manufacture of any medicinal product and medicated oil and balms are exempted from the requirement to be licensed by the HSA. Similarly, Chinese proprietary medicines are exempted from the requirement to be licensed by the HSA under the Medicines (Chinese Proprietary Medicines) (Exemption) Order.

An advertising permit must be obtained under section 3 of the Medicines (Medical Advertisements) Regulations in order for a person to market all medicinal products in Singapore. The advertisement and promotion of medicinal products are controlled under the Medicines Act and its subsidiary legislation, the Medicines (Medical Advertisements) Regulations. A person who advertises or promotes medicinal products without a valid permit commits an offence and may be liable to a fine of up to S$5,000 or to imprisonment of up to 12 months, or both.

16 Which authorities may grant marketing authorisation in your jurisdiction?

The HSA is the government authority endowed with the powers and functions to grant marketing authorisations in Singapore. It is a requirement under the Medicines Act and Health Products Act that all medicinal products and health products be registered with the HSA before they can be marketed in Singapore. The marketing of medicinal products and health products must be in accordance with any relevant guidelines issued by the HSA.

17 What are the relevant procedures?

Medicinal products

All applications to obtain a product licence in respect of a medicinal product must be in compliance with the Medicines Act, the Poisons Act, the Misuse of Drugs Regulations (subsidiary legislation promulgated under the Misuse of Drugs Act), the Sale of Drugs Act, the Medicines (Advertisement and Sale) Act as well as the HSA's Guidance on Medicinal Product Registration in Singapore (Drug Registration Guidance).

The considerations that the HSA would take into particular consideration in determining whether to grant a product licence as set out in section 12 of the Medicines Act include:

- safety;
- efficacy;
- quality, according to the specification and the method or proposed method of manufacture, and provisions proposed for securing that the products sold or supplied would be of that quality; and
- whether the grant of the product licence would be in the public interest.

Based on the Drug Registration Guidance, the registration process involves the following steps:

- pre-submission preparation;
- application submission;
- application screening;
- application evaluation;
- regulatory decision; and
- post-approval changes.

Pre-submission preparations

In respect of new product licences, an application can either be in respect of a new drug application or a generic drug application.

A generic product is essentially similar to a currently registered product in Singapore (known as the 'Singapore reference product') but excludes biologics. 'Essentially similar' is defined as having the same qualitative and quantitative composition in terms of active substances, having the same pharmaceutical form and being bioequivalent. By extension, the concept of essentially similar also applies to different conventional immediate release oral dosage forms (ie, tablets and capsules) that contain the same active ingredient or ingredients.

There are three forms of evaluation routes, namely the full dossier, the abridged dossier and the verification dossier. The full dossier route applies to any product that has not been approved by any drug regulatory agency at the time of submission. The abridged dossier route applies to any product that has been evaluated by at least one drug regulatory agency. The verification dossier route applies to any product that has been evaluated and approved by one of the HSA's reference drug regulatory agency, which includes the European Medicines Agency, the US Food and Drug Administration, Health Canada, Australia's Therapeutics Goods Administration and the UK Medicines and Healthcare Products Regulatory Agency.

Applicants are encouraged to make an appointment with the HSA for a pre-submission consultation.

Application submission

All applications are to be made in two parts: through an online submission through the HSA's PRISM web portal and a hard-copy submission of the registration dossier (which is to be submitted within two working days from the PRISM submission). The registration dossier is to be in the CTD format, based on the 'Common Technical Document for Registration of Pharmaceuticals for Human Use' as promulgated by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Humans.

Application screening

After submission, the HSA will screen the application to ensure that the correct application type has been chosen and that there are no deficiencies that would delay the process. The HSA puts in place a stop-clock whenever it raises any queries in relation to the application. The stop-clock ends when a complete and satisfactory response is received by the HSA.

