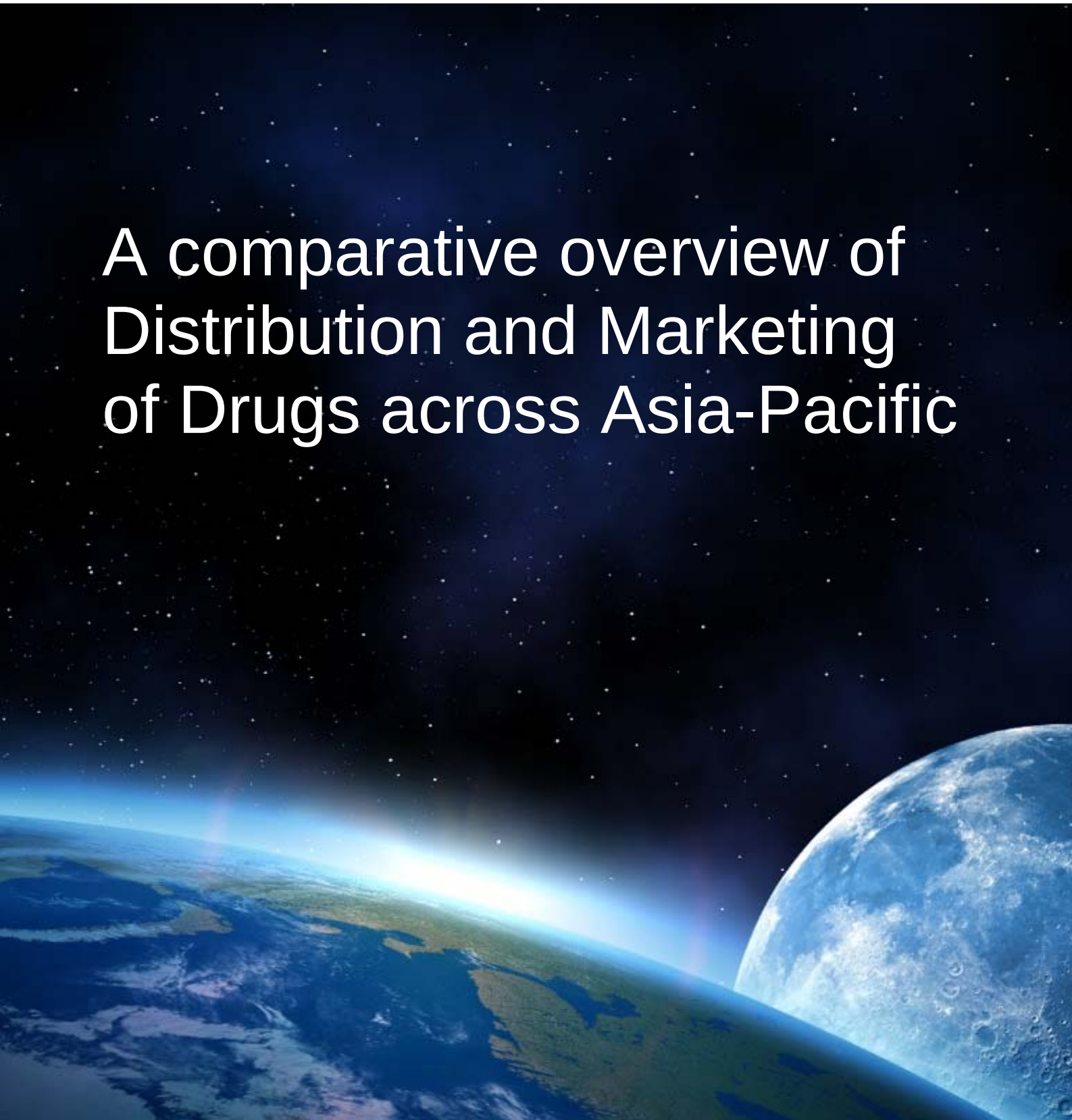
LAN
Lifesciences Asia-Pacific Network

A comparative overview of Distribution and Marketing of Drugs across Asia-Pacific



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Foreword

Lifesciences Asia-Pacific Network (LAN)

For many years, emerging markets have been strategically important for the growth and development of the Lifesciences sector. Almost 90% of the sector now operates in an emerging market, including the Asia-Pacific region.

For many Lifesciences companies, including those based in Japan, Singapore has become the regional hub, many now having offices, manufacturing sites or other bases there. We have also seen the rapid and significant growth of China to become the third largest market in the sector over the last 10 years, with the market still growing.

The opportunities available to the Lifesciences sector in Asia-Pacific are promising, but they are not without challenges and risks, particularly in

IP and regulatory areas. For example, in light of the highly reported anti-bribery investigations many global pharmaceutical companies have reviewed their regulatory policies and also the distribution of registered and unregistered drugs. Many companies in the region also continue to protect and enforce their IP rights as drugs are copied and sold at reduced cost.

The Lifesciences Asia-Pacific Network (LAN) has been established for the Lifesciences sector to support and guide clients on all their legal and regulatory needs in the Asia-Pacific region, offering a highly knowledgeable ‘one-stop shop’. LAN brings together eight of the leading and largest law firms in the region, including Assegaf Hamzah & Partners, Atsumi & Sakai, Chen & Lin, CMS, Corrs Chambers Westgarth, Rajah & Tann Singapore LLP, Tilleke & Gibbins and Yulchon LLC.

This guide by LAN provides a comparative overview of the distribution and marketing of drugs in Australia, China, India, Indonesia, Japan, Korea, Singapore, Taiwan, Thailand and Vietnam. It also highlights the key legal and commercial issues to consider when doing business to help you maximise opportunity and minimise risk.

We hope that you find this guide helpful and informative, as you explore and continue to do business in the Asia-Pacific region.

If you would like to discuss specific issues and questions, we would be delighted to hear from you.

Distribution

Australia

Pre-conditions for distribution

1. What legal pre-conditions must be satisfied before a drug can be distributed within the jurisdiction?

In Australia, if a drug meets the definition of a '**therapeutic good**' under the Therapeutic Goods Act 1989 (Cth) ('**Therapeutic Goods Act**'), it must be entered into the Australia Register of Therapeutic Goods ('**ARTG**') before it can be supplied in Australia, unless it is exempt from being entered in the ARTG or is otherwise authorized by the Therapeutic Goods Administration ('**TGA**').

Subject to various exceptions, a '**therapeutic good**' is defined as a good that is:

– represented as being or likely to be taken for therapeutic use, for use as an ingredient or component in the manufacture of therapeutic goods or for use as a container or part of a container for such items; or
– included in a class of goods the sole or principle use of which is (or ordinarily is) a therapeutic use or use as an ingredient or component in the manufacture of therapeutic goods or for use as a container or part of a container for such items.

'**Therapeutic use**' is defined as use in or in connection with:

– preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons;
– influencing, inhibiting or modifying a physiological process in persons;
– testing the susceptibility of persons to a disease or ailment;
– influencing, controlling or preventing conception in persons;
– testing for pregnancy in persons; or
– the replacement or modification of parts of the anatomy in persons.

A therapeutic good will not be approved by the TGA and authorized for supply unless all of the relevant legal requirements are met.

2. Are there any circumstances in which there are exceptions to the normal pre-conditions (such as an urgent need for the drug)?

There are a number of schemes whereby the normal pre-conditions for the supply of a therapeutic good which would ordinarily be required to be entered into the ARTG in Australia are exempted. These include the following:

– **Special Access Scheme**

Under the Special Access Scheme ('**SAS**') an application can be made to the TGA by a medical practitioner or health practitioner (dependent on the circumstances) for the import and/or supply of an unapproved therapeutic good for a single patient and this is assessed on a case-by-case basis. The SAS can allow individual patients access to a therapeutic good not entered into the ARTG (an '**unapproved therapeutic good**') including where the patient is critically ill and requires urgent, early access to a therapeutic good (including experimental and investigational therapeutic goods), the therapeutic good is available overseas but not marketed in Australia and the therapeutic good has been withdrawn from the Australian market for commercial or other reasons.

– **Authorized Prescribers**

The Authorized Prescriber scheme ('**APS**') allows for a medical practitioner to become an authorized prescriber of an unapproved therapeutic good or class of unapproved therapeutic goods to specific patients or class of patients with a particular medical condition without further approval from the TGA.

The medical practitioner must have their application approved by a Human Research Ethics Committee ('**HREC**') or be endorsed by a specialist college and have:

- appropriate training and expertise for the relevant medical condition and proposed use of the therapeutic good;
- the ability to best determine the patient's needs; and
- the ability to monitor the therapy outcome.

– **Importation for Personal Use**

Under this Personal Importation scheme, a person may, subject to a number of limitations, bring an unapproved therapeutic good into Australia or arrange for it to be sent to him or her for his or her treatment or for the treatment of a member of his or her immediate family only. There are a number of limitations for the importation of an unapproved therapeutic good for personal use including that the goods cannot contain a substance which is prohibited under the *Custom (Prohibited Imports) Regulations 1965*, it cannot be an injection which contains material of animal or human origin (except insulin), the import quantity cannot exceed three months' supply and the total quantity imported per year cannot exceed 15 months' supply at the manufacturer's maximum recommended dosage, and for prescription medicines, the goods must be the subject of a prescription issued by a registered medical practitioner.

– **Clinical Trials**

The TGA regulates the use of therapeutic goods used in clinical trials in Australia and for unapproved therapeutic goods, these are either conducted under the Clinical Trial Notification ('**CTN**') scheme or the Clinical Trial Exemption ('**CTX**') scheme. Under the CTN scheme, the sponsor of the clinical trial notifies the TGA of its intent to sponsor a clinical trial involving an unapproved therapeutic good and a HREC reviews the data relating to the clinical trial as well as monitors the conduct of the trial. The CTX scheme requires the sponsor to submit an application for approval by the TGA for the supply of an unapproved therapeutic good in a clinical trial and the HREC is responsible for considering the scientific and the ethical issues of the proposed clinical trial. Note: As of July 2018, the TGA reports that the CTX scheme application process is undergoing review and strongly encourages a sponsor to contact the TGA directly regarding the CTX application process.

– **Access During Medicine Shortage**

In circumstances where there is a shortage of a registered medicine which cannot be replaced by another medicine entered into the ARTG, the TGA may approve the importation and supply of an unapproved therapeutic good. Approval under this scheme will be granted if the TGA considers it to be in the interests of public health and will be subject to the same advertising and pharmacovigilance activities as those therapeutic goods entered into the ARTG.

Licenses and market authorization

3. What are the legal requirements and procedures for authorizing a drug for distribution?

Legal requirements

In general, and in addition to complying with Commonwealth legislation (in particular, the Therapeutic Goods Act) and applicable State and Territory legislation, a therapeutic good must be entered into the Australian Register of Therapeutic Goods ('**ARTG**') to be distributed in Australia.

In Australia there is a two-tiered system for the regulation of therapeutic goods. For higher risk medicines, these must be registered on the ARTG and the procedure for authorizing such a medicine involves evaluating the quality, safety and effectiveness of the medicine. Lower risk medicines which contain pre-approved, low-risk ingredients and that make limited claims however, may be listed on the ARTG.

Procedure

An application is made via the TGA's online system for market authorization and with the exception of lower risk therapeutic goods (which includes some over-the-counter medicines and complementary medicines), the applicant must provide data which supports the quality, safety and efficacy of the therapeutic good. If the application does not meet the regulatory requirements for format and content, the TGA will consider the application as '**not effective**' and will not accept the application for evaluation.

If the therapeutic good meets the applicable requirements and the applicant is a resident of Australia or is an incorporated body in Australia and conducting business in Australia where the representative of the company is residing in Australia, the TGA will grant the applicant market authorization and the therapeutic good will be entered into the ARTG. The applicant then becomes the sponsor of the therapeutic good.

4. What are the costs and timelines of obtaining licenses?

A summary of the fees payable to the TGA are set out at www.tga.gov.au/schedule-fees-and-charges.

As of 1 July 2018, for a new chemical entity classified as a prescription medicine, the application and evaluation fees are AUD 47,800 and AUD 191,800 respectively. Once registered, there are ongoing annual charges, the amount of which depends on the type of prescription medicine.

There are a range of application and evaluation fees (as applicable) for non-prescription medicines depending on the therapeutic good for which market authorization is being sought. Annual charges are also payable to the TGA.

Fees can be waived for a drug that is designated as an 'orphan drug' if it meets the four eligibility criteria which includes that it is used to treat, prevent or diagnose a life-threatening or seriously debilitating condition and it must meet the drug prevalence threshold (for example, the medicine is intended to treat a condition which affects fewer than 5 in 10,000 individuals in Australia or it not likely to be financially viable for the sponsor to market the medicine in Australia unless the fees are waived).

The legislated timeline for notification of accepting or rejecting an application for a prescription medicine is 40 working days from receipt of that application. From acceptance for evaluation of an application for prescription medicines, the legislated timeframe for a delegate's decision is 255 working days.

5. Are there streamlined procedures in certain situations, such as when a drug has already been authorized in another country?

Comparable overseas regulators

This process is open to an application for the registration of a prescription medicine which has already received full overseas marketing approval following a new evaluation. The application must include evidence that the reference product used in any assessment of bioequivalence is identical to the therapeutic good under the Australian application and must be supported by previous approvals and independent evaluation reports from two acceptable countries. The countries and jurisdictions that the TGA will accept reports from are Canada, Singapore, Switzerland, the United Kingdom, the United States and the European Union. The need for the TGA to review the data contained within the dossier provided as part of the application for registration can be reduced to a greater or lesser degree (depending on the quality and scope of the overseas assessment provided to the TGA).

Priority Review registration review

For vital and life-saving prescription medicines there is a formal Priority Review pathway for faster assessment. The target timeframe is 150 working days from acceptance for evaluation and the application and evaluation fees are higher than the standard prescription medicines process.

Provisional approval pathway

Where there is a potential for a substantial benefit to Australian patients, there is formal Provisional Approval pathway for the provisional registration of prescription medicines on the basis of preliminary clinical data. Prior to submitting an application for provisional registration, an applicant must make an application for determination by the TGA that the medicine is eligible for registration under this pathway and have it approved. The TGA's target to notify an applicant of its decision with respect to the determination application is within 20 working days of receiving the determination application.

Listed medicines

Given that listed medicines are composed of pre-approved low-risk ingredients (such as vitamin or mineral products), applications to list a medicine on the ARTG are assessed by the TGA for quality and safety but not efficacy. It is the responsibility of the sponsor to retain all necessary information to substantiate all of the product's claims.

Options for foreign pharmaceutical companies to establish presence

6. What are the options for foreign pharmaceutical companies to establish legal or commercial presence within the jurisdiction?

The Corporations Act 2001 (Cth) ('**Corporations Act**') is the primary source of company regulation in Australia and is administered by the Australian Securities and Investments Commission ('**ASIC**'). A company can establish a legal or commercial presence in Australia through an Australian or overseas incorporated company.

Companies incorporated in Australia

A company incorporated in Australia must be registered with ASIC, upon which it will be provided with an Australian Company Number ('**ACN**'). There are various types of company structures, with the most common being a company limited by shares – either a proprietary (or private) company or a public company. Under the Corporations Act, a proprietary company must have at least one member, but may not have more than 50 non-employee members and may not raise funds from the public, whereas a public company has no limits on membership and may raise funds from the public. Public companies may also be listed on the Australian Securities Exchange ('**ASX**').

Proprietary limited companies are subject to less onerous reporting requirements than public companies, including in relation to the preparation of financial accounts, holding meetings, the appointment, qualification and removal of directors, and the power to allot shares.

Companies incorporated overseas

Companies that are incorporated outside of Australia that wish to carry out business in Australia must be registered with ASIC. Unincorporated bodies that do not have their head office or principal place of business in Australia must also register with ASIC if they wish to carry out business in Australia. A foreign company applying for registration must lodge an application accompanied by certain prescribed documentation, including a copy of its constitution or equivalent (if any) and a list of its directors, with ASIC. ASIC does not have discretion whether or not to grant registration. A determination of whether or not a foreign company is "carrying out business" in Australia and is required to be registered with ASIC necessitates an examination of all of the circumstances of the company's activities in Australia. When a foreign company registers with ASIC, it will be given an Australian Registered Body Number ('**ARBN**').

7. What are the limitations, if any, of each option?

Companies incorporated in Australia

Tax: Generally speaking, companies that are residents of Australia for taxation purposes will be taxed on income and gains from sources both in and outside Australia, reduced by any allowable deductions. Post incorporation, the company will also need to obtain an Australian Business Number ('**ABN**') and Tax File Number ('**TFN**') in order to trade in Australia. Conversely, companies that are non-residents of Australia will generally only be taxed on income with sources in Australia and gains arising from dealing with certain assets that have the "**necessary connection**" with Australia.

Fundraising: Australian proprietary limited companies cannot have more than 50 non-employee members and cannot raise money other than through an excluded offer that does not require regulated disclosure.

Companies incorporated overseas

- **Right to sue**: Failing to register with ASIC as a foreign company may inhibit the company's right to sue.
- **Public documents**: Foreign companies may only trade under the specific name registered with ASIC and a company must display its ARBN, name and place of origin on all public documents and negotiable instruments published or signed by the company in Australia.
- **Local Agent:** Foreign companies must appoint a local agent who will be responsible for any company obligations and may be personally liable for breaches or penalties of the Corporations Act.
- **Registered office**: The company must have a registered office in Australia to which all communications and notices may be addressed. The registered office must be open to the public (a) from at least 10 a.m. to 12 p.m. and 2 p.m. to 4 p.m. or (b) for at least 3 hours between 9 a.m. and 5 p.m., each business day.