Application evaluation

Once the application is accepted, evaluation by the HSA commences. A stop-clock is again put in place in respect of any queries raised. Application evaluations take between 60 working days (for verification evaluations) to 270 working days (for full-dossier evaluations).

Regulatory decision

Once the application has been evaluated, the HSA will issue a regulatory decision of 'approval', 'approvable', 'non-approvable' or 'rejection'.

Approval and rejection are final decisions issued by the HSA. If an approvable regulatory decision has been reached, the conditions for approval will be stated in writing and the applicant will be required to fulfil these conditions within the stipulated time frame. If a non-approvable regulatory decision has been reached, the applicant will be informed of the non-approvable issues in writing, and a reply should be made within the specified time frame if the applicant wishes to continue with the application. The reply should be based on the original data set as submitted to the HSA; additional data that require evaluation will not be accepted. No extension of timeline will be considered, unless mutually agreed between the HSA and the applicant.

An application will be considered withdrawn if the applicant fails to reply within the stipulated time frame subsequent to an approvable or a non-approvable decision. Once an application is withdrawn, the applicant may submit a new application according to prevailing submission requirements. Upon an approval regulatory decision, a product licence will be issued.

Post-approval changes

Upon issuance of a product licence, applicants will be responsible for maintaining the product's quality, efficacy and safety to the end of its life cycle. Any aspect of the product may change throughout its life cycle – for example, there can be a change in the manufacturer or manufacturing process, in the indication or dosage regimen, or in the safety profile. The HSA must be notified of any changes to the product's quality, efficacy and safety.

Confidentiality

Pursuant to section 19A of the Medicines Act, (introduced in 1998 to enable Singapore to comply with its obligations under article 39 of the World Trade Organization TRIPS Agreement), the HSA is obliged to maintain the confidentiality of information received in respect of innovative medicinal products, subject to the exclusions set out in section 19B of the Medicines Act (which include disclosing the confidential information if, in the opinion of the HSA, it is necessary to protect the health or safety of members of the public; disclosing the confidential information to another governmental department or statutory body, if the HSA is of the opinion that such department or body would take reasonable steps to protect the confidentiality of such information; and disclosing the confidential information to any specific international bodies, such as the World Health Organization).

Patent protection

Pursuant to section 12A of the Medicines Act, all applications for new product licences must be accompanied by patent declarations in the form set out in part I of the Sixth Schedule of the Medicines (Licensing, Standard Provisions and Fees) Regulations. Such patent declaration forms must be submitted at the time of application submission, and at any other time as the HSA may require. Generally, a confirmatory declaration will be requested when an approvable regulatory decision is issued. The applicant is required to furnish the confirmatory declaration within the time frame stipulated by the HSA.

Such an application may not be made earlier than 18 months before the expiry of the patent if:

- there is a patent in force in respect of the medicinal product to which the application relates;
- the applicant is not the proprietor of the patent;
- the proprietor has not consented to or acquiesced in the grant of the product licence; and

- the applicant is requesting the grant of a product licence after the expiry of the patent (ie, a Category A3 patent declaration).

Medical devices

A company that wishes to register a medical device on the Singapore Medical Device Register may make an application to the HSA via the HSA's MEDICS web portal.

The HSA classifies medical devices based on a series of factors, including:

- how long the device is intended to be in use;
- whether the device is invasive;
- whether the device is implantable;
- whether the device is active; and
- whether the device contains a drug or biologic component.

The HSA applies the following risk level classifications for medical devices:

Class	Risk level	Device examples
A	Low risk	Wheelchairs/tongue depressors
B	Low to moderate risk	Hypodermic needles/suction equipment
C	Moderate to high risk	Lung ventilator/bone fixation plate
D	High risk	Heart valves/implantable defibrillator

The HSA has adopted the guidance developed by the Global Harmonization Task Force in developing Singapore's risk classification model.

With effect from 1 May 2012, HSA has exempted all Class A medical devices except for sterile devices from the registration requirements. Sterile devices with the 'CE' mark will also be cleared faster.

From 1 September 2012, the registration process for Class B medical devices has also been expedited. For instance, a Class B medical device may be immediately registered where it has already been approved by any two of the following independence reference agencies specified by the HSA – the US Food and Drug Administration, the European Union Therapeutic Goods Administration, Australia's Therapeutic Goods Administration; Canada's Medical Devices Bureau and Japan's Ministry of Health Labour and Welfare – and has been marketed for at least three years without safety concerns.

18 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

There is no specific expiry date if the medicinal product is not marketed by the applicant company once approved by the HSA. However, under the SAPI Code of Marketing Practices, the date of first use of all promotional materials circulated to the market shall not be more than two years from the date of approval. Any materials used beyond this point must be reapproved by the SAPI, which will maintain a local register of all approved materials, the approval folder and a sample of each approved item. All published promotional materials should be dated and updated regularly, and the date of print must be printed on the promotional or advertisement document.

19 Which medicines may be marketed without authorisation?

In Singapore, medicines may not be marketed without authorisation. However, it is possible for a doctor or a pharmacist (pursuant to a prescription given by a doctor or dentist) to apply for special approval to import an unregistered medicinal product on a named-patient basis. It should be noted, however, that this would not apply to medicines containing ingredients controlled under the Poisons Act or the Misuse of Drugs Act (and their subsidiary legislation). For such medicines, the relevant licences must be obtained as required under the respective laws.

The application to import an unregistered medicinal product on a named-patient basis must be made to the Health Products Regulation Group of the HSA. The application must include details of the product to be imported for use and the particulars of the importer, the physician responsible as well as the patient to be treated, and submitted to the Therapeutic Products Branch. The consignment of the medicinal product must be imported into Singapore within six months from the approval date, unless otherwise stated. Currently, no fee is charged for approval. Both the importer and the physician responsible must maintain proper records on the supply and use of the medicinal product.

20 Are any kinds of named patient programmes in place? If so, what are the requirements for pre-launch access?

An application will need to be made to the HSA by the medical practitioner treating the patient, as well as the importer of the medicinal product, to obtain special approval from the HSA to import the unregistered medicinal products into Singapore. Such approvals are granted on a case-by-case basis (see question 19).

Pricing and reimbursement of medicinal products

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

The market price of a medicinal product is not generally governed by law or regulation in Singapore. However, the MOH administers several drug subsidy schemes (the Standard Drug List (SDL), Medication Assistance Fund, in-patient drug subsidy, etc).

The SDL, 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. Currently, the SDL comprises approximately 1,000 drugs (see www.moh.gov.sg/content/moh_web/home/costs_and_financing/schemes_subsidies/drug_subsidies.html).

The Drug Advisory Committee (DAC) is responsible for assessing whether a drug should be included in the SDL. The DAC, with inputs from other clinicians and the Pharmacoeconomics and Drug Utilisation Unit (which operates under the purview of the HSA), reviews the SDL on a yearly basis to take into account changes in clinical practice and advances in medical science. It considers three main factors when determining whether a drug should enter into the SDL:

- whether the drug is essential for the treatment of medical conditions that are important causes of morbidity and mortality in Singapore;
- whether the drug offers a major improvement in terms of efficacy and effectiveness, as compared with existing standard drugs; and
- whether there is sufficient evidence of long-term safety and cost-benefits of the drug.

22 Must pharmaceutical manufacturers negotiate the prices of their products with the public health-care providers?

Public health-care 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 health-care providers and the pharmaceutical manufacturers.

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

As mentioned in question 2, 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 health care institutions to qualifying Singaporeans. In addition, all Singaporeans must maintain an individual medical savings account scheme, Medisave. A secondary level of medical insurance scheme, MediShield, allows Singaporeans to pool against the financial risks of major illnesses, whereas ElderShield allows 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 Medisave and MediShield coverage. The Medication Assistance Fund (which was implemented in August 2010) also assists patients who require costly medication. Through the 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 health-care costs for life (see the 'Update and trends' section for more details).