Wholesale and retail distribution

8. Who is authorized to import foreign drugs into the jurisdiction?

A sponsor may import foreign therapeutic goods into Australia. A sponsor must be an incorporated body in Australia and conducting business in Australia where the representative of the company is residing in Australia or be a resident of Australia. (Please also see the exemption '**Importation for Personal Use**' set out in the response to question 2.)

9. Are drugs separated into any different categories for distribution?

In Australia there is a national classification scheme whereby medicines are assigned to a particular Schedule published in the Poisons Standard (a legislative instrument). Medicines are classified into one of the following four Schedules according to the level of regulatory control over availability required to protect public health and safety (this list has increasingly restrictive regulatory controls on availability).

Schedule 2 – Pharmacy medicine (pharmacist advice should be available)

Schedule 3 – Pharmacist-only medicine (expert advice is required for safe use but medicines are available to consumers without a prescription)

Schedule 4 – Prescription-only medicine (prescribed by a medical practitioner and dispensed by a pharmacist on prescription)

Schedule 8 – Controlled drug (same as schedule 4 but generally require a higher level of security and control given their high abuse potential)

10. Who is authorized to distribute prescription drugs and over-the-counter drugs to consumers?

The party that is authorized to distribute prescription drugs and over-the-counter drugs is determined by which Schedule of the Poisons Standard the drug is classified in as well as the particular State or Territory that the drug is being distributed in (as the domestic supply chain for drugs is governed by State and Territory legislation). The following sets out the general position regarding drugs that are classified in a particular Schedule of the Poisons Standard. In addition, some drugs which are unscheduled (such as small packets of paracetamol), may be sold in retailers such as supermarkets as long as certain conditions are met.

Over-the-counter drugs that are classified in Schedule 2 are distributed through a pharmacy as consumers may require advice from a pharmacist. Most States and Territories also grant a license to a retailer to sell these types of over-the-counter drugs if the retail premises are a prescribed distance away from a retail pharmacist. For example, in New South Wales the premises to which the application relates must be at least 20 kilometers (measured along the shortest practicable route) from the nearest retail pharmacist.

An over-the-counter drug that is classified in Schedule 3 may only be distributed by a pharmacist but are available to consumers without a prescription.

Prescription medicines classified in Schedule 4 and Schedule 8 may only be dispensed by a pharmacist on receipt of the consumer's prescription. As the drugs classified in Schedule 8 are those with a high potential of addiction or abuse (such as fentanyl and pethidine), there are different State and Territory regulations as to what type of healthcare professional can write a valid prescription for these types of drugs but, in general, it is limited to specialists in the relevant field or healthcare practitioners that have been granted a license to prescribe Schedule 8 drugs.

11. What is the legal regime for the wholesale distribution of drugs?

Each State and Territory has its own poisons, therapeutic goods and/or controlled substances legislation governing the wholesale distribution of drugs. In general, a person may not supply by wholesale any substance which is for therapeutic use and included in Schedule 2, 3, 4 or 8 of the Poisons Standard unless they hold the requisite license to do so. Also, the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8 (the 'Code') requires wholesalers (defined as persons or organizations, including wholesalers, importers and distributors who store and/or supply by wholesale substances and preparations set out in Schedules 2, 3, 4 and 8) to comply with the Code. In addition, there are other statute law requirements (such as in relation to customs and excise) which must be complied with for the wholesale distribution of drugs.

12. What is the legal regime for the retail distribution of drugs?

The retail distribution of drugs is governed by the relevant State or Territory poisons, therapeutic goods and/or controlled substances legislation. (Please also see the response to question 10.)

13. What is the regulatory authority overseeing wholesale and retail distribution?

Each State and Territory has its own regulatory authority responsible for overseeing the wholesale distribution of drugs as follows: NSW Health, Department of Health (Northern Territory), Queensland Health, ACT Health, Department of Health and Human Services (Victoria), Department of Health and Aging (South Australia) and Department of Health and Human Services (Tasmania).

The regulatory authority that is responsible for overseeing the retail distribution of drugs is performed by the relevant government agency in each State and Territory. Also, the Pharmacy Board of Australia has developed codes, guidelines and policies (such as a Code of Conduct for pharmacists and guidelines on continuing professional development and dispensing of medicines) to provide guidance to pharmacists as to the Board's views and expectations on a range of issues.

China

Pre-condition for distribution

1. **What legal pre-conditions must be satisfied before a drug can be distributed within the jurisdiction?**

According to the Drug Administration Law of the People's Republic of China, drugs to be distributed in mainland China must satisfy the main pre-conditions set out below:

– The drug must hold certain kinds of marketing approvals from the National Medical Products Administration ('**NMPA**'). Drugs imported from other countries to be distributed in China ('**Import Drugs**') must hold an Import Drug License ('**IDL**').

– Drugs must be distributed by qualified enterprises. For Import Drugs, the distributors must hold at least a Drug Distribution Certificate and a Certificate of Good Supply Practice ('**GSP**').

– Certain kinds of drug may be tested by the authority before distribution, including drugs to be marketed in China for the first time.

2. Are there any circumstances in which there are exceptions to the normal pre-conditions (such as an urgent need for the drug)?

Small amounts of drugs which are imported for urgent clinical need and samples or comparator drugs which are required for research or drug registration procedures can be imported and distributed without the IDL, but must have corresponding approval from the NMPA.

Licences and Market Authorisation

3. What are the legal requirements and procedures for authorising a drug for distribution?

Import Drugs which have been granted an Import Drug License are licensed for distribution. The legal structure for obtaining an IDL is set out below:

– **Pre-conditions:**

- The manufacturing process of the drugs must be in strict compliance with both the Chinese and home country Good Manufacturing Practice requirements.

– **Qualified applicants**
  - Foreign drug manufacturing companies must be duly registered in foreign jurisdictions. However, the application should be made through their branch in China or through an appointed domestic agency.

– **Approval procedure**

Clinical trial approval

Imported drugs must undergo clinical trials in order to obtain market approval. Before starting clinical trials, the applicant must apply to the NMPA for approval. The process for doing so is set out below:

- Application for conducting clinical trials filed with the NMPA
- Preliminary review by the NMPA (possible on-site inspection abroad)
- Inspection of samples by the National Institutes for Food and Drug Control ('**NIFDC**')
- Technical assessment by the NIFDC
- Comprehensive evaluation by the Centre of Drug Evaluation ('**CDE**')
- Final inspection by the NMPA
- Approval for Drug Clinical Study issued by NMPA.

Market approval

Upon conclusion of the clinical trial, the CDE will conduct a complete evaluation based on the data and materials obtained from the clinical trials and will then provide its complete evaluation report to the NMPAA for final review and market approval.

If the drug to be imported and marketed in China meets the relevant requirements, the NMPAA will grant an IDL to the applicant.

4. What are the costs and timelines for getting this authorisation?

In practice, the approval procedure for an IDL takes approximately three to five years. Currently, the NMPA is reviewing the drug registration regime, which may shorten the process.

Meanwhile, the NMPA has established a priority review and approval process for orphan drugs, drugs for severe life-threatening diseases without effective treatment measures and drugs which have an apparent clinical advantage. Drugs for which applications have also been made for marketing authorisation in the U.S. or E.U. and have passed local on-site inspections can enjoy this priority process or use the overseas clinical trial data for registration. The priority status of the submitted application, the arrangement of on-site inspection and the testing and the evaluation procedure is expected to shorten the current waiting time and expedite the whole approval procedure.

The total official fee for an IDL for a new drug is 969,900 RMB. This figure includes fees for the clinical trial (376,000RMB) and fees for market approval (593,900 RMB). The registration fee for an imported generic drug that does not need a clinical trial is 367,600 RMB and the registration fee for an imported generic drug that needs a clinical trial is 502,000 RMB.

Please note that the registration procedures for drugs can vary, and the corresponding official fees could change accordingly. Agency fees vary depending on the type of drug.

5. Are there streamlined procedures in certain situations, such as when a drug has already been authorised in another country?

The NMPA will accept overseas clinical trial data for drug registration, allowing for a possible simplification, including exemptions, of the clinical trial process for drug registrations in China.

Where the applicant has conducted early phase clinical trials abroad and then carried out clinical development in China, the applicant should evaluate the clinical trial data obtained in the earlier clinical

trials. If this data is complete, the applicant can communicate with the CDE and submit the data to support the following clinical trials.

For drugs that have conducted all clinical trials abroad but have not yet been marketed, the applicant should submit a complete package of overseas clinical trial data. If the drug has been marketed abroad, the applicant should also submit updated data on safety and effectiveness.

Options for foreign pharmaceutical companies to establish presence

6. What are the options for foreign pharmaceutical companies to establish legal or commercial presence within the jurisdiction?

Generally, life science companies setting up a pharmaceutical business in China may choose to invest either through an existing Chinese company, or by incorporating a representative office.

– **Subsidiary or joint venture**

Joint venture ('JV')

- Equity joint venture ('**EJV**'): An EJV is a Sino-foreign company which is invested in by both foreign and Chinese parties. The parties share profits and bear losses in proportion to their respective equity interest ratio.
- Cooperative joint venture ('**CJV**'): A CJV is a cooperative arrangement between Chinese and foreign investors. This may be in the form of a contract, or a company may be established for these purposes. The parties are permitted to determine the allocation of profits between them, therefore allowing more flexibility. Parties usually choose to establish a CJV when it is agreed that one party shall recover its investment through an accelerated refund scheme.

In practice, EJVs are preferred by foreign companies as the Chinese government has tended to not approve CJVs in recent years.

Wholly foreign-owned enterprise ('WFOE')

- A WFOE is a company that is wholly owned by one or more foreign investors. If there is more than one foreign investor, the parties share profits and bear losses in proportion to their respective equity interest ratio.

– **Representative office**

- A representative office of a foreign enterprise in China is not a separate legal entity in itself, but rather an extension of its parent company. A representative office can be set up relatively quickly with lower costs than other types of business entities.

7. What are the limitations, if any, of each option?

JVs and WFOEs are separate legal persons and are considered to be Chinese entities, and so can partake in all the business activities listed in their business scope that are approved by the relevant authorities.

Representative offices of foreign enterprises are not allowed to carry out any profit-making business activities or to issue invoices. They may only engage in non-profit activities such as business liaisons, marketing or market research. Representative offices are not permitted to recruit Chinese employees directly. Instead, they must engage the services of a human resources service provider, which will then employ Chinese individuals who are sent to work at the representative office on a secondment basis.

Foreign companies can determine which of these three legal entities is most suitable at their discretion.

Wholesale and retail distribution

8. Who is authorised to import foreign drugs into the jurisdiction?

Foreign manufacturing companies may not import foreign drugs or distribute these drugs directly to hospitals and clinics in China, but must instead use a Chinese pharmaceutical company which holds a Business License, Drug Distribution License and GSP Certificate to import the drugs into China.

9. Are drugs separated into any different categories for distribution?

Generally drugs are categorised as either prescription drugs or over-the-counter drugs ('**OTC**', non-prescription drugs) depending on their varieties, specifications, indications, dosage and route of administration. OTC drugs are further divided into two subcategories: '**Type A**' and '**Type B.**' This categorisation refers to the drugs' safety, with Type A OTC drugs considered to be more risky and more strictly regulated by the authorities in the distribution process.

10. Who is authorised to distribute prescription drugs to consumers? Is there a difference between prescription and over-the-counter drugs, or other categories?

– **Prescription drugs**

Drug retailers which hold Drug Distribution Certificates and are staffed with pharmacists can sell prescription drugs listed on the Drug Distribution Certificates to consumers, on the condition that the consumer has provided the prescription from a licensed physician and the pharmacist at the retailer has reviewed and signed such prescription.

– **OTC drugs**

OTC drugs can be sold to consumers without a physician's prescription.

As with the retail of prescription drugs, retailers of Type A OTC drugs must hold a Drug Distribution Certificate and sell the drugs listed on it by a licensed pharmacist.

Other commercial enterprises approved by provincial drug administrations or the drug administrations authorised by them may engage in the retailing of Type B OTC drugs. Such commercial enterprises must be staffed with full-time personnel who are trained and authorised to sell Type B OTC drugs.

11. What is the legal regime for the wholesale distribution of drugs?

The legal regimes regarding wholesale and retail distribution of drugs are generally the same, with the exception of the approval authority.

A drug wholesaler will be subject to approval from, and granted a drug distribution certificate by, the NMPA's local branches at a provincial level. A drug retailer will be subject to approval from, and granted a Drug Distribution Certificate, by, the NMPA's local branches at or above the county level.

Distributors (including both wholesale and retailers) must have a GSP certificate and take effective quality-control measures to meet the requirements of the GSP.

A drug distributor must meet the following requirements to be established:

– Have legally qualified pharmaceutical professionals;
– Have the business premises, equipment, warehouses and hygienic environment required for drug distribution;
– Have the institutions or personnel for quality management for the drugs to be distributed; and
– Have rules and regulations to ensure the quality of the drugs to be distributed.

For the purchase of drugs, drug distributors must establish and apply an examination and acceptance system for the drugs to be purchased, and check the certificate of drug quality and other marks. If a drug fails to meet the prescribed requirements, it cannot be purchased.

When purchasing and selling drugs, drug distributors must keep authentic and complete records of all such purchases and sales.

A drug distributor must establish and apply a system for drug storage, and take the necessary measures to ensure the quality of drugs, such as cold storage, protection against freezing and humidity and the avoidance of insects and rodents. An examination system must be introduced for placing drugs in, and releasing them from, storage.

12. What is the legal regime for the retail distribution of drugs?

Please see question No. 11 for the legal regime regarding retail distribution of drugs.

Drug retailers must sell drugs correctly and provide a clear description of usage, dosage and cautions. Prescriptions being dispensed must be checked, and no drugs listed in the prescription may be changed or substituted without authorisation. They must refuse to dispense incompatible or over-dose prescriptions but, when necessary, they may do so only after a correction or re-signing by the prescribing physicians.

13. What is the regulatory authority overseeing wholesale and retail distribution?

– The NMPA and its provincial branches are the main administrative authority for supervising wholesale and retail distribution in their respective geographic districts. NMPA and its provincial branches review and approve certificates for drug distribution, inspect the business of distributors and publish information about the illegal behaviors distributors commit.
– The State Administration for Market Regulation ('**SAMR**') and its local branches, can also supervise drug distribution activities from a marketing perspective within their respective geographic districts.
– The State Council of the PRC ('**State Council**') and local government departments, which are responsible for almost all civil and criminal affairs in their respective geographic districts, also have overall supervision rights regarding drug distribution.

14. Are there any specific requirements for the distribution of drugs online?

Only manufacturing or trading companies which are specifically life science companies are authorised to offer drugs and medical devices for sale online.

A company may either use a third party's website or set up its own website. If the company uses a third-party online service, the third party must hold a valid Certificate for Online Pharmaceutical Trading Service granted by the NMPA. If the company sets up its own website for online sales, it must record its details with the provincial drug administration.

In addition to the above, pharmaceutical trading companies engaging in online sales to end consumers must also maintain an online enquiry service operated by licensed pharmacists.

Currently, prescription drugs are not allowed to be distributed online. However, the restriction may be relaxed in the near future. The State Council has issued a guideline where a licensed physician writes a prescription online and the pharmacist at the retailer has reviewed and signed such prescription, the retailer can entrust a qualified third party to deliver the drugs which may be prescription drugs.

Please note that the reform of online drug distribution is currently under discussion and there could be a different legal regime in the future.

15. Are there any specific regimes applied in the drug distribution process, such as the tendering scheme with hospitals?

China has adopted a statutory tendering scheme applicable to the purchase of drugs by state-sponsored hospitals, which currently purchase most of the drugs distributed in the Chinese market.

There are two forms of tender: public tender and selective invitational tender. A public tender means that the purchaser, through a public announcement, invites all qualified bidders to bid. A selective invitational tender means that the purchaser only notifies selected bidders of the tendering process.

India

Pre-conditions for distribution

1. **What legal pre-conditions must be satisfied before a drug can be distributed within the jurisdiction?**

The manufacture and distribution of drugs in India is governed by the Drugs and Cosmetics Act, 1940 ("**Act**") and the Drugs and Cosmetics Rules, 1945 ("**Rules**"). At the central level, the Central Drugs Standard Control Organization ("**CDSCO**"), headed by the Drug Controller General of India ("**DCGI**"), is the body empowered to ensure compliance with the Act and Rules.

At the state level, bodies have been empowered as drug control authorities and are responsible for specific matters under the Act and Rules, i.e., the granting of wholesale and retail trading licenses, for setting up manufacturing facilities, etc.[1]

The Rules inter alia lay down the process for importing and manufacturing drugs for sale and distribution in India. They provide for different treatments for drugs depending on the end-use of such drug and the manner of sale, i.e., drugs for personal use, wholesale/retail trade, etc.

The general classification of drugs is as follows:[2]

– Non-scheduled Drugs which do not fall in the below categories
– Schedule C Drugs
– Schedule C1 Drugs
– Schedule X Drugs

The process of distribution of a drug in India requires procuring certain licenses depending on the nature of the drug i.e., whether it is classified as a drug[3] or as a new drug4.

[1] **KCO Comment**: The Rules empower state governments to appoint licensing authorities for specified activities and they may prescribe additional rules. This questionnaire, however, has restricted itself to the Act and Rules made thereunder.
[2] **KCO Comment**: This questionnaire will restrict itself to non-scheduled drugs (i.e., those drugs not falling under Schedules C, C1 or X) and general licensing procedures involved thereunder because varying procedures for different categories have been prescribed. Answers have been provided with regards to scheduled drugs as and when required. We have excluded homeopathic, Ayurvedic and Unani drugs from the purview of this questionnaire.
[3] **KCO Comment**: Section 3(b) of the Act defines the term "drug" broadly to include medicines for internal and external use, substances (other than food) affecting the structure or function of the human body, all substances intended for use as components of a drugs and notified medical devices.
[4] **KCO Comment**: Section 122E of the Act defines the term "new drug" to inter alia include drugs not approved by the CDSCO, approved drugs now proposed to be marketed with modified/new claims, fixed dose combination which consists of approved drugs now proposed to be combined in a fixed ratio for the first time. A new drug shall continue to be considered as a new drug for a period of 4 (four) years from the date of its first approval from the CDSCO.