It should be noted that Medisave, MediShield, ElderShield and any Integrated Shield Plans do not reimburse the cost of medicines only, but also provide the patient with reimbursement for hospitalisation and certain outpatient expenses.

Claims under MediShield can be made through the hospital where the patient is being treated. The hospital will inform the CPF Board that the patient is insured under the MediShield scheme and submit the claim to the

CPF Board. After determining the amount payable from MediShield, 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. From the end of 2015, the MediShield scheme will be replaced by the MediShield Life scheme, which will offer better protection and higher payouts to Singapore citizens and permanent residents for life, regardless of changes in their health or life circumstances (see the 'Update and trends' section for more details).

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 and Medisave. Such 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 Medication Assistance Fund is available to patients who face difficulties affording their medical bills, after MediShield or Medisave claims or deductions. Patients who are prescribed with Medication Assistance Fund-listed drugs can apply for the Medication Assistance Fund by approaching a medical social worker in the restructured hospitals and institutions or polyclinics. At present, only a very limited number of drugs are eligible under the Medication Assistance Fund.

Under the CHAS, low to middle-low income or disabled Singaporeans with any of the following 15 chronic diseases or medical conditions – diabetes mellitus, hypertension (high blood pressure), lipid disorders (eg, high cholesterol), stroke, asthma, COPD, schizophrenia, major depression, dementia, bipolar disorder, osteoarthritis, benign prostate hyperplasia (enlargement of prostate gland), anxiety, Parkinson's disease and nephritis/nephrosis (chronic kidney disease) – enjoy subsidised charges when seeking common outpatient medical treatment or basic dental charges at participating clinics. From 1 June 2015, the CHAS will cover four more chronic conditions, which are epilepsy, osteoporosis, psoriasis and rheumatoid arthritis.

In addition, the government introduced the Pioneer Generation Package in February 2014 to help over 450,000 eligible senior citizens with their health-care 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 (see the 'Update and trends' section for more details).

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

As mentioned in question 21, the Drug Advisory Committee is the competent body for decisions regarding the pricing of certain medicinal products under the SDL.

The reimbursement of medical costs (including hospitalisation costs and costs of medicines) under the Medisave, MediShield and ElderShield schemes is decided by the CPF Board. The Medifund Committee determines the reimbursement of medical costs under the Medifund scheme, whereas the MOH is responsible for reimbursements under the Medication Assistance Fund.

25 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

No; there are no statutory obligations on manufacturers or distributors of medicinal products to give a discount. On the contrary, the offering of any gift or prize in connection with a promotion of or sale of any medicinal product is an offence under the Medicines (Medical Advertisements) Regulations. An offender may be liable to a fine of up to S$5,000 or to imprisonment of up to 12 months, or both.

Medicine quality and access to information

26 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

There is no specific legislation in Singapore on counterfeiting that applies across all products or industries, or that applies specifically to medicines. However, there are relevant provisions in various existing legislative provisions that are relevant in protecting against counterfeit drugs, including the following that govern the manufacture, importation and supply of medicinal products:

- the Sale of Drugs Act;
- the Medicines Act;
- the Poisons Act; and
- the Medicines (Advertisement and Sale) Act.

Medicinal products legislation

Section 31 of the Medicines Act makes it an offence to adulterate medicinal products by adding a substance to or abstracting a substance from a medicinal product so as to affect injuriously the composition of the product. It is also an offence to sell or supply such adulterated medicinal products. A contravention of any of the above provisions may attract a fine up to S$5,000 or imprisonment of up to two years, or both.