The general procedures[5] applicable to both scenarios have been specified below.

Import of drugs

Any drug to be imported into India must be registered with the CDSCO prior to import along with the site on which the drug is manufactured. For new drugs, however, a new drug approval[6] is required from the CDSCO even prior to, inter alia, submitting an application for registering the premises where such new drug is proposed to be manufactured or for the import of such new drug.

For importing drugs, a comprehensive process which primarily revolves around the manufacturer procuring an import license, a registration certificate, and a wholesale license (the requirement to have a wholesale license can be done away with if the manufacturer's agent possesses a wholesale license), has to be undertaken. The wholesale license is to be procured from the state agencies empowered in this regard.

Some important aspects of the process of importing drugs are set forth below:

– As per the Rules pertaining to import, the term "**manufacturer**" of drugs includes a company/unit outside India having its drug manufacturing facilities duly approved by the National Regulatory Authority of that country, and which has a free sale approval of drugs approved by the said authority in the concerned country, and/or in other major countries.
– Further, when granting an import license, the licensing authority will bear in mind whether the premises for the storage of imported drugs are adequately equipped for the same. The occupation, trade or business carried out ordinarily by the applicant is also considered by the licensing authority while deciding to grant the import license.
– Further, the licensing authority may ask the applicant to furnish, either before or after the granting of a license, documentary ownership/occupation evidence or any relevant matter specified by the applicant.
– Other major legal pre-conditions found in this process include the submission of specified information and signing certain undertakings. Accordingly, with respect to the registration certificate, Schedules D(I), D(II), D(III) state the list of information to be submitted with the application. This, inter alia, includes:
    - general information of the manufacturer, the list of countries where marketing authorization or import permission for the said drug is granted (with authorization enclosed) or canceled/withdrawn/pending, biological and pharmaceutical information of drugs, etc.;
    - details of manufacturing premises, proprietors/directors, authorized agent, brief profiles of the manufacturer's business activity domestically and globally and its research activity, duly notarized copies of plant master file and plant registration/approval certificate issued by the Minister of Health/National Regulatory Authority of the foreign country concerned; and
    - particulars of drugs (which are to be registered) and copy of good manufacturing practice certificates issued by foreign National Regulatory Authority are also to be provided.

Further, other conditions as found in the Act, Rules and the licenses have to be complied with at all times.

Distribution of drugs

The permissions required to "sell, stock, exhibit, offer for sale or distribute" drugs are offered jointly as one license (hereinafter referred to as "**sell and distribute**"), common across domestic and foreign manufactured drugs. A wholesale license to sell and distribute drugs has to accompany the import license application.

[5] **KCO Comment**: The process of domestically manufacturing drugs has not been dealt with in this questionnaire.
[6] **KCO Comment**: New drug approval applications need to be filed with results of the clinical trial, conducted with prior permission along with the prescribed fees.

2. Are there any circumstances in which there are exceptions to the normal pre-conditions (such as an urgent need for the drug)?

Schedule D provides for certain substances to which the normal procedure pertaining to import specified above will not apply or will apply to the extent specified in the said schedule. The listed substances include, *inter alia*, certain substances not intended for medical use, and specified substances used as both food and drugs (such as oats and related cereal preparations, condensed milk powder, chicken essence and also drugs and cosmetics imported for manufacture and exports by units situated in special economic zones).

Similarly, Schedule K provides for certain exemptions from the standard manufacture, sale and distribution process, from specified provisions of the Act and Rules, to the extent specified therein.

As stated in answer 1 above, the process of distribution of foreign drugs (including new drugs) begins with the import of such drugs. While distribution does not specifically have any exceptions, the import process does provide for certain exceptions as follows:

– In the event of an emergency, the licensing authority may, with the Central Government's approval, issue an import license without requiring the registration certificate after recording of the reasons for the same. Further, a separate provision exists for eliminating the requirement of procuring a registration certificate for import licenses pertaining to in-vitro diagnostic kits and reagents, except for certain specified kinds.
– Similarly, registration certification, which is normally to be provided within nine months of applying, can be provided within three months for certain exceptional circumstances.
– No registration certificate is required for inactive bulk substances to be used for a drug formulation with or without pharmacopoeial conformity.
– With respect to new drugs, the licensing authority may dispense with the submission of local clinical trial results, on the basis of data from foreign countries, in public interest.
– Similarly, new drugs which have been approved and marketed for several years in other countries may be exempted from or conditions may be relaxed for submission of certain data, if there is adequate public evidence regarding the safety of the drug.

Licenses and market authorization

3. What are the legal requirements and procedures for authorizing a drug for distribution?

The legal structure for licensing a drug involves procuring an import license (whereby the said drug is to be imported into India), a registration certificate and a wholesale license to sell and distribute drugs. The import license and registration certificate are issued by the CDSCO while the wholesale license has to be obtained from the state agencies empowered in this regard.

4. What are the costs and timelines for getting this authorization?

The timelines and major costs have been stated below:

Import license costs

– License fee of INR 1,000 and an additional fee of INR 100 per additional drug
– Import license, upon fulfillment of all rules and filings, is typically granted within 45 days
– Import license is valid for 3 years

A request for permission to import a new drug can be made under Form 44 accompanied by a fee of INR 50,000.

Registration certificate

- Registration fee for premises manufacturing a drug intended for import is approximately USD 1,500
- Registration fee for a single drug (and every additional drug) is approximately USD 1,000
- Fee for inspection/visit to manufacturer's premises by licensing authority is approximately USD 5,000
- Registration certificate is to be granted by the licensing authority upon the fulfillment of all conditions in a span of nine months. In exceptional circumstances, it can be granted within three months.
- Registration certificate is valid for 3 years

5. Are there streamlined procedures in certain situations, such as when a drug has already been authorized in another country?

With respect to new drugs, the licensing authority may dispense with the submission of local clinical trial results, on the basis of data from foreign countries, in public interest. Similarly, new drugs which have been approved and marketed for several years in other countries, may be exempted or have submission requirements of certain data relaxed if there is adequate public evidence regarding the safety of the drug.

Options for foreign pharmaceutical companies to establish presence

6. What are the options for foreign pharmaceutical companies to establish legal commercial presence within the jurisdiction?

The options available for a foreign pharmaceutical company to establish legal/commercial presence in India would depend upon its business objectives. We have briefly discussed the various options available hereunder.

To establish its presence as a foreign company in India, a liaison office or a branch office can be set up, subject to applicable Indian exchange control regulations.

A liaison office is restricted to liaising activities and cannot undertake business or earn any income in India. It is primarily in place to gather information for possible market opportunities and to inform prospective Indian customers about their company and their products. A branch office, on the other hand, can engage in the export/import of goods, rendering of professional services, representation of the parent company and can act as their agent for buying and selling, etc. However, a branch office is not allowed to undertake retail trading and manufacture or processing activities in India.

If the foreign company wishes to carry out business in India, it would be required to set up a business vehicle in India, such as an Indian company under the Companies Act, 2013 or a limited liability partnership under the Limited Liability Partnership Act, 2008.

Currently in the pharmaceutical sector, 100% foreign direct investment ("**FDI**") is permitted in greenfield projects and up to 74% can be made under brownfield via the automatic route. Investment can be made beyond 74% in brownfield via the government route, i.e., with the prior approval of the government of India. The liberalization of brownfield investment allows for mergers and acquisitions among Indian and foreign companies in a very realistic timeframe via the automatic route.

Though FDI investment in the pharmaceutical sector has been liberalized to a large extent, the FDI Policy imposes certain restrictions on the terms that can be contractually agreed upon between Indian and foreign companies in brownfield projects, i.e., non-compete clauses cannot be agreed upon without prior permission of the Government.

Further, while granting approval under brownfield, the government may include additional requirements that must be met. Also, production levels of medicines on the National List of Essential Medicines have to be maintained for five years and research and development expenditure has to be maintained over five years.

7. What are the limitations, if any, of each option?

The limitations of each option and the suitability of a particular option or mode of entry into India, or the selection of business presence in the country, would depend on the business objectives and end goals of the incumbent. Broadly speaking, the extent of commercial activity that a branch or a liaison office can perform in India is quite restricted, for instance, manufacturing of any kind is not permitted by a branch office or a liaison office and is permissible through an Indian legal entity.

Wholesale and retail distribution

8. Who is authorized to import foreign drugs into the jurisdiction?

As specified in answer 1, a manufacturer of drugs or its authorized agent, upon completion of the import processes, is authorized to import drugs into India. The applications for the same have to be made either by the manufacturer of the drug or its authorized agent.

9. Are drugs separated into any different categories for distribution?

The licensing (which includes licensing for distribution) for drugs is broadly divided as follows:

– Schedule C, C1 and X drugs (license to sell and distribute has been clubbed together)
– Drugs other than Schedule C, C1 and X.
– Homeopathic drugs
– Ayurvedic (including Siddha) or Unani Drugs

While the Act requires all drugs to be sold under a license (and in accordance with its conditions), additional requirements are prescribed for certain drugs (Schedule H, H1 and X). They can be sold only upon the submission of a prescription from a registered medical practitioner. Non-prescription drugs can be sold over the counter.

Schedule K drugs have been exempted from certain conditions (as mentioned therein) relating to distribution, e.g., persons selling quinine and anti-malarial drugs under arrangements made by state governments for sale and distribution are exempt from taking certain retail licenses.

10. Who is authorized to distribute drugs to consumers? Is there a difference between prescription and over-the-counter drugs, or other categories?

Schedule H, H1 and X drugs can be sold only upon the basis of a registered medical practitioner's prescription by or under the personal supervision of a registered pharmacist. Drugs which do not need a prescription can be sold over the counter.

11. What is the legal regime for the wholesale distribution of drugs?

Wholesale licenses for sale and distribution are given by state authorities subject to filing specified forms with prescribed fees and meeting legal pre-conditions specified under the Act, Rules and the license itself. One of the major requirements is having premises of at least 15 square meters under the charge of a competent person7. Further, the licensing authority has to be satisfied that the premises are adequate and

[7] **KCO Comment**: A "competent" person in relation to a wholesale license is a person who meets any of the following criteria:
(i) is a registered pharmacist;
(ii) has passed the matriculation examination or its equivalent examination from a recognized board with four years' experience in dealing with sale of drugs; or
(iii) holds a degree from a recognized university with one years' experience in dealing with drugs.

equipped with proper storage accommodation for preserving the properties of the drugs ("**adequacy of premises**").

The wholesale license also specifies certain conditions, i.e., no drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer. Further, no sale of any drug can be made to a person not holding the requisite license to sell and distribute the drug.

12. What is the legal regime for the retail distribution of drugs?

The legal regime of retail drug distribution is similar to wholesale licensing. Accordingly, the licensing authority should be satisfied as to the adequacy of the premises, which shall be at least 15 square meters and under the charge of a person competent in the eyes of the authority to supervise and control the sale of drugs. The supply by retail of any drug must be made against a cash or credit memo containing prescribed information and carbon copies of such memos should be maintained. Sale of Schedule C, C1 and X mandates more intensive documentation by the sellers inter alia.

In order to run a pharmacy8, further requirements of Schedule N must be met. The requirements include the specifications pertaining to its premises, furniture, apparatus, books, etc.

13. What is the regulatory authority overseeing wholesale and retail distribution?

The CDSCO and state agencies empowered in this regard are the regulatory authorities supervising wholesale and retail distribution activities.

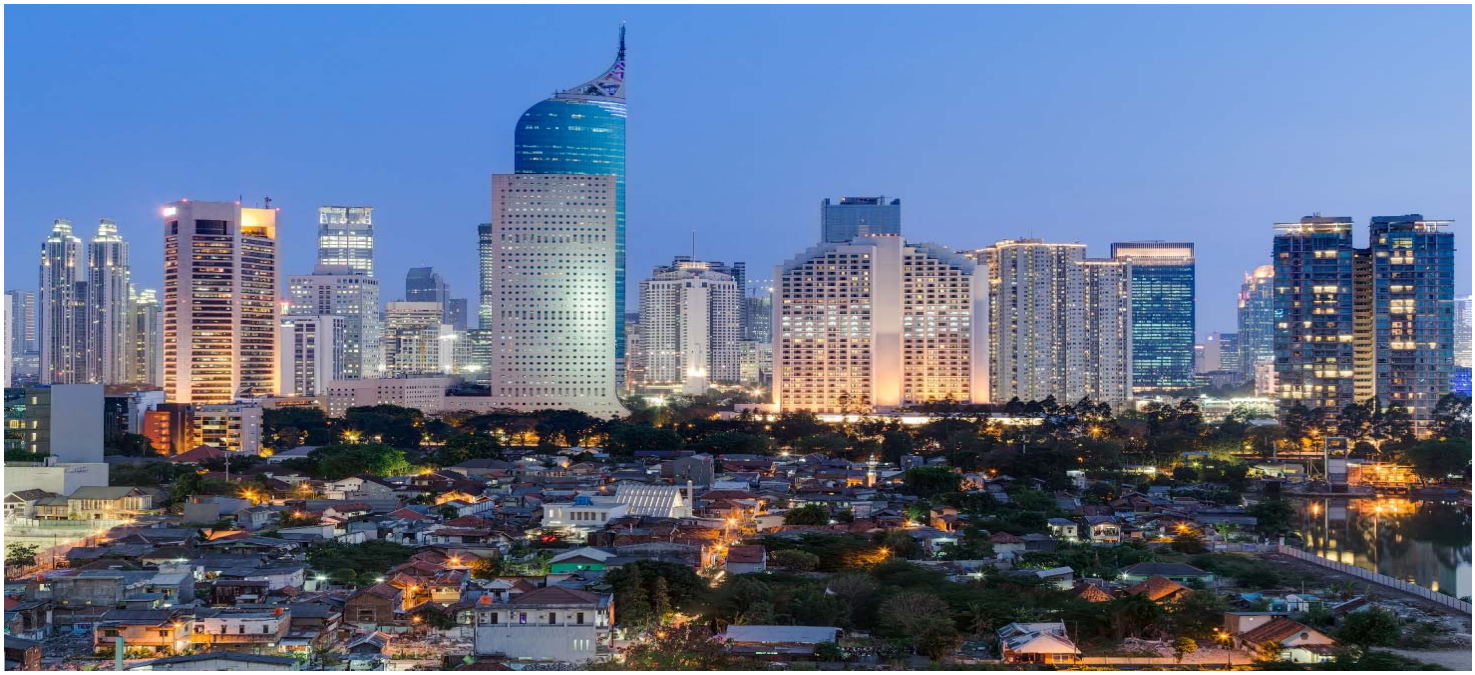
14. Are there any specific requirements for the distribution of drugs online?

There are no specific requirements for distribution of drugs online. Those who sell drugs online have to comply with provisions of the Act and the Rules at all times. However, due to the nature of transactions involving online drug sales, there is ambiguity surrounding the exact compliances required for online transactions and the extent of permissible activities of drug distribution online. It is understood that the Indian Government is planning to establish a legal framework for online sale of drugs in the near future.

15. Are there any specific regimes applied in the drug distribution process, such as the tendering scheme with hospitals?

There are specific regimes applicable in the distribution process, like those applicable to certain drugs including those specified in Schedule K. For example, drugs supplied by a hospital or dispensary maintained or supported by the government or local body are exempted by Schedule K from complying to certain rules relating to sale, to the extent provided thereunder.

[8] **KCO Comment** As per the Rules, licensees who employ the services of a Registered Medical Practitioner and maintain a pharmacy for compounding against prescriptions are considered to be operating a pharmacy. On the other hand, licensees who do not require the services of a medical practitioner are considered to be operating a "drugstore".



Indonesia

Pre-conditions for distribution

1. What legal pre-conditions must be satisfied before a drug can be distributed within the jurisdiction?

Pursuant to the Regulation of the Minister of Health No.1010/Menkes/Per/XI/2008 as amended by No. 1120/Menkes/Per/XII/2008 on the Registration of Drugs ('**RMOH 1010/2008 as amended**') and the Regulation of the Head of the National Agency of Drugs and Food Control/*Badan Pengawas Obat dan Makanan* ('**BPOM**') No.HK.03.1.23.10.11.08481 on the Criteria and Guidelines of Drug Registration ('**BPOM Regulation No. HK.03.1.23.10.11.08481**'), any drugs to be distributed within the Indonesian territory must first be registered in order to obtain marketing authorization (MA)/*Izin* Edar.

The application to obtain the MA/*Izin* Edar must be submitted to BPOM as it is the government body that has the authority to conduct an evaluation and assessment on drugs that will be distributed in Indonesia.

2. Are there any circumstances in which there are exceptions to the normal pre-conditions (such as an urgent need for the drug)?

Drugs that are used for special purposes are exempted from the registration requirement, and they include:

- Drugs as requested by physicians;
- Donated drugs;
- Drugs for clinical sampling; and
- Sample drugs

Licences and Market Authorisation

3. What are the legal requirements and procedures for authorizing a drug for distribution?

RMOH 1010/2008 as amended provides that a drug to be distributed in Indonesia must be registered with BPOM. The BPOM will issue an MA/*Izin* Edar, if the drug meets the following criteria:

- Procedure brings benefits and is safe, as proven through animal testing and clinical examination trials or other scientific evidence;

– Its quality fulfills the requirements of, and its production is in accordance with, good drug manufacturing practices/*Cara Pembuatan Obat Yang Baik* ('**CPOB**') as provided for by the Decree of the Head of BPOM No. HK.00.05.3.02152 of 2002;
– The relevant product information contains complete and objective information to ensure its correct, rational and safe use; and
– It satisfies a public need.

4. What are the costs and timelines for getting this authorization?

Registration documents are to be submitted to the BPOM together with the official fee. A drug produced in Indonesia (whether for domestic use or for export) must be registered by the relevant pharmaceutical producer (which must have an industrial business license).

An imported medicine needs to be registered by a domestic pharmaceutical producer that has obtained written approval from the foreign pharmaceutical producer. The written approval must provide for a transfer of technology so that the drug can be produced locally within a five-year period, except if it is patented. The foreign pharmaceutical producer must also comply with the CPOB, as evidenced by relevant documents or an inspection by the Indonesian authorities. The documents must be attached to the application, together with the latest data on inspections conducted by the relevant local authorities (that is, for at least the last two years). The BPOM either approves or rejects the application for the MA/*Izin* Edar based on the recommendation of the committees. The BPOM reports the issuance of MAs/*Izin* Edar to the Ministry of Health annually. If the registration is rejected, the applicant is allowed to submit a request for re-examination.

Once an MA/*Izin* Edar has been issued, the holder must produce/import and circulate the drug within one year from the date of issuance.

Pursuant to Government Regulation No. 48 of 2010 on Applicable Non-Tax State Revenue in the BPOM, the costs of obtaining a license ranges from IDR 50,000 to IDR 30,000,000 per drug, depending on the type of drug that will be registered.

5. Are there streamlined procedures in certain situations, such as when a drug has already been authorized in another country?

There is no simplified procedure for drugs that have already been approved in other jurisdictions. The drugs must still be registered with and obtain an MA/Izin Edar from the BPOM.

Options for foreign pharmaceutical companies to establish presence

6. What are the options for foreign pharmaceutical companies to establish legal commercial presence within the jurisdiction?

For the purpose of engaging in business in Indonesia, a foreign pharmaceutical company may decide between two forms of incorporation, which are establishing (i) a representative office, or (ii) a local subsidiary in the form of a foreign direct investment company that engages in the pharmaceutical industry.

7. What are the limitations, if any, of each option?

With regards to the representative office, it is limited to act as a supervisor, connector or coordinator of the foreign company or its affiliates in Indonesia. Further, it will not be able to act as a business entity and, consequently, it will not be able to enter into agreements, deeds, etc., or gain any profit from Indonesian customers. In case a foreign pharmaceutical company intends to establish a representative office in Indonesia, any sale of a product may only be undertaken between the foreign company and the Indonesian customers.

As for the establishment of a foreign direct investment company, there is a limitation under the current Negative Investment List, which is regulated by Presidential Regulation No. 39 of 2014 ('**GR 39/2014**'). Under GR 39/2014, the maximum foreign ownership in a foreign direct investment company that engages in the pharmaceutical industry is 85%

Wholesale and retail distribution

8. Who is authorized to import foreign drugs into the jurisdiction?

Pursuant to RMOH 1010/2008 as amended, the domestic pharmaceutical industry is authorized to import foreign drugs into Indonesia. Further, the importer must obtain written approval from the foreign pharmaceutical industry in order to have the imported drugs registered in Indonesia

9. Are drugs separated into any different categories for distribution?

There are three main categories of drugs:

– Over-the-counter drugs;
– Hard drugs (or prescription drugs); and
– Narcotic and psychotropic drugs.

10. Who is authorized to distribute drugs to consumers? Is there a difference between prescription and over-the-counter drugs, or other categories?

– Prescription drugs

Pharmacies, hospital pharmacies, clinics and community health centers/*pusat kesehatan masyarakat* (Puskesmas) are authorized to distribute prescription drugs directly to customers.

– Over-the-counter drugs

Over-the-counter drugs can be distributed by pharmacies and drug stores.

11. What is the legal regime for the wholesale distribution of drugs?

Under the Regulation of Minister of Health No. 1148/Menkes/Per/VI/2011 on Large Pharmaceutical Distributors, the wholesale distribution of drugs is carried out by 'large pharmaceutical distributors' (*Pedagang Besar Farmasi*), which must secure a license issued by the Ministry of Health, specifically the Director General of Pharmaceutical and Medical Equipment ('**DGPM**'). The license is valid for five years and can be extended if certain requirements are fulfilled. In addition, only a limited liability company or cooperation can apply for such license.

Pharmaceutical producers and pharmaceutical wholesalers cannot sell drugs to end customers. However, they are allowed to sell the drugs to other large pharmaceutical distributors, pharmacies, hospital pharmacies, clinics, drug stores and community health centers/*pusat kesehatan masyarakat* (Puskesmas).

According to the Negative Investment List, a large pharmaceutical distributor is closed to foreign investment.

12. What is the legal regime for the retail distribution of drugs?

The retail distribution of drugs is regulated under the Regulation of the Minister of Health No. 167/Kab/B.VII/72 as amended by the Decree of Minister of Health No. 1331/Menkes/SK/X/2002 on Drug Retailers. Pursuant to this regulation, a drug retailer must obtain a drug retailer license, which is issued by the Head of the Health Agency at the regency level. The Health Agency is required to submit a copy of the license to the Minister of Health, the Health Agency at the provincial level and the BPOM. Moreover, a

drug retailer is required to employ an assistant pharmacist as the person who is responsible in conducting the business. A drug retailer is prohibited to receive prescription drugs.

Under the prevailing regulation, retail business is closed to foreign investment.

13. What is the regulatory authority overseeing wholesale and retail distribution?

The Ministry of Health periodically carries out inspections to protect the public from possible dangers posed by drugs that are distributed in the market. If the inspection findings do not satisfy the quality, safety and/or benefit requirements, the MAs/*Izin* Edar can be revoked, and the product must be withdrawn from circulation by the producer/importer and be destroyed. The Ministry of Health is required to inform the general public in such cases.

In addition, the BPOM is authorized to supervise the manufacture and distribution of drugs in Indonesia. The BPOM's supervision is mainly implemented through periodical reports submitted by large pharmaceutical distributors.

14. Are there any specific requirements for the distribution of drugs online?

Law No. 7 of 2014 on Trade ('**Trade Law**') stipulates that an entrepreneur that intends to market or trade any goods and/or services using an electronic system is required to provide complete and accurate data and information regarding the traded goods and/or services which must contain at least:

– The identity and legality of the entrepreneur as a producer or distributor of the goods;
– The technical conditions of the goods and/or services;
– The price and payment method; and
– The delivery method to the customer.

Moreover, under government regulation No. 82 of 2012 on the Operation of Electronic Systems and Transactions, it is possible in the electronic transaction that the distributor/merchant creates an electronic contract with its customer as the evidence of sale and purchase of goods. Such electronic contract must contain at least:

– The object of the contract;
– The conditions of the electronic transaction;
– The price and other fees incurred;
– The procedure in the event of cancellation by the parties;
– A provision which entitles the aggrieved customer to be able to return the goods and/or request a replacement of product due to hidden defects; and
– A dispute settlement clause in the electronic transaction.

It should be noted that online distribution/marketing of drugs may only be conducted by parties that have obtained licenses from the BPOM, such as pharmacies or drug stores.

15. Are there any specific regimes applied in the drug distribution process, such as the tendering scheme with hospitals?

Yes, large pharmaceutical distributors/pedagang besar farmasi must comply with the good drug distribution practices/Cara Distribusi Obat Yang Baik ('**CDOB**') under the Regulation of the Head of BPOM No. HK.03.1.34.11.12.7542 Tahun 2012 on Technical Guidelines of Good Drug Distribution Practices.

The CDOB is a drug distribution guideline which aims to ensure that the quality of the drugs and/or ingredients in the drugs is maintained during the chain of distribution in accordance with the condition and purpose of use. The CDOB applies to aspects of procurement, storage, distribution and return of drugs.

Japan

Pre-conditions for distribution

1. What legal pre-conditions must be satisfied before a drug can be distributed within the jurisdiction?

The marketing of pharmaceuticals requires that each individual product receive the approval of the Minister of Health, Labor and Welfare ("**MHLW**"). After the required tests related to the quality, effectiveness and safety of the pharmaceuticals have been conducted, approval of the marketing of each individual product must be received from either the MHLW or the prefectural governor before marketing of the pharmaceutical may be carried out. In order to receive approval for marketing each manufactured item, the licensed place of manufacture must, among other things, be in compliance with the Good Manufacturing Practice ("**GMP**") regulations which provide the standards for (i) the building facilities necessary for the item to be manufactured, (ii) manufacturing management for each manufactured item and (iii) quality management.[9]

With regard to the sale and provision of pharmaceuticals that have received marketing approval, it is necessary to have both (1) the license for marketing from the MHLW and (2) a license for sale of pharmaceuticals from the prefectural governor in order to conduct the same as a business. The license for sale of pharmaceuticals has the following categories: (1) store-based distribution (sale and provision in a shop of "**face-to-face selling**" OTC pharmaceuticals and OTC pharmaceuticals); (2) household distribution (sale and provision through distribution of OTC pharmaceuticals); (3) wholesale sales (sale or provision of pharmaceuticals to proprietors of pharmacies, pharmaceutical marketing authorization holders, manufacturers and marketers of pharmaceuticals, or hospitals, clinics, and others as specified by ordinance of the MHLW). The license for sale of pharmaceuticals is valid for a period of 6 years.[10]

2. Are there any circumstances in which there are exceptions to the normal pre-conditions (such as an urgent need for the drug)?

Pharmaceuticals that are expected to have extremely high effectiveness with a major effect upon the lives of those patients suffering from serious illnesses due to having a functional mechanism that differs from

[9] Article 14, Paragraph 2 of the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the "Pharmaceutical and Medical Devices Law")
[10] Articles 24 and 25 of the Pharmaceutical and Medical Devices Law

previously approved pharmaceuticals are designated as items subject to the "**Priority Approval System**", and are handled with priority in consultations and evaluations related to pharmaceutical approval.[11]

Also, in order that pharmaceuticals designated as Orphan Pharmaceuticals may be provided for actual use in medical treatment as soon as possible, these may be given priority over other pharmaceuticals in the approval process.[12]

Licenses and market authorization

3. What are the legal requirements and procedures for authorizing a drug for distribution?

In order to receive marketing approval from the MHLW and the prefectural governor, pharmaceuticals must undergo required evaluation of their quality, effectiveness, and safety based on the clinical test data for each individual pharmaceutical product.

Evaluation of pharmaceuticals is primarily handled by the Pharmaceutical and Medical Devices Agency (the "**PMDA**"). Evaluation involves, among other things, a credibility review, in which the content of the materials submitted is evaluated for ethical and scientific credibility; the approval review, in which the effects, side effects, and quality of the product submitted for review are evaluated based on the current scientific and technical standards considering the result of the credibility review; and the GMP/Quality Management System ("**QMS**")/Good Gene, Cellular, and Tissue-based Products Manufacturing Practice ("**GCTP**") reviews, which are evaluations as to whether the applicant has the ability to manufacture the product submitted for review.[13]

4. What are the costs and timelines of obtaining licenses?

While this depends on the category and nature of the pharmaceutical in question, in general, for a new pharmaceutical, the time required from the submission of the marketing application to receipt of the marketing approval is 1 year.[14] Also, the fees for the evaluations of a new pharmaceutical, including evaluation of the pharmaceutical's compliance, will cost from JPY 10 million to JPY 50 million.[15]

5. Are there streamlined procedures in certain situations, such as when a drug has already been authorized in another country?

It is permitted to substitute overseas clinical trial data for data on clinical trials in Japan, which leads to speeding up of the clinical testing as well as shortening the time for approval by the PMDA. Where data from overseas clinical testing is used, in order to avoid domestic duplication of the tests, and to confirm that the results can be reproduced with Japanese patients, so-called "**bridging tests**" are conducted, and it is possible for approval evaluations of the pharmaceutical to be carried out based on the results of such tests.[16]

Additionally, even with the use of overseas clinical testing data, in an effort to keep pace with the pharmaceutical sales in foreign countries and to further eliminate the problem of "**drug lag**", the Japanese government recommends carrying out international joint clinical trials.[17] Due to the recent increase in international joint clinical trials, it has become possible for Japanese development times to match those of foreign countries, with the result being a reduction in the difference between Japanese approval times and those of other countries.[18]

[11] https://www.mhlw.go.jp/seisakunitsuite/bunya/kenkou_iryou/iyakuhin/topics/tp150514-01.html
[12] Article 14, paragraph 7 of the Pharmaceutical and Medical Devices Law
[13] https://www.pmda.go.jp/review-services/drug-reviews/0001.html
[14] https://www.pmda.go.jp/review-services/drug-reviews/about-reviews/p-drugs/0014.html
[15] https://www.pmda.go.jp/files/000217764.pdf
[16] http://www.nihs.go.jp/mss/ICH-E5.pdf
[17] https://www.pmda.go.jp/files/000157000.pdf
[18] https://www.jstage.jst.go.jp/article/fpj/139/1/139_1_22/_pdf

6. What are the options for foreign pharmaceutical companies to establish a legal or commercial presence within the jurisdiction?

In order for foreign pharmaceutical marketing companies to sell pharmaceuticals in Japan, one option is to sell the rights related to such pharmaceuticals to a domestic Japanese pharmaceutical marketing company or to delegate sales to a Japanese pharmaceutical marketing company.

Another option for foreign pharmaceutical marketing companies that do not have an office in Japan is to designate a company that has a marketing authorization for pharmaceuticals to fill the role of being responsible for safety management after marketing in Japan ("**designated marketing authorization holders**"), and then after obtaining a license for marketing and approval, it is possible to sell its own products by itself.[19]

7. What are the limitations, if any, of each option?

Whether a foreign pharmaceutical company (1) sells the rights to a pharmaceutical to a Japanese pharmaceutical marketing company; or (2) delegates the sales to a Japanese pharmaceutical marketing company, the foreign manufacturing facility where such pharmaceutical is manufactured must meet the Japanese standards of licensing for manufacture, and must receive accreditation as a foreign manufacturer of pharmaceuticals [by the MHLW].[20]

Wholesale and retail distribution

8. Who is authorized to import foreign drugs into the jurisdiction?

In order to import pharmaceuticals into Japan, a marketing business license from the MHLW is necessary.[21]

9. Are drugs separated into any different categories for distribution?

Pharmaceuticals are categorized by their use and means of supply as follows:[22]

- **Pharmacy-only pharmaceuticals**: Pharmaceuticals other than "**face-to-face selling OTC pharmaceuticals**" and "**OTC pharmaceuticals.**" These include prescription pharmaceuticals (pharmaceuticals that are provided for the purpose of being used by physicians or dentists, or used by prescription from a physician or dentist.)
- **Face-to-face selling OTC pharmaceuticals**: Pharmaceuticals without any significant action on the human body in terms of efficacy, that must be sold face-to-face by a pharmacist, because it will be used based on a selection by the consumer based on information received from the pharmacist, and so that it may be used properly. Examples of face-to-face selling OTC pharmaceuticals would be so-called "**powerful drugs**" and pharmaceuticals that were previously only sold by prescription but have recently been approved for OTC sales.
- **OTC pharmaceuticals**: Pharmaceuticals without any significant action on the human body in terms of efficacy, and which are used after selection by a consumer based on information from a pharmacist, etc. OTC pharmaceuticals are divided into categories based on the level of risk: Type 1 pharmaceuticals (particularly high risk); Type 2 pharmaceuticals (comparatively high risk); and Type 3 pharmaceuticals (comparatively low risk).

Also, because some pharmaceuticals have a high degree of toxicity, strong side effects, or can be habit-forming or cause dependence, from the perspective of safety, they are classified and regulated by the Pharmaceutical and Medical Devices Law and the Stimulants Control Act, among others. Additionally,

[19] Article 19-2 of the Pharmaceutical and Medical Devices Law
[20] Article 13-3 of the Pharmaceutical and Medical Devices Law
[21] Article 2, paragraph 13 and Article 12 of the Pharmaceutical and Medical Devices Law
[22] Article 25 of the Pharmaceutical and Medical Devices Law

there are classifications and regulations related to biotechnology-derived products ("**Biological Products**") and Regenerative Medicine Products, among others.

10. Who is authorized to distribute prescription drugs and over-the-counter drugs to consumers?

Prescription pharmaceuticals

Other than pharmaceutical marketing companies, parties who have not received a license for wholesale distribution may not sell pharmaceuticals, including prescription pharmaceuticals, to pharmacy proprietors, pharmaceutical marketing authorization holders, manufacturers, sellers, or hospitals, or proprietors of clinics or medical facilities for human-reared animals.23

Also, proprietors of pharmacies or sellers of prescription pharmaceuticals must not, without a justifiable reason, sell or provide prescription pharmaceuticals to any person who has not received a prescription from a physician, dentist, or veterinarian.24

OTC pharmaceuticals

Among OTC pharmaceuticals, face-to-face selling pharmaceuticals may not be sold from a shop except by those parties who have received a license for store-based distribution. These licenses for store-based distribution are granted separately for each individual shop by the prefectural governor for the place where the relevant shop is located.25

Other OTC pharmaceuticals may not be sold or provided from a shop by those who do not have a license for store-based distribution, and they may not be distributed to households by those who have not received a license for household distribution. The license(s) for household distribution are granted by the prefectural governor for each area where the distribution is to take place.26

11. What is the legal regime for the wholesale distribution of drugs?

The license for wholesale distribution of drugs is granted by the prefectural governor for the place where the business establishment is located, for each business establishment.[27] In order to receive a license for wholesale sales, the primary requirement is to satisfy the following four conditions:[28]

– the buildings and facilities making up such business establishment are in compliance with standards established by ordinances of the MHLW;
– in principle, a business establishment manager is placed in each business establishment;
– depending on the pharmaceuticals sold, a pharmacist or sales manager is placed in the business establishment; and
– the applicant must not fall under the grounds for disqualification.