In addition, section 10 of the Sale of Drugs Act 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;
- any drug containing prohibited substances;
- any drug containing a greater proportion of substances than is permitted by law;
- any drug for internal use that contains methyl alcohol, isopropyl alcohol or denatured alcohol; and
- any drug that is not of the nature, substance or quality of the drug demanded by the purchaser.

It should also be noted that the sale of adulterated drugs is an offence under the Sale of Drugs Act, but such sale will only constitute an offence if the purchaser is not fully informed of the nature of the adulteration at the time of purchase. Under section 15 of the Sale of Drugs Act, a drug will be considered to have been adulterated if:

- it contains or is mixed or diluted with any substance that diminishes the nutritive or other beneficial properties of the drug or which in any other manner operates or may operate to the prejudice or disadvantage of the purchaser or consumer;
- any substance or ingredient has been extracted or omitted from the drug, such that the nutritive or other beneficial properties are less than those of the drug in its pure and normal state;
- it contains or is mixed or diluted with any substance of a lower commercial value;
- it does not comply with the prescribed standard; or
- a substance or constituent is added or abstracted from the drug such that the quality, constitution or potency of the drug is affected injuriously.

An offence under the Sale of Drugs Act may attract a fine of up to S$1,000 for first-time offenders and a fine of up to S$4,000 for subsequent offenders. If an offence is committed by the personal act, default or culpable negligence of the offender, the offender may be liable to a fine up to S$4,000 or up to three months of imprisonment, notwithstanding that it is a first offence.

Additionally, section 5 of the Poisons Act makes it an offence for a person to possess for sale, or to sell or offer for sale any poison, without holding a licence to do so. A poison means any poison that is listed under the Poisons List in the Schedule of the Poisons Act. There is an exemption under section 7 of the Poisons Act in respect of medicines supplied by medical practitioners, registered dentists and veterinary surgeons for purposes of medical, dental or animal treatment, as well as medicines dispensed by licensed pharmacists. Such medicines must be distinctly labelled with the name and address of the firm or person by whom it is supplied or dispensed and with a serial or other identification number or mark. Section 8 of the Poisons Act also provides for certain exemptions in respect of poisons sold (eg, sale of poisons to a person or institution concerned with scientific education or research where the poison is required for educational or research

purposes) or poisons being exported (eg, exemption applies for sale of poisons to be exported from Singapore to a place other than Malaysia). A person who commits an offence under the Poisons Act may be liable to a fine of up to S$10,000 or to imprisonment of up to two years, or both.

Trade Marks Act
If a Singapore trademark holder's trademarks are infringed in the manufacture and sale of such counterfeit drugs, the Trade Marks Act provides further protection and sanctions, such as commencing an action for the infringement of trademark as a civil liability, or a criminal offence. It may also be possible to commence an action under the common law of passing-off.

Patents Act
Further, it is possible that a Singapore patent may have been granted in relation to the medicinal product. If a counterfeit product infringes a patent (eg, the counterfeit product with a particular active ingredient uses a formulation that falls within a patented formulation), the Singapore patent holder may be able to commence patent infringement proceedings under the Patents Act. The Singapore patent holder may seek, among other remedies, an injunction to prohibit the sale of the counterfeit product against the seller or damages, or both.

Health Products Act
In addition, section 15 of the Health Products Act prohibits the supply of any health product unless that health product is a registered health product. A person who contravenes section 15 will be guilty of an offence and may be liable to a fine of up to S$50,000 or to imprisonment of up to two years, or both.

The supply of health products that are adulterated, counterfeited or that have been tampered with is an offence under section 16 of the Health Products Act. An offender may be liable to a fine of up to S$100,000 or imprisonment of up to three years, or both.

The supply of health products that are unwholesome health products is also an offence under section 16 of the Health Products Act, and may attract a fine of up to S$50,000 or imprisonment of up to two years, or both.