The manager of each business establishment where pharmaceuticals are distributed must exercise necessary care with regard to supervision of the pharmacists and other employees who work at such business establishment, management of the buildings and facilities making up such business establishment, and the pharmaceuticals, other things, and other business operations of such business establishment so as to prevent any hazard to public hygiene.

[23] Article 24 and Article 25 (iii) of the Pharmaceutical and Medical Devices Law
[24] Article 49 of the Pharmaceutical and Medical Devices Law
[25] Article 25 (i) and Article 26 of the Pharmaceutical and Medical Devices Law
[26] Article 25 (i) and (ii), and Article 30 of the Pharmaceutical and Medical Devices Law
[27] Article 34 of the Pharmaceutical and Medical Devices Law
[28] Articles 34 and 35 of the Pharmaceutical and Medical Devices Law

12. What is the legal regime for the retail distribution of drugs?

For retail distributors carrying out so-called "**store-based distribution**", it is necessary for each shop to receive a license from the prefectural governor for the place where the shop is located. The primary requirement to receive a license for store-based distribution is to satisfy the following two requirements:[29]

– The buildings and facilities of such shop comply with the standards determined in ordinances of the Ministry of Health, Labour and Welfare; and
– In addition to having a pharmacist or registered sales clerk placed in such shop, the system of carrying out the business of selling or providing of pharmaceuticals at such shop complies with the standards provided in ordinances of the Ministry of Health, Labour and Welfare for selling or providing pharmaceuticals in an appropriate manner.

"**Face-to-face selling pharmaceuticals**" may be sold or provided only by a pharmacist.[30]

As mentioned in item 9 above, OTC pharmaceuticals are broadly divided into three types, based on the level of risk. Type 1 pharmaceuticals may be sold or provided only by a pharmacist. In contrast, both Type 2 and Type 3 pharmaceuticals may be sold or provided by both pharmacists and registered sales clerks.[31]

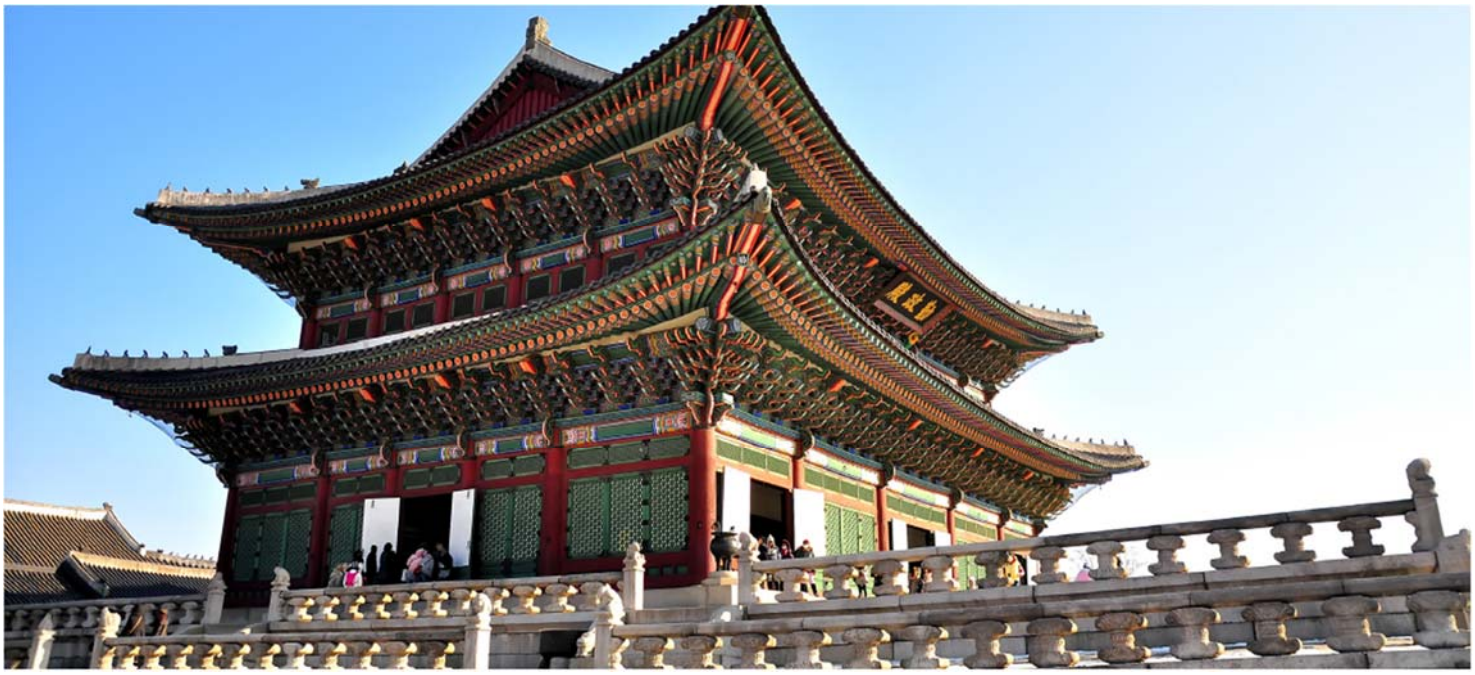
Also, with regard to OTC pharmaceuticals, parties who have received a license for specified sales (for, the sale of OTC pharmaceuticals, etc., by such pharmacy or shop to individuals who are located in a place other than the pharmacy or shop), are permitted, under specific conditions, to sell via the Internet.[32]

13. What is the regulatory authority overseeing wholesale and retail distribution?

The MHLW can require wholesale and retail distributors ("**marketing authorization holders**") to report as necessary pursuant to the provisions of ordinances of the MHLW, and cause its officers to enter factories, offices, and other locations where any pharmaceuticals, non-medical goods, cosmetics, medical devices or regenerative medical products are handled in the course of business, or inspect the building and facilities constituting such business establishment, or ledger books and other things, or question employees or other relevant persons.[33]

Also, when it is determined to be necessary, the MHLW or the prefectural governor may order that necessary measures be taken, such as ordering that the marketing authorization holder undergo inspection by a designated party, or ordering that the method of quality management or post-marketing safety management be improved, or ordering that until such improvement is carried out, operations must be ceased in whole or in part.[34]

[29] Article 26, paragraph 4 of the Pharmaceutical and Medical Devices Law
[30] Article 36-5 of the Pharmaceutical and Medical Devices Law
[31] Article 36-9 of the Pharmaceutical and Medical Devices Law
[32] Article 4, paragraph 3 (iv) (b) of the Pharmaceutical and Medical Devices Law
[33] Article 69 of the Pharmaceutical and Medical Devices Law
[34] Articles 71 and 72 of the Pharmaceutical and Medical Devices Law



Korea

Pre-conditions for distribution

1. What legal pre-conditions must be satisfied before a drug can be distributed within the jurisdiction?

A person who intends to import drugs in final packaged form for distribution must file a report on the importation business with the Minister of the Ministry of Food and Drug Safety ('**MFDS**') and obtain an approval from, or file a report with, the MFDS for each drug product to be imported under the Pharmaceutical Affairs Act.

A person who intends to manufacture drugs in Korea for distribution in Korea must obtain an approval for manufacturing drugs from the Minister of the MFDS and, in order to distribute such drugs, the person must obtain additional approval from, or file a report with, the Minister of the MFDS for each manufactured drug product to be distributed.

2. Are there any circumstances in which there are exceptions to the normal pre-conditions (such as an urgent need for the drug)?

The Minister of National Defense may import drugs for urgent military purposes without obtaining an approval from the MFDS if he or she consults in advance with the MFDS on the items and quantity of such drugs.

A person may manufacture a drug without obtaining an approval from the Minister of MFDS if the drug is already approved for clinical trials or will be used for the purpose of obtaining an approval from the Minister of the MFDS.

Licenses and market authorization

3. What are the legal requirements and procedures for authorizing a drug for distribution?

As detailed in question No 1 above, the appropriate approvals and/or reports must be obtained and/or filed with the Minister of the MFDS in order to distribute drugs in Korea.

4. What are the costs and timelines of obtaining licenses?

The processing fee for filing a report on an importation business with, or obtaining a manufacturing approval from, the MFDS is roughly KRW 385,700, and the processing time takes up to 25 business days.

The processing fee for obtaining an approval from, or filing a report with, the MFDS for each drug product to be imported or manufactured for sale varies from KRW 38,950 to KRW 6,795,350, with 10 to 95 business days of processing time depending on the very detailed classification of drugs set out by the MFDS. Normally, newly developed or biological drugs have higher costs and require more time to process.

5. Are there streamlined procedures in certain situations, such as when a drug has already been authorized in another country?

There are a number of documents and data required to be submitted to the MFDS in order to obtain an approval for distribution of imported or manufactured drugs under the Regulations for Safety of Drugs, etc. (the '**Regulation**'). However, if the drug subject to approval falls within the criteria set out in the Regulation, certain documents and/or data may be omitted. For example, if a drug which is not classified as a biological medicine or similar is listed in the Korean Pharmacopoeia, data on safety and efficacy of such drug will not be required.

There is no simplified licensing proceeding or relaxed licensing conditions if a drug to be imported or manufactured has already been licensed for distribution in another jurisdiction. However, the evaluation process of data on safety and efficacy of the drug may be omitted if an approval from the MFDS for the drug has been obtained by another person and such person authorizes the use of data he or she has in the new licensing proceeding.

Options for foreign pharmaceutical companies to establish presence

6. What are the options for foreign pharmaceutical companies to establish legal or commercial presence within the jurisdiction?

A foreign pharmaceutical company may structure its business presence in Korea by establishing a branch or subsidiary.

7. What are the limitations, if any, of each option?

Unlike a subsidiary, a branch office is not an independent legal entity that is recognized as a legal '**Person**' who can obtain an approval from, or file a report with, the MFDS. In this regard, a subsidiary would be a more appropriate form of doing business in Korea.

For a foreign entity that wishes to establish a subsidiary in Korea, the most common corporate forms are: Chusik-Hoesa (joint stock company) and Yuhan-Hoesa (limited company).

Wholesale and retail distribution

8. Who is authorized to import foreign drugs into the jurisdiction?

Any person who has filed a report on an importation business with the Minister of the MFDS and obtained an approval from, or filed a report with, the MFDS for the specific drugs to be imported is authorized to import foreign drugs into Korea.

9. Are drugs separated into any different categories for distribution?

No, however it should be noted that an importer or manufacturer of prescription drugs is required to request the Minister of Health and Welfare to determine whether the drug will be covered by the National Health Insurance Program if he or she wishes the subject prescription drug to be eligible for insurance reimbursement under the National Health Insurance Act. All other approval processes for the importation or manufacture of prescription drugs are the same as over-the-counter drugs as prescribed under the Pharmaceutical Affairs Act.

10. Who is authorized to distribute prescription drugs to consumers? Is there a difference between prescription and over-the-counter drugs, or other categories?

In general, only pharmacists and licensed herb druggists who own or work for a pharmacy are allowed to sell or obtain drugs for the purpose of selling them to consumers.

11. What is the legal regime for the wholesale distribution of drugs?

A person who intends to become a drug wholesaler must have facilities satisfying the requirements in the Pharmaceutical Affairs Act and be licensed by the regional government, as prescribed by the Ordinance of the Ministry of Health and Welfare ('**MOHW**'). A licensed drug wholesaler is required to employ a pharmacist to manage the wholesale business and is generally not allowed to engage in retail distribution of drugs.

12. What is the legal regime for the retail distribution of drugs?

Only a pharmacist or herb druggist may establish a pharmacy and sell prescription drugs and over-the-counter drugs to consumers.

13. What is the legal regime for the retail distribution of drugs?

– MOHW
– MFDS
– Regional government authorities

Singapore

Pre-conditions for distribution

1. What legal pre-conditions must be satisfied before a drug can be distributed within the jurisdiction?

We assume that the drugs which are to be the subject of any distribution in Singapore are likely to be medicinal products. Under the Medicines Act (Chapter 176, Singapore) ('**Medicines Act**'), a '**medicinal product**' is defined as any substance or article (not being an instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways:

– By being administered to one or more human beings or animals for a medicinal purpose (as defined below); and/or
– As an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose.

For the purpose of the Medicines Act, '**medicinal purpose**' means any of the following purposes:

– Treating or preventing disease;
– Diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;
– Contraception;
– Inducing anesthesia; and
– Otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

A product license issued by the Health Sciences Authority ('**HSA**') is required in order for one to import or sell medicinal products in Singapore. Prior to market entry, the medicinal product must first be registered with the HSA. If an applicant's registration has been approved by the HSA, a product license in respect of the specific medicinal product will be issued.

2. Are there any circumstances in which there are exceptions to the normal pre-conditions (such as an urgent need for the drug)?

Any exceptions to the normal pre-conditions will be decided by the HSA on a case-by-case basis.

Licenses and market authorization

3. What are the legal requirements and procedures for authorizing a drug for distribution?

– **Legal Requirements**

As mentioned in our response to question No. 1 above, a product license is required for a medicinal product to be distributed in Singapore.

– **Procedure**

The detailed procedure for the application for a new product license is set out in the Guidance on Medicinal Product Registration in Singapore provided by the HSA, which should be read in conjunction with applicable laws governing medicinal products in Singapore. We have set out a general overview of the procedure below.

In applying for a new product license for a medicinal product in Singapore, there are two categories of applications: a new drug application ('**ND application**') and a generic drug application ('**GD application**').

An ND Application is typically required for medicinal products containing new chemicals or any biological entity that has not been registered before in Singapore.

A GD Application is typically required for medicinal products containing a generic chemical product. A generic product is essentially similar to a currently registered product in Singapore but excludes biologics.

There are three types of evaluation routes for registration of a new product:

– **Full dossier**: applies to any product that has not been approved by any drug regulatory agency at the time of submission.
– **Abridged dossier**: applies to any product that has been evaluated and approved by at least one drug regulatory agency.
– **Verification dossier**: applies to any product that has been evaluated and approved by HSA's reference drug regulatory agencies.

An application submission comprises of two parts: the PRISM application form and the registration dossier. The registration dossier contains the documents to support the evaluation of the submitted application.

After submission of the PRISM application and registration dossier, the application will be screened to ensure that the correct application type has been chosen and that there are no deficiencies that would delay the registration process. If the application type needs to be re-categorized, the applicant will be notified and, subsequently, the PRISM application will need to be amended.

Upon acceptance of an application, evaluation by the HSA is based on the data set submitted by the applicant. A query letter will be issued to the applicant if clarification or additional information is required.

A regulatory decision is made based on the outcome of the HSA's evaluation of the submitted data package. Applicants will be notified by letter of one of the following outcomes:

– Approval: the application has satisfied the registration requirements for quality, safety and efficacy;
– Approvable: when the application has minor deficiencies;
– Non-approvable: when the application has major deficiencies; or
– Rejection: when the response provided by the applicant fails to address the major deficiencies highlighted in HSA's non-approvable decision.

If an '**approvable**' regulatory decision has been reached, the conditions for approval will be stated in writing and the applicant will be required to fulfill these conditions within the stipulated timeframe.

If a '**non-approvable**' regulatory decision has been reached, the applicant will be informed of the non-approvable issues in writing. If the applicant wishes to address the non-approvable concerns raised by HSA, a reply should be made within the specified timeframe. The reply should be based on the original data set as submitted to HSA – additional data that requires evaluation will not be accepted.

A product license will be issued when an '**approval**' regulatory decision has been given.

4. What are the costs and timelines for getting this authorization?

– **Timeline**

The timeline for the registration process of a medicinal product is as follows:

Application submission:

An application submission comprises of two parts: the PRISM application form and the registration dossier. The complete dossier should be submitted within two working days after the PRISM application submission. The date of submission will be defined as the date when the HSA receives the complete data set for the application.

Application screening:

After the date of submission, the application will be screened to ensure the correct application type has been chosen and there are no deficiencies that would delay the registration process. The target processing timeline for screening of the dossiers is 25 working days before the first communication (in the form of an input request or an acceptance/non-acceptance notification) is issued.

If any deficiencies are identified, a screening query letter via an input request will be issued to the applicant. The stop-clock starts whenever the HSA requests for clarification or additional information. The stop-clock ends when the HSA receives a complete and satisfactory response to the query. The applicant will be required to submit all of the requested information and documents within 30 calendar days from the date of the screening query letter. Any deficiencies noted must be addressed before the dossier can be accepted for evaluation.

If the applicant fails to provide the requested information, or the submitted information is incomplete or contains unsolicited information, the application will not be accepted for evaluation.

Application acceptance:

An acceptance notice will be issued to the applicant via email upon acceptance of an application. The date of acceptance of the application will be considered as the start of the evaluation timeline.

Application evaluation:

Upon acceptance of an application, evaluation by the HSA is based on the data set submitted by the applicant.

A query letter will be issued to the applicant if clarification or additional information is required. The stop-clock starts whenever the HSA issues a query letter and ends when the HSA receives a complete and satisfactory response from the applicant.

The target processing timeline for evaluation of an application is the period from the date of acceptance to issuance of a regulatory decision letter, excluding all stop-clocks. The target timeline for evaluation varies from 60 to 270 working days, depending on the specific evaluation route taken.

Regulatory decision:

A regulatory decision is made based on the outcome of the HSA's evaluation of the submitted data package. Issuance of a regulatory decision letter signals the end of the evaluation timeline.

– **Costs**

The fees payable for the registration of a medicinal product are as follows:

– Screening fee (payable upon submission of application):
  - Submission of abridged or verification dossier: S$550
  - Submission of full dossier: S$2,750
– Evaluation fee (payable upon acceptance of application):
  - ND Application Abridged Dossier (Chemical Drugs & Biologics): S$5,500 – S$11,000
  - ND Application Verification Dossier (Chemical Drugs & Biologics): S$5,500 – S$16,500
  - ND Application Full Dossier: S$82,500
  - GD Application Abridged Dossier: S$2,200 – S$3,850
  - GD Application Verification Dossier: S$5,000 – S$10,000

- GD Application Verification Dossier (under the India-Singapore Comprehensive Economic Cooperation Agreement ('**CECA**') Scheme): S$5,000 – S $10,000

5. Are there streamlined procedures in certain situations, such as when a drug has already been authorized in another country?

The procedure is streamlined for the registration of generic medicinal products manufactured in India under the CECA Scheme, provided that the application meets the eligibility and documentary requirements. The CECA Scheme is intended to facilitate the market authorization of Indian generic products in Singapore.

The application process under the CECA Scheme is the same as all other applications (please see above). However, the timeline for an application under the CECA Scheme is shorter in comparison to the timeline for an application under the general medicinal product registration route. The timeline targets for an application under the CECA Scheme are as follows:

– **Fourteen working days** from the date of submission to issuance of the first correspondence; and
– **Ninety working days** from the date of acceptance to a regulatory decision excluding stop-clocks.

Options for foreign pharmaceutical companies to establish presence

6. What are the options for foreign pharmaceutical companies to establish legal or commercial presence within the jurisdiction?

We assume that the question is in relation to the establishment of a pharmacy in Singapore. Under the Medicines (Registration of Pharmacies) Regulations, a pharmacy must be registered with the HSA to carry out dispensing and retail sales of medicinal products.

The registered pharmacy must be under the control and management of a full-time qualified pharmacist registered with the Singapore Pharmacy Council, and provide at least 35 hours of dispensing services per week.

Alternatively, where a new pharmacy is an additional outlet of a chain pharmacy (with at least one outlet already registered with the HSA), the new pharmacy may be eligible for a simplified registration scheme (the '**simplified scheme**'). Under this simplified scheme, a certificate of registration of a pharmacy can be issued before an onsite audit is conducted if this new pharmacy is essentially the same as the other registered outlets with respect to legal and general pharmacy dispensing requirements.

7. What are the limitations, if any, of each option?

The simplified scheme is limited in its applicability. Pharmacies intending to provide telepharmacy and compounding (other than simple dissolving, diluting or mixing of medicinal products) services are not eligible for the simplified scheme.

Wholesale and retail distribution

8. Who is authorized to import foreign drugs into the jurisdiction?

We set out the persons authorized to import different categories of drugs into Singapore as follows:

– **Medicinal products**

A person may only import any medicinal product in accordance with a product license or an import license issued by the HSA.

Importers of medicinal products who do not hold the relevant product licenses may apply for an import license to import registered medicinal products. The import license (for authorized agents) for medicinal

products will only be issued to local importers who have been authorized by the product license holders to import licensed products on their behalf.

In addition, the importers must demonstrate their compliance with the HSA's Good Distribution Practice ('**GDP**') standard before the granting of the import license would be considered. The products authorized for importation would be listed in the license.

– **Chinese Proprietary Medicines** ('**CPMs**')

CPMs falls under the definition of '**medicinal product**' under the Medicines Act, and as such are regulated by the Medicines Act. A person may only import any CPMs in accordance with a product license or an import license issued by the HSA.

– **Controlled drugs**

Controlled drugs are substances specified in the First Schedule to the Misuse of Drugs Act.

A company is required to apply for an import/export license from the HSA to import or export any consignment of controlled drugs into Singapore for legitimate and authorized use of controlled drugs. The import/export license enables the applicant to import/export a controlled drug listed in the Second to Fourth Schedules to the Misuse of Drugs Regulations into Singapore.

The company should authorize a registered pharmacist to apply for the import/export license. The applicant should hold a valid poisons license. The purposes of the import or export of controlled drugs would be assessed before the licenses can be processed and issued. The license is issued on a per consignment basis and the consignment should be imported or exported out of Singapore within six months from the date that the license is issued. The applicant should also be the one who has overall responsibility for the import/export, use, storage, security, sale and supply of controlled drugs.

– **Psychotropic substances and restricted substances**

Psychotropic substances are substances specified in the Medicines (Export License for Psychotropic Substances) Regulations. Restricted substances are substances which require an import authorization issued by the importing authority to authorize the importation. These substances are more stringently controlled overseas, but are controlled as poisons locally in Singapore.

A company is required to apply for an import authorization or export license from the HSA to import or export any consignment of psychotropic substance or restricted substance in or out of Singapore for legitimate and authorized use of these substances. The import authorization enables the applicant to import a psychotropic substance or restricted substance.

The company should authorize a registered pharmacist to apply for the import authorization and export license. The applicant should hold a valid poisons license. The purposes of the import or export of psychotropic substances or restricted substances would be assessed before the import authorizations and export licenses can be processed and issued. The import authorizations and export licenses are issued on a per consignment basis and the consignment should be imported or exported out of Singapore within six months from the date that the authorization or licenses are issued. The applicant should also be the one who has overall responsibility for the import/export, use, storage, security, sale and supply of Psychotropic Substances or Restricted Substances.

– **Poisons**

Poisons are defined as any substances specified in the Schedule of the Poisons Act. Any company, unless exempted under the Poisons Act, requires a license to import any poisons. The form A poisons license is issued under the Poisons Act to allow the licensee to import, store and sell poisons by way of wholesale at the premises stated in the license. The licensee for a form A poisons license must be working full time for the company and be given the responsibilities and accountabilities for all poisons transactions.

Companies whose core business is wholesale dealing of active pharmaceutical ingredients intended for local sales or medicinal products are expected to comply with the HSA's GDP Standard.

9. Are drugs separated into any different categories for distribution?

Yes. Medicines in Singapore are classified as prescription only ('**PO**'), Pharmacy only ('**P**') or General Sales List ('**GSL**').

PO medicines are medicinal products specified under the First Schedule of the Medicines (Prescription Only) Order and are regulated by both the Medicines Act and the Medicines (Prescription Only) Order.

P medicines are generally medicinal products which are not on the list of PO medicines and/or on a general sale list.

GSL medicines are defined under the Medicines (General Sale List) Order as medicinal products which, in the opinion of the Minister, can with reasonable safety be sold or supplied otherwise than by or under the supervision of a pharmacist, and are regulated by the Medicines Act.

10. Who is authorized to distribute drugs to consumers? Is there a difference between prescription and over-the-counter drugs, or other categories?

Under the Medicines Act, PO medicines can only be supplied by a doctor or by a pharmacist according to a prescription by a doctor. P medicines can be supplied by or under the personal supervision of a pharmacist without a doctor's prescription at a registered pharmacy, while GSL medicines can be purchased off the shelves.

11. What is the legal regime for the wholesale distribution of drugs?

The legal regime for the wholesale distribution of different categories of drugs is as follows:

Medicinal products

Wholesale dealing is defined under the Medicines Act as selling (a product) to a person who buys it for the purpose of selling or supplying it in the course of a business carried on by that person except that it does not include any such sale by the person who manufactured it.

Any person (except for licensed manufacturers) who intends to sell registered medicinal products to others for the purpose of resale will have to apply for a wholesale dealer's license for medicinal products.

The granting of the wholesale dealer's license would be considered when the company has been audited and found to comply with the HSA's GDP standard. Licensed wholesale dealers can only deal in registered medicinal products and are not allowed to deal in medicinal products with invalid product licenses.

CPM

Any person (except for licensed manufacturers) who intends to sell registered medicinal products to others for the purpose of resale will have to apply for a wholesale dealer's license for CPM, unless the Medicines (Traditional Medicines, Homeopathic Medicines and other Substances) (Exemption) Order applies.

Controlled Drugs

Companies involved in the supply, distribution and wholesale activities of controlled drugs are required to apply to the HSA for the controlled drug wholesale license, which is issued to a registered pharmacist authorized by the company. The license holder is responsible for the wholesale activities of the controlled drugs as listed in the license.

12. What is the legal regime for the retail distribution of drugs?

Under the Medicines (Registration of Pharmacies) Regulations, a pharmacy must have a certificate of registration issued by the HSA to carry out dispensing and retail sales of medicinal products. A pharmacy must at all times be under the control and management of a pharmacist who is employed on a full-time basis to control and manage that pharmacy.

13. What is the regulatory authority overseeing wholesale and retail distribution?

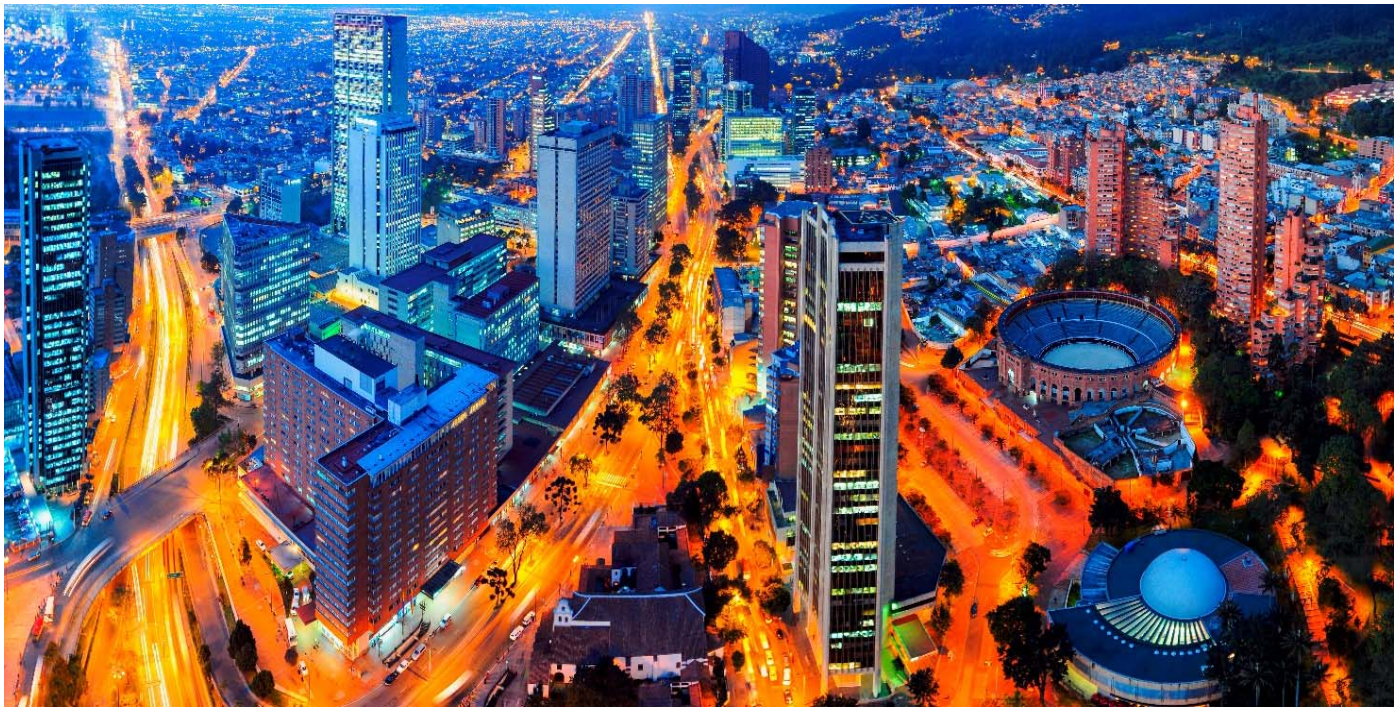
In general, the Ministry of Health and the HSA oversee wholesale and retail distribution of drugs.

14. Are there any specific requirements for the distribution of drugs online?

Based on an informal check with the HSA in relation to this issue, we understand that currently drugs may not be distributed online in Singapore.

15. Are there any specific regimes applied in the drug distribution process, such as the tendering scheme with hospitals?

There are no specific regimes applied in the drug distribution process. Requirements for public tenders vary depending on the nature of the tender and, as such, there are no specific regimes applied in the drug distribution process in relation to such tenders.



Taiwan

Pre-conditions for distribution

1. **What legal pre-conditions must be satisfied before a drug can be distributed within the jurisdiction?**

The distribution of drugs including importing, retailing, wholesaling, or manufacturing is under the supervision of the Food and Drug Administration of Taiwan (TFDA) in accordance with the Pharmaceutical Affairs Act. Generally, companies must obtain pharmaceutical company licenses for drug traders or drug manufacturers if they would like to engage in the distribution of drugs, while pharmacies obtaining pharmacy licenses can concurrently engage in retailing pharmaceuticals without acquiring the pharmaceutical company license of drug traders.

2. Are there any circumstances in which there are exceptions to the normal pre-conditions (such as an urgent need for the drug)?

For the purpose of preventing and giving treatment for life-threatening or severely debilitating diseases under the circumstance that there is no appropriate domestic drug or alternative treatment, or responding accordingly to the necessity of emergency public health circumstances, teaching hospitals or psychiatric teaching hospitals which are higher level than regional hospitals can file an application for a special case of manufacturing or importing specified drugs.

Licenses and market authorization

3. What are the legal requirements and procedures for authorizing a drug for distribution?

The TFDA is in charge of reviewing protocols, examining registrations and granting market approvals of drugs in accordance with the Pharmaceutical Affairs Act and the relevant regulations.

– **Clinical Trials**

Pharmaceutical companies applying for clinical trials of investigational new drugs (IND) have to upload a summary of the protocol to the website of the Center for Drug Evaluation, and submit the hard copy of the protocol to the Center for Drug Evaluation 7 days before filing an application to the TFDA in accordance with the Application Guide to Pharmaceutical Clinical Trial. The protocol would be examined by the Integrated Medicinal Products Review Office of the TFDA.

Clinical trials of IND may only be conducted in qualified teaching hospitals so the pharmaceutical company must submit the protocol to the Institutional Review Board of the qualified hospital. Only after the protocol is approved by both the TFDA and the qualified hospital can the clinical trial be executed.

The conducting of the clinical trial must meet the standard or guidelines under Good Clinical Practice (GCP), and the result report of the clinical trial, which is one of the required documents for market approval (New Drug Application, NDA), shall be submitted to the TFDA for examination as well.

– **Medicament manufacture licenses or recordation**

Pharmaceutical companies who comply with Good Manufacturing Practice (GMP) and pass the inspection of the TFDA can acquire medicament manufacture licenses to manufacture drugs in Taiwan. Manufacturing factories shall be established under relevant standards and complete factory registrations.

As for pharmaceutical importation, pharmaceutical companies must prepare a Plant Master File (PMF) of foreign manufacturing factory to submit to the TFDA for recordation, or they cannot submit an application for market approval.

– **Registrations and market approvals**

Pharmaceutical companies with licenses of drugs traders or licenses of drug manufacturers must submit an application and be granted market approval to import or manufacture INDs, respectively.

As for generic drugs, the result report of the clinical trial would be substituted by documentation regarding bioequivalence studies (BE).

– **Western pharmaceutical distribution licenses**

Western pharmaceutical distribution licenses are required for pharmaceutical companies who engage in importing or wholesaling approved drugs. The licenses would be granted only after passing the inspection by the TFDA in accordance with Western Pharmaceutical Good Distribution Practice Regulations.

4. What are the costs and timelines for getting this authorization?

The costs of review or examination by the TFDA are as follows:

– **Examination fee for clinical trials**
  - Review of protocol: NTD 30,000.
  - Review of the result report: NTD 20,000.

– **Examination fee for registrations and market approvals**
  - New composition: NTD 800,000.
  - New therapeutic compounds or new method of administration: NTD 300,000.
  - Other kinds of new drugs: NTD 150,000.
  - Generic drugs under safety monitoring: NTD 80,000.
  - Generic drugs without safety monitoring: NTD 50,000.

The timelines of review or examination by the TFDA are as follows:

– **Examination period for clinical trials**
  - Review of the protocol: 45 to 120 days.
  - Review of the result report: 120 to 240 days.

– **Examination period for registrations and market approvals**
  - New composition, new therapeutic compounds or new method of administration: 200 to 300 days.
  - Generic drugs: 180 days.

5. Are there streamlined procedures in certain situations, such as when a drug has already been authorized in another country?

Pharmaceutical companies obtaining at least two of the market approvals of new composition granted by the U.S. FDA (FDA), European Medicines Agency (EMA) or Ministry of Health, Labor and Welfare of Japan (MHLW) can use the simplified procedures to apply for market approvals if there is no race and ethnicity difference and the following requirements are met:

– Providing the latest reports of Risk Management Plan (RMP) and Post-marketing Commitment required by the FDA, EMA or MHLW/PMDA.
– Providing the official examination reports of the FDA, EMA or MHLW/PMDA.

The TFDA would focus on the examination of Chemistry, Manufacturing and Controls (CMC), pharmacokinetic/pharmacodynamic (PK/PD) and clinical trials data.

Options for foreign pharmaceutical companies to establish presence

6. What are the options for foreign pharmaceutical companies to establish legal or commercial presence within the jurisdiction?

Foreign pharmaceutical companies intending to conduct business in Taiwan must conform to the Company Act and related investment regulations such as the Statute for Investment by Foreign Nationals. Pharmaceutical companies can choose one of the following entities at their discretion, while different types of entities have different functions and limitations.

– **Subsidiary company**: Foreign companies shall submit an investment application to the Investment Commission for examination in accordance with the Statute for Investment by Foreign Nationals, and shall complete company registration after remitting approved capital contribution in full into Taiwan within the specified time limit.
– **Branch office**: Foreign companies shall apply for business registration, obtain a certificate of recognition, and complete the procedure for branch office registration to conduct business in Taiwan.
– **Representative office**: A representative office in Taiwan is not a legal entity so that conducting business is prohibited, while it would be suitable for companies only meant to designate a representative for the performance of juristic acts relating to its business. Even if a foreign company which is willing to establish a representative office need not file an application to the competent authority for authorization, recordation is still required.