To facilitate the general public in making more informed choices as well as in protecting themselves from the dangers of illegal health products, the HSA has compiled a list of detected and tested illegal health products. Consumers and health-care professionals who wish to obtain more information may conduct a search on illegal health products via the HSA's website (www.hsa.gov.sg/publish/hsaportal/en/for_public/illegal_health_products/ihp_search_page.html).

27 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

Pursuant to section 10 of the Medicines Act, the HSA is required to maintain a register of all medicinal products in respect of which product licences have been granted and remain in force. This register is made available to the public on the HSA website at www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Western_Medicines/Overview.html.

Section 4 of the Medicines (Labelling) Regulations also requires that the container of a dispensed medicinal product (ie, supplied by a doctor or dentist to a patient, or dispensed by a pharmacist) be labelled to show certain particulars, including:

- the patient's name;
- name and address of the medical or dental practice, pharmacy, hospital or other institution;
- date upon which the medicinal product was dispensed;
- name of the medicinal product; and
- where the appropriate non-proprietary name is labelled, the appropriate quantitative particulars of the active ingredients of the medicinal product.

There are also specific requirements, such as the requirement that the above particulars, when printed on a label or on the package of a medicinal product, must not be less than 1.5 millimetres in height, and shall be clearly legible and appear conspicuously in a prominent position on the label so as to be easily read by an intending purchaser or user of the medicinal product under normal conditions of purchase or use.

28 Outline major developments to the regime relating to safety monitoring of medicines.

The Vigilance and Compliance Branch and Product Vigilance Advisory Committee (PVAC) of the HSA employs a number of post-marketing risk assessment approaches to ensure the continued safe use of health products. Persons who hold a product licence under the Medicines Act or the Health Products Act must report any adverse drug reactions, while health professionals are strongly encouraged to do so. The Vigilance and Compliance Branch, together with the PVAC publishes an Adverse Drug Reaction News Bulletin three times a year and distributes the Bulletin to all medical practitioners, dentists and pharmacists. The aim is to increase awareness of adverse drug reactions among health-care professionals and to promote adverse drug reaction reporting. The HSA also maintains a list of 'Dear Healthcare Professional Letters' on its website, which detail product recalls, product alerts and other news related to medicinal and health products (see www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Safety_Information_and_Product_Recalls/Dear_Healthcare_Professional_Letters.html).

The PVAC encourages the reporting of any events that are considered as medically significant in the judgement of the health-care professional. Some examples are events that are fatal or life-threatening, result in or prolong hospitalisation, cause persistent or significant incapacity or disability, or cause birth defects. Reports can be made by health-care professionals and pharmaceutical companies in respect of drugs and complementary health products as well as vaccines using the relevant form available on the HSA's website (www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Safety_Information_and_Product_Recalls/Report_Adverse_Events_related_to_health_products.html).

All Adverse Event Reports submitted to the Vigilance and Compliance Branch are keyed into a national computer database for use in aggregate analysis. HSA will then communicate safety information through Press Releases, Dear Healthcare Professional Letters posed on the Ministry of Health-Health Professional Portal website and the Adverse Drug Reaction News Bulletin. These Adverse Event Reports are also submitted to the WHO-Uppsala Monitoring Centre in Sweden for collation into the world bank of adverse drug reactions.

Where the adverse event reported identifies an unexpected adverse event or indicates that certain adverse events occur more commonly than as previously expected, or that some patients are more susceptible to some problems than others, the HSA may decide to change the marketing authorisation for that particular product. For instance, the HSA may impose restrictions in the use of the product, or make refinements to the instructions for use or require the printing of specific warnings of adverse events in the product package insert. Rarely, when the HSA considers that a hazard is unacceptable, a registered health or medical product may have to be withdrawn from the market.

Further, there are mandatory record-keeping requirements on all pharmacists for the supply of pharmacy-only medicines to ensure accountability and traceability, as well as to enhance the safe and responsible use of medicines. The information required to be recorded includes the date of supply of the medicine; the name, identity card number, address, phone number and e-mail of the person to whom the medicine is dispensed; the name, strength and quantity of medicine dispensed; and the dose, frequency and purpose of the treatment.