7. What are the limitations, if any, of each option?

– **Representative office**: The scope of juristic acts relating to its business covers signing contracts, participating in tenders, quoting the price, purchasing, and bargaining. If a foreign pharmaceutical company which only sets up its representative office goes beyond the scope of the aforementioned acts and conducts business, its Taiwan representative office could be sentenced to fixed-term imprisonment or a criminal fine.

Wholesale and retail distribution

8. Who is authorized to import foreign drugs into the jurisdiction?

Pharmaceutical companies obtaining licenses of drug traders and their licensees can import specified drugs if they have completed the registration and been granted the market approval.

9. Are drugs separated into any different categories for distribution?

Pharmaceuticals can be categorized into four types determined by their medical risk, and the method of distribution would also vary by category.

– **Medicines to be prescribed by physicians (prescription drugs**)
– **Medicine**s designated by physicians, pharmacists and/or assistant pharmacists
– **Over-the-counter drugs (OTC drugs):** Drugs characterized by mild action, non-accumulativeness, long storage life and easy administration can be used for the treatment of illnesses without the instructions of physicians.
– **Preparations of inherited formulation**: Drugs selected and published by TFDA, that are prepared in accordance with traditional Chinese prescriptions and have medical efficacy.

10. Who is authorized to distribute prescription drugs to consumers? Is there a difference between prescription and over-the-counter drugs, or other categories?

– **Medicines to be prescribed by physicians (prescription drugs)**: The drugs shall only be prescribed and restricted to use by physicians.
– **Medicines designated by physicians, pharmacists and/or assistant pharmacists**: The taking of the drugs shall be indicated by specified medical professionals.
– **Over-the-counter drugs (OTC drugs):** OTC drugs can be divided into Type A and Type B, and Type B can be distributed by means of the internet by licensed pharmaceutical companies/pharmacies, department stores, grocery stores or hospitality service providers.
– **Preparations of inherited formulation**: Preparations for wholesale or offering to others to sell shall be manufactured by companies obtaining the license of drug manufacturers, while Chinese prescription traders can manufacture preparations and retail in their own business offices.

11. What is the legal regime for the wholesale distribution of drugs?

Pharmaceutical companies obtaining licenses of drug traders can wholesale drugs, while licensed drugs manufacturers can wholesale their own products without acquiring licenses of drug traders. The label, package insert or packaging marked in manufactured drugs shall be indicated in Chinese for wholesaling.

In case of engaging in wholesaling of western drugs, pharmaceutical companies shall obtain western pharmaceutical distribution licenses in accordance with Western Pharmaceutical Good Distribution Practice Regulations (GDP), which covers a wide range of administration and compliance matters, such as product procuring, holding, and supplying related to quality management, organization and personnel, premises and equipment, documentation, operation procedures, customer complaints, returns and recalls, outsourced activities, self-inspections, transportation and other pharmaceutical distribution practice.

12. What is the legal regime for the retail distribution of drugs?

Pharmaceutical companies who would like to retail drugs must obtain licenses of drug traders. Licensed drug manufacturers can concurrently engage in retailing their own products while the label, package insert or packaging of their products must be indicated in Chinese for retailing.

13. What is the regulatory authority overseeing wholesale and retail distribution?

The TFDA is generally in charge of managing and supervising wholesale and retail distribution affairs, and the department of health in every municipal authority is also responsible for inspection of drug packaging/labeling and administration of pharmaceutical companies.

14. Are there any specific requirements for the distribution of drugs online?

Only Type B OTC drugs—for example, ointments for external use—can be distributed online by qualified entities, such as licensed pharmaceutical companies/pharmacies, department stores, grocery stores or hospitality service providers.

The qualified provider must provide specified information in a visible location on the webpage in an identifiable way, such as name, address, service line and service time of the provider, the certificate documents of the provider, information on the market approval of drugs, and pictures of approved drug packaging and package inserts.

The internet service provider who provides an online channel for retailing drugs is obligated to confirm the qualification of the provider and the specified information enclosed by the provider and to regularly inspect the aforementioned information.

In addition, the internet service provider must also be aware of not publishing unauthorized medicament advertisements, which shall be applied for publication only by pharmaceutical companies.

15. Are there any specific regimes applied in the drug distribution process, such as the tendering scheme with hospitals?

A public hospital engaged in pharmaceutical procurement is required to conform to the regulations and limitations set by the Government Procurement Act, and joint pharmaceutical procurement is the most common way to tender for drugs.

As for procurement of new drugs, medical institutions subordinate to the TFDA shall conform to the application procedure that medical practitioners shall submit the application form and relevant materials and be approved by the pharmaceutical affairs commission. The recusal of the applicant medical practitioner in the examination process would be required due to conflict of interest.

Thailand

Pre-conditions for distribution

1. What legal pre-conditions must be satisfied before a drug can be distributed within the jurisdiction?

Before distributing modern and traditional drugs in Thailand, a pharmaceutical company or its distributor must apply for an import license or a manufacturing license.

A modern drug is a '**drug intended for use in the practice of modern medicine or the cure of an animal disease**' (Section 4 of the Drug Act, as amended), whereas a traditional drug is 'a drug intended for use in the practice of the traditional medicine or the cure of an animal disease which appears in a pharmacopoeia of traditional drug notified by the Minister of the Ministry of Public Health (Minister), or a drug notified by the Minister as a traditional drug, or a drug of which formula has been registered as that of a traditional drug' (Section 4 of the Drug Act, as amended).

The importer or manufacturer must:

- Be the owner of the business and have sufficient assets and structure to be able to establish and operate the business;
- Be at least 20 years of age;
- Be a resident of Thailand;
- Not have been convicted for an offense against certain laws (for example, laws concerning narcotics and psychotropic substances);
- Have the premises to produce, sell, import or store drugs and equipment for use in the production, sale or storage of drugs and the control or maintenance of drug quality and quantity as prescribed in ministerial regulations; and
- Use a trade name for the drug business that is not a repetition of, or similar to, the trade name used by another active licensee or a licensee whose license has been suspended or revoked for less than a full year.

After the manufacturing license or import license is obtained, modern and traditional drugs must be registered with the Thai Food and Drug Administration ('**FDA**') prior to being distributed in Thailand.

2. Are there any circumstances in which there are exceptions to the normal pre-conditions (such as an urgent need for the drug)?

There are some rare exceptions under which certain drugs do not need product registration. According to section 79(4) of the Drug Act (BE 2510 (AD 1967)), a drug imported for research, analysis, exhibition or charitable purposes does not require registration if it complies with the requirements set up by the Notification of the Ministry of Public Health No.14 (BE 2532 (AD 1989)) regarding Bases, Procedures, and Conditions Respecting Importation of Medicines with No Need to Apply for Pharmacopeia Registration, as amended in 2009. Additionally, active pharmaceutical ingredients, semi-finished products, and sample drugs for registration purposes do not require product registration. With regard to the sale of drugs, the drug store requires a license to sell, yet the hospitals or clinics can sell drugs directly to his or her patients without having applied for a license to sell.

Licenses and market authorization

3. What are the legal requirements and procedures for authorizing a drug for distribution?

– **Structure**

Companies and individuals wishing to place a drug on the market must:

– Obtain a license from the FDA to manufacture, sell or import drugs in Thailand (an import license must be renewed every year and is valid from 1 January to 31 December);
– After obtaining the import license, obtain an authorization to manufacture or import drug samples; and
– Submit a full marketing approval application, together with samples, to the FDA for review and registration. Registration requirements differ for general drugs (which include generics, new medicines and new generics) and traditional drugs. A drug product license does need to be renewed.

– **Regulatory authority**

The regulation of drugs in Thailand is overseen by the Ministry of Public Health. The Drug Control Division of the FDA, under the supervision of the Ministry of Public Health, handles the four main aspects of drug regulation:

– Pre-marketing control (including licensing and registration);
– Post-marketing monitoring and surveillance;
– Consumer education and dissemination of information; and
– Promotion of technological development and research for export.

4. What are the costs and timelines for getting this authorization?

The government fee for a drug import license is THB10,000 per year. A drug import license covers different types of drugs, but does not cover narcotics.

The government fee for the registration of pharmaceutical products is THB2,000 per product. There are no renewal fees.

5. Are there streamlined procedures in certain situations, such as when a drug has already been authorized in another country?

No. Even if a company has already obtained a marketing authorization ('**MA**') issued in a foreign jurisdiction, it would not be able to benefit from a simplified or relaxed licensing and registration process. However, the application requires the applicant to inform the FDA of any approved and pending MAs for the product granted in other countries.

If the foreign MA has been obtained in a country where the regulatory practice is credible and globally accepted, it would support the registration process and could be used as evidence to support the application for marketing approval.

Additionally, following the ASEAN Harmonization on Pharmaceutical Product Registration of 1 January 2009, the FDA implemented the ASEAN Common Technical Requirements and Dossier on Quality, Safety and Efficacy, which provides guidelines on analytical and process validation, stability studies and bioavailability/bioequivalence. This means that in ASEAN the same requirements exist for all drug products, which facilitates the registration process. However, some local specificities still remain.

Parallel imports are not regulated in Thailand because the exhaustion of rights principle is recognized by most intellectual property laws in Thailand.

However, parallel imports are not permitted in the pharmaceutical sector because it is mandatory for a company to preliminarily obtain an import license and product registration locally.

Moreover, it is important to note that the FDA will not accept an application for a product with a trademark that is identical to other products in the Thai market, unless this product has the same manufacturer and the manufacturer has given its authorization to use and sell the product.

Options for foreign pharmaceutical companies to establish presence

6. What are the options for foreign pharmaceutical companies to establish legal or commercial presence within the jurisdiction?

Generally, there are several types of legal entities in Thailand, such as a private limited company, a public limited company, ordinary partnership, limited partnership, branch office or a representative office. The choice of entity depends on the activities the local establishment intends to operate.

Under Thai law, there are two types of limited companies: (1) public limited companies and (2) private limited (closely held) companies. The formation of a public company is governed by the Public Limited Companies Act, while the formation of a private company is governed by the Thai Civil and Commercial Code.

A public limited company can be incorporated by at least 15 individual promoters, who must prepare the Memorandum of Association ('**MOA**') and register the MOA with the Registrar.

A private limited company requires a minimum of three individual promoters. During its existence, a minimum of three shareholders, either natural or juristic persons, must be maintained.

A foreign entity may establish a branch office in Thailand which will be deemed as the same entity as its parent entity. If the branch office engages in a business that is reserved under the Foreign Business Act ('**FBA**'), it must obtain a Foreign Business License ('**FBL**') from the competent authority, prior to commencing its operation.

Under Thai law, a representative office (which is also deemed to be the same entity as its parent company) may be established by a foreign entity, and this is allowed to conduct only the activities prescribed below:

- Finding sources of goods or services in Thailand for the head office;
- Checking and controlling the quantity of goods purchased in Thailand by the head office;
- Providing advice and assistance concerning goods of the head office which are sold to agents or consumers in Thailand;
- Disseminating information concerning new goods or services of the head office; and
- Reporting on business developments in Thailand to the head office.

As the representative office performs service activities, which are covered by List 3 (21) of the FBA, it must obtain an FBL. The representative office cannot generate any income in Thailand and, thus, it does not need to pay tax. All operational expenditure incurred by the representative office in connection with its activities, must be covered by foreign remittances from the head office only.

Normally, if the company plans to operate a business and generate income in Thailand, the limited company is the simplest option.

7. What are the limitations, if any, of each option?

The major restriction for a foreign entity or a foreign majority-owned entity in Thailand in respect to doing business is the Foreign Ownership Limitation.

Under the FBA, a company is considered a '**foreigner**' if half or more of its shares are held by non-Thai natural or juristic persons. The FBA reserves many business activities from foreign investors, such as retail business, wholesale business and any kind of service activities. Business activities indicated in List 1 of the FBA are strictly closed to foreigners. Foreigners wishing to engage in one of the activities indicated in List 2 of the FBA must obtain permission from the Minister of Commerce with the approval of the Cabinet. For activities indicated in List 3 of the FBA, permission from the Director-General of the Business Development Department, together with the approval of the Foreign Business Committee (collectively, an FBL), is required.

For example, wholesale and retail businesses are also under List 3 of the FBA. As such, if the local entity is deemed a foreigner under the FBA and it wishes to engage in a wholesale and/or a retail business, such local entity may need to apply for an FBL, unless it meets the exemptions as follows: (i) for a wholesale business, if the local entity is to engage in a wholesale business without an FBL, such local entity must have at least THB 100 million of registered capital (fully paid-up) per one wholesale shop/office; (ii) for a retail business, such local entity must have at least THB 100 million of registered capital (fully paid-up), and it will be allowed to have no more than five retail shops/offices, and if additional retail shops/offices are needed, additional capital of THB 20 million will be required. Please note that this registered capital must be reserved for a retail or wholesale business only. If the entity wishes to engage in both businesses, then minimum registered capital for the two businesses will be THB 200 million.

Please also note that a marketing business may also fall under a service business under List 3 of the FBA, depending on the details of the marketing activities that the local entity wishes to operate.

Exceptions from the restrictions of the FBA can be granted as promotional privileges by the BOI or the IEAT, or as a temporary measure, in the form of a government approval issued by the Thai government.

Exceptions can also be provided based on international treaties that Thailand has entered into. U.S. companies, or nationals under the Treaty of Amity and Economic Relations between Thailand and the United States, can be eligible for '**national treatment,**' whereby, with some exceptions, they are treated in the same way as Thai nationals. Other international treaties, such as the Thai-Australia Free Trade Agreement, the Japanese Thai Economic Partnership Agreement, the ASEAN Comprehensive Investment Agreement, and the ASEAN Framework Agreement on Services also provide exceptions with conditions. By virtue of these international treaties, together with the FBA, qualified entrepreneurs may file a request for the issuance of a Foreign Business Certificate from the Director-General of the Department of Business Development.

Wholesale and retail distribution

8. Who is authorized to import foreign drugs into the jurisdiction?

Section 13(3) of the Drug Act states that drugs sold by medical practitioners to their patients only are not required to obtain a license from the regulator (i.e., the FDA). However, a doctor would still be required to apply for an import license. Only ministries, sub-ministries (in their official disease prevention and treatment duties), the Thai Red Cross Society and the Government Pharmaceutical Organisation may be allowed to import drug products without applying for an import license or product license (section 13(5)).

In addition, section 79(4) of the Drug Act states that medicines may be granted permission to be imported into Thailand based on the procedures and conditions prescribed by the Minister, with the approval of the Drug Board. The Drug Board is a governmental body consisting of, among others, the Permanent Secretary of the Ministry of Public Health as Chairman and Directors-General of the Departments of Medical Services, Communicable Disease Control, Medical Sciences, and Health, and not less than five but not more than nine qualified members, at least two of which must be practitioners of traditional medicine, appointed by the Minister.

The Notification of the Ministry of Public Health No.14 (B.E. 2532 (A.D. 1989)) Regarding Bases, Procedures, and Conditions in Respect to Importation of Medicines with No Need to Apply for Pharmacopeia Registration, as amended in 2009, states that medicines imported into Thailand may be exempted from product registration with the FDA if they are used for research, analysis, exhibition or charitable purposes. However, the right to import is limited to certain entities. For example, importation for research and analysis is limited to a manufacturer, importer, Ministry, Department with duties of prevention and treatment of diseases, the Thai Red Cross Society and the Government Pharmaceutical Organisation.

9. Are drugs separated into any different categories for distribution?

Under Thai laws, there are four main drugs categories:

– New drugs;
– New generic drugs;
– Generic drugs; and
– Traditional drugs.

Other drug categories exist, namely biological drugs and narcotic drugs, but those are governed by a different sub-department at the FDA and have different requirements with which to comply. For example, narcotic drugs in categories 1 and 2 have to go through a tender process. There is also an orphan drugs category with an easier registration process. However, the list of orphan drugs is strictly controlled and limited.

10. Who is authorized to distribute drugs to consumers? Is there a difference between prescription and over-the-counter drugs, or other categories?

– **Prescription drugs**

The MA holder or distributor who holds the drug import license and product registration licenses which have been approved by the FD is responsible for the distribution of drug products to hospitals, clinical institutes or pharmacies.

The MA holder or distributor needs to register its company in order to get the drug import license.
In addition, it also needs to register a drug product with the FDA before distributing such drug product to consumers in Thailand.

– **Over-the-counter drugs**

The MA holder or distributor who holds the drug import license and product registration licenses which have been approved by the FDA is responsible for the distribution of over-the-counter drugs to hospitals, clinical institutes or pharmacies.

11. What is the legal regime for the wholesale distribution of drugs?

The MA holder or the legal distributor who holds the import license, the sales license and/or the product license of a drug approved by the FDA is responsible for wholesale distribution of drug products to hospitals, clinical institutes or pharmacies.

12. What is the legal regime for the retail distribution of drugs?

See No. 7 above.

13. What is the regulatory authority overseeing wholesale and retail distribution?

See No. 7 above.

Regulatory authority

As with other distribution, applications for licenses must be conducted in accordance with the rules, measures and conditions prescribed in Ministerial Regulations.

Supervision

Like in the regime regarding consumers, responsibility for supervision of wholesale distribution activities falls on the FDA, which is also responsible for licensing the sale of pharmaceutical products. In addition, the Import and Export Inspection Division is also involved in the logistics and distribution activities at the border.