Vaccination

29 Outline your jurisdiction's vaccination regime for humans.

It is a legal requirement for all children in Singapore to be vaccinated against the diseases specified under the Fourth Schedule of the Infectious Diseases Act (namely, diphtheria and measles). However, under the National Childhood Immunisation Programme (NCIP), it is generally recommended that all children are also vaccinated against mumps and rubella, tuberculosis, hepatitis B, pertussis, tetanus and poliomyelitis, as well as against human papillomavirus (for females aged nine to 26 years). In addition to these, children may commonly also receive vaccinations against other diseases such as haemophilus influenza type B, influenza, chickenpox, meningococcal and pneumococcal.

The NCIP is based on the recommendations of the Expert Committee on Immunisation, which comprises senior officials from the MOH, consultant paediatricians and experts in communicable disease control. The Committee monitors and reviews the NCIP in Singapore, and consults

with the World Health Organization and other international bodies when necessary.

The Health Promotion Board's Health Surveillance and Informatics Department, Research and Strategic Planning Division maintains a National Immunisation Registry (NIR), which collects and maintains the vaccination records of children from birth to 18 years of age. All vaccinations given at polyclinics will automatically be updated into the NIR's records. For vaccinations given at family or paediatric clinics, the doctor will keep the NIR updated as and when a vaccination is completed. If a child misses any vaccination, the NIR will send a reminder letter to the parents.

Under the NCIP immunisation schedule, the first vaccinations (against tuberculosis and hepatitis B) are administered when the child is born. Subsequently, parents would need to bring their child for regular vaccinations at a family clinic, polyclinic or paediatric clinic. The following three types of vaccinations are provided free-of-charge to Singapore citizens through polyclinics:

- DTPa – a three in one vaccination against diphtheria, tetanus and acelluar pertusiss;
- MMR (vaccination against measles, mumps and rubella); and
- BCG (vaccination against tuberculosis). Singapore permanent residents are required to pay a discounted rate for these vaccinations. School-going children may also receive free vaccinations provided by the School Health Service according to the NCIP (ie, at six to seven years of age, and at 10 to 11 years of age) and where their parents or guardians give consent.

According to statistics published by the World Health Organization in 2014, the immunisation coverage among one-year-olds in Singapore for diphtheria, tetanus and toxoid, hepatitis B and measles over the past decade has been 93 to 97 per cent. The NIR aims to achieve 95 per cent coverage for immunisations under the NCIP.

Update and trends

MediShield Life

On 1 November 2015, MediShield was replaced by MediShield Life. This is a major step in strengthening Singapore's health-care safety net and providing Singaporeans with peace of mind for high medical bills. MediShield Life is a basic health insurance, administered by the CPF Board, which helps to pay for large hospital bills and costly outpatient treatments, such as dialysis and chemotherapy for cancer. MediShield Life will offer better protection and coverage for life for all Singapore citizens and permanent residents, including the very old and those who have pre-existing illnesses and will offer higher payouts so that patients pay less Medisave/cash for large hospital bills.

As part of the Pioneer Generation package, all pioneers will get special premium subsidies and Medisave top-ups under MediShield Life. Those aged 81 and above in 2015 will have their premiums fully covered, while those aged 66 to 80 and are fully insured under MediShield before MediShield Life is implemented will only be required to pay half of their current premiums.

DREW & NAPIER

Benjamin Gaw **benjamin.gaw@drewnapier.com**
Tony Yeo **tony.yeo@drewnapier.com**

10 Collyer Quay
#10-01 Ocean Financial Centre
Singapore 049315

Tel: +65 6535 0733
Fax: +65 6535 4906
www.drewnapier.com

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ISSN 2042-4329

THE QUEEN'S AWARDS FOR ENTERPRISE: 2012

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