Rights of appeal

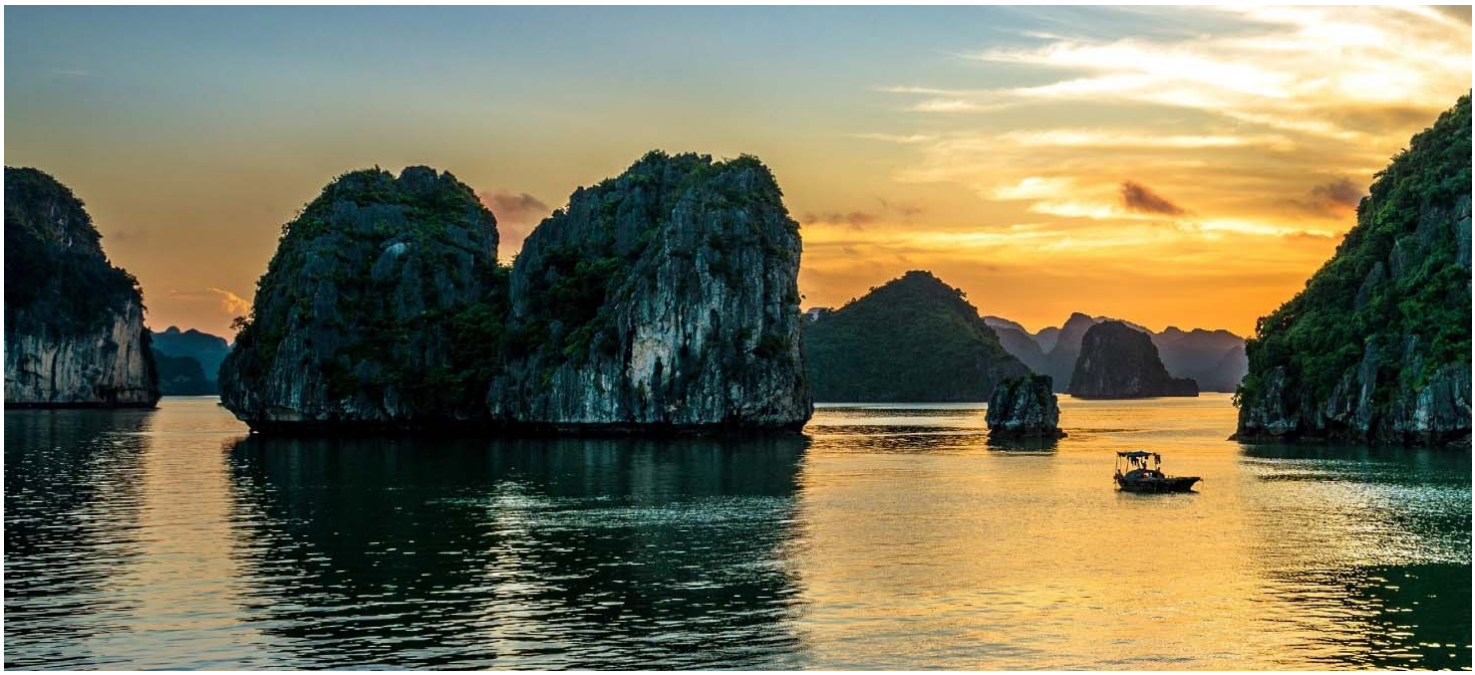
Decisions of the FDA may be appealed to the Minister of Public Health within 30 days from the receipt of the decision.

14. Are there any specific requirements for the distribution of drugs online?

It is not legally possible to market pharmaceutical products online, by email or by mail order. If a company has applied for an import license and a drug product license but does not actually import such product within two consecutive years, the company would have its product license for that product withdrawn, according to section 85 of the Drug Act.

15. Are there any specific regimes applied in the drug distribution process, such as the tendering scheme with hospitals?

No.



Vietnam

Pre-conditions for distribution

1. What legal pre-conditions must be satisfied before a drug can be distributed within the jurisdiction?

According to Law No. 105/2016/QH13 on Pharmacy ("**Law on Pharmacy**"), a drug must be registered in the form of a Marketing Authorization ("**MA**") before being distributed in Vietnam. The Drug Administration of Vietnam ("**DAV**"), under the Ministry of Health of Vietnam ("**MOH**") is the authority responsible for receiving and evaluating drug registration dossiers and granting MAs.

In addition to the MA, a drug which requires special management, such as an addictive and psychotropic drug, must be granted an Import License for each shipment before being imported and circulated in Vietnam.

2. Are there any circumstances in which there are exceptions to the normal pre-conditions (such as an urgent need for the drug)?

Yes. In some special cases, foreign drugs can be imported and circulated in Vietnam without an MA. In such cases, an Import License (for a certain quantity within one year) issued by the DAV is required. An Import License can replace an MA for the following types of drugs:

- Finished drug products containing active ingredients (with or without MA) which are in insufficient supply for treatment demands.
- Finished drug products containing herbal ingredients (previously used medicinally in Vietnam, or being used medicinally in Vietnam for the first time) which are in insufficient supply for treatment demands.
- Rare drugs.
- Drugs with:
  - the same trade name, active ingredients, concentration and dosage form as an original brand name drug that is granted a certificate of free sale in Vietnam;
  - the same manufacturer as the original brand name drug or an authorized manufacturer; and
  - a price lower than that of the original brand name drug being sold in Vietnam, at the request of the Minister of Health.
- Drugs used for emergency demands of national defense and security, prevention and elimination of epidemics, disaster recovery, or need for special treatment.
- Drugs used for health programs of the state.
- Drugs for aid or humanitarian aid.

– Drugs used for clinical trials, bioequivalence studies, bioavailability assessments, as samples for registration, testing, or scientific research, or for display at fairs or exhibitions.
– Drugs used for other non-commercial purposes.

Licenses and market authorization

3. What are the legal requirements and procedures for authorizing a drug for distribution?

– **Main legislation**
– Law on Pharmacy No. 105/2016/QH13 passed by the National Assembly on 6 April 2016 (Law on Pharmacy).
– Decree No. 54/2017/ND-CP of the Government dated 8 May 2017 guiding the implementation of the Law on Pharmacy, amended by Decree No. 155/2018/ND-CP dated 12 November 2018 (Decree 54);
– Circular No. 44/2014/TT-BYT dated 25 November 2014 of the MOH on drug registration. (As of November 2018, Circular 44 was the main legislation on requirements and procedures for authorizing a drug for distribution, but a new circular was being finalized to replace it.)
– **Legal requirements**

In general, a drug product must be manufactured by a manufacturer that satisfies Good Manufacturing Practice ("**GMP**") requirements. In addition, foreign drugs must be authorized in at least one other country before being registered in Vietnam. The efficacy, safety and quality of the drug must be proved via a technical dossier which harmonizes with the ASEAN Common Technical Dossier ("**ACTD**").

In particular, an application dossier for registration of a new drug or biological product should include the following parts:

Part I	Administrative data and product information dossier;
Part II	Quality dossier;
Part III	Preclinical dossier; and
Part IV	Clinical dossier.

However, an application dossier for registration of a generic drug only needs to include Part I and Part II.

– **Procedures**

The applicant submits a drug registration dossier to the DAV and pays the government fee. After receiving the completed dossier and government fee, the DAV will assess the dossier. More specifically, the dossier will be evaluated by six sub-committees of the DAV before being sent to the Drug Committee for its final evaluation on whether the concerned drug will be approved. The Drug Committee will convene from four to five meetings per year to review and give opinions on such applications. The DAV will only issue an MA for a drug if its application has been approved by the Drug Committee. After being granted an MA, a drug can be legally imported and/or distributed in Vietnam.

4. What are the costs and timelines for getting this authorization?

Under the Law on Pharmacy, an MA must be issued within 12 months from the date of submission of a complete dossier for drug registration. However, in practice, it often takes from 14-18 months for generics and 18-24 months for new drugs.

The government fee for registration of generic drugs is VND 5,500,000 (approximately USD 200); for new drugs and drugs which require bioequivalence data, the fee is VND 5,500,000 (approximately USD 250).

5. Are there streamlined procedures in certain situations, such as when a drug has already been authorized in another country?

There is no streamlined procedure for a drug which has been authorized in another country. However, a drug can be granted an MA in a shorter period than the statutory period if it is: (i) a rare drug used for

special treatment demands; (ii) a drug used for treatment demands in urgent cases, epidemics, or disasters; (iii) a domestic drug manufactured in a new production chain that has been granted GMP certification within the past 18 months; or (iv) a vaccine pre-qualified by the World Health Organization.

Options for foreign pharmaceutical companies to establish presence

6. What are the options for foreign pharmaceutical companies to establish legal or commercial presence within the jurisdiction?

Previously, there were two common options for a foreign pharmaceutical company to set up its commercial presence in Vietnam: (i) a representative office ("**Rep. Office**") or (ii) a foreign direct-invested company ("**FDI Company**"). However, under the new Law on Pharmacy and Decree 54 (as defined above) took effect, the scope of permissible activities of the Rep. Office is very limited. As a result, foreign pharmaceutical companies are now generally choosing to establish or convert to FDI Companies.

7. What are the limitations, if any, of each option?

– **Rep. Office**

The scope of permitted activities granted to a Rep. Office is limited to market research, functioning as a liaison office, and conducting certain marketing activities. A Rep. Office is not allowed to engage in any activity which directly creates revenue in Vietnam. A Rep. Office can no longer employ medical representatives or directly organize drug seminars.

– **FDI Company**

At the moment, by law, an FDI Company may be licensed to engage in importing foreign drugs into Vietnam and reselling them to duly licensed local pharmaceutical companies. In practice, however, the FDI Company may not be able to exercise the right to import the foreign drug into Vietnam because there is lack of a detailed guidelines issued by the MOH. Please refer to our response to question No. 8 below for more information.

Wholesale and retail distribution

8. Who is authorized to import foreign drugs into the jurisdiction?

Under domestic legislation and Vietnam's WTO commitments, local pharmaceutical companies and FDI Companies may import foreign drugs into Vietnam. To import the drugs, the companies are required to obtain the following mandatory licenses/certificates:

– Investment Registration Certificate;
– Enterprise Registration Certificate; and
– Certificate of Eligibility for Pharmaceutical Business ("**CEPB**") for conducting drug-related business (drug importation in this case).

9. Are drugs separated into any different categories for distribution?

The drug distribution system in Vietnam includes wholesale pharmaceutical companies, retail pharmacies and pharmaceutical departments of hospitals. All of them can distribute both prescription drugs and over-the-counter (OTC) drugs. However, retail pharmacies are only permitted to sell prescription drugs when there is a prescription issued by relevant doctors. Retail pharmacies are also prohibited from selling vaccines.

In addition, only certain wholesale pharmaceutical companies indicated by the government can distribute addictive and psychotropic drugs.

10. Who is authorized to distribute drugs to consumers? Is there a difference between prescription and over-the-counter drugs, or other categories?

Retail pharmacies and pharmaceutical departments of hospitals can distribute drugs to consumers (i.e., patients). While pharmaceutical departments may only distribute drugs to their inpatients, retail pharmacies, including pharmacies in hospitals, can distribute drugs to all consumers. As mentioned in question No. 9, the difference between prescription and OTC drugs is that pharmacies can freely sell OTC drugs but they only can sell prescription drugs if prescriptions are presented.

11. What is the legal regime for the wholesale distribution of drugs?

The legal regime regarding wholesale distribution of drugs includes:

– Vietnam's Commitments to the World Trade Organization ("**WTO Commitments**");
– Law on Pharmacy No. 105/2016/QH13 passed by the National Assembly on 6 April 2016 ("**Law on Pharmacy**");
– Decree No. 54/2017/ND-CP of the Government dated 8 May 2017 guiding the implementation of the Law on Pharmacy ("**Decree 54**");
– Circular No. 03/2018/TT-BYT dated 9 February 2018 of the Ministry of Health, promulgating good distribution practices for pharmaceutical products and pharmaceutical starting materials ("**Circular 03**");
– Decision No. 1369/BYT-QLD dated 14 March 2018 of the Ministry of Health, promulgating the distribution right of FDI Companies in Vietnam.

FDI Companies are prohibited from distributing drugs in Vietnam. Local companies manufacturing or trading in pharmaceuticals may be approved for wholesale distribution of drugs. To be duly licensed in wholesale distribution of drugs, local pharmaceutical companies must obtain a CEPB for drug trading in wholesale distribution. The conditions for obtaining the CEPB, among others, are:

- The pharmaceutical professional managers must have the appropriate pharmaceutical practice certificates required for the establishment.
- Material and technical foundations and personnel of the establishment must satisfy criteria set out in the Good Distribution Practice standard.

The provincial Departments of Health are responsible for granting the CEPBs to local drug wholesale establishments.

12. What is the legal regime for the retail distribution of drugs?

The legal regime regarding retail distribution of drugs includes:

– WTO Commitments;
– Law on Pharmacy;
– Decree 54; and
– Circular No. 02/2018/TT-BYT dated 22 January 2018 of the Ministry of Health on Good Pharmacy Practices ("**Circular 02**").

Under the applicable laws and regulations of Vietnam, only local pharmaceutical companies are allowed to carry out retail drug distribution in Vietnam. A local retail establishment must be registered with and obtain a CEPB in retail drug selling from the provincial Department of Health to be duly licensed in the retailing of drugs.

The conditions to obtain the CEPB, among others, are:

- The pharmaceutical professional managers must have the appropriate pharmaceutical practice certificates required for the establishment.
- Material and technical foundations and personnel of the establishment must satisfy criteria set out in the GPP standard.

13. What is the regulatory authority overseeing wholesale and retail distribution?

The pharmaceutical inspection department under the DAV and pharmaceutical inspection unit under the provincial Department of Health are the main authorities for supervising wholesale and retail distribution activities, respectively. Supervision is implemented periodically based on an inspection plan, or irregularly. For inspections based on an inspection plan, a copy of such decision must be delivered to the object of the inspection prior to implementation and must include information about the inspected object, content of the inspection, and time and location of the inspection.

14. Are there any specific requirements for the distribution of drugs online?

Currently, there is no specific legislation governing the distribution of drugs online.

However, distribution of drugs is strictly managed. In general, to distribute drugs, companies and/or pharmacies must satisfy certain physical conditions on human resources and facilities. Pharmacies must satisfy conditions in GPP. As there is no specific legislation, it is likely impossible to adapt all requirements of GPP for selling drugs online.

15. Are there any specific regimes applied in the drug distribution process, such as the tendering scheme with hospitals?

Yes. In addition to the normal drug distribution process, tenders can be organized for drugs which are listed in the Bidding Drug List issued by the Ministry of Health for state-owned medical hospitals/entities. The tender scheme is divided into three categories as follows:

– National centralized tenders organized by the Ministry of Health;
– Provincial centralized tenders organized by the provincial Department of Health; and
– Tenders organized by each hospital.

For centralized tenders (national and provincial), the competent authorities will conduct the tenders, select the winning bidders and enter into master contracts with the winners. After that, depending on the demand of each hospital, the hospitals will enter into sale and purchase contracts with the winning bidders to supply drugs to the hospitals. It is not required to have all drugs in the Bidding Drug List purchased through centralized tenders. Centralized tenders are only used for certain drugs listed in the list of drugs that are required to organize centralized tenders, which is issued by the Ministry of Health.

With regard to tenders organized by hospitals, all drugs listed in the Bidding Drug List must be purchased by bidding.

Marketing

Australia

General Overview

1. What is the general legal regime for the marketing of drugs?

The marketing of drugs is regulated by the Therapeutic Goods Act 1974 (Cth) (Act), and associated regulations.

In general:

– advertising of prescription medicines to consumers is prohibited;
– advertising of over the counter (**OTC**) and complementary medicines is permitted, but in TV, radio and certain print advertisements, requires pre-approval; however, this requirement will cease from 1 July 2020;
– specific regulations in relation to advertising to consumers are set out in the Therapeutic Goods Advertising Code (2015) (**Code**), which is a mandatory code under the Act; significant changes to the Code will take effect from 1 January 2019;
– advertising to health care professionals is not regulated by the Act or Code, but is instead regulated by various industry codes of conduct; and
– consumer protection law will also govern claims made, in particular in relation to claims that are misleading or deceptive or likely to mislead or deceive.

2. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organizations)?

Yes, various industry codes of conduct apply, depending on the type of medicine:

– Prescription medicines: *Medicines Australia Code of Conduct*
– OTC medicines*: Australian Self Medication Industry (**ASMI**) Code of Practice*
– Complementary medicines: *Complementary Medicines Australia (**CMA**) Marketing & Supply Code of Practice: Complementary Medicines.*

These are codes that are binding only to organization members, but non-members are also encouraged to comply.

3. What kinds of licenses/registrations need to be obtained to engage in marketing or promotion activities?

A medicine must be registered or listed on the Australian Register of Therapeutic Goods before it can be advertised. The claims made in advertisements (whether to consumers or healthcare professionals) about a medicine must be consistent with the approved indications set out in its registration or listing.

Marketing to consumers

4. What kinds of marketing activities are permitted, restricted and forbidden in relation to consumers?

Marketing of prescription medicines to consumers is prohibited.

Medicines that contain a substance included in Schedule 3 of the Australian Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Schedule) are known as "**pharmacist-only**" medicines; while these are available to patients without a prescription, marketing of these medicines to consumers is generally prohibited. An exception applies to those pharmacist-only medicines that contain substances set out in Appendix H of the Poisons Schedule.

Under the ASMI Code, "**awareness activities**" in relation to pharmacist-only medicines are also permitted. These are activities that provide information in relation to health and conditions or diseases that are treatable by pharmacist-only medicines. These activities may not refer to any specific medicines; they also need to emphasize the role of the healthcare professional in recommending actual products and direct consumers to their healthcare professional for further information (including a mandatory statement in this regard).

Marketing of other OTC medicines and complementary medicines to consumers is generally permitted; however, certain types of claims are restricted or prohibited, including the following:

– "Prohibited representations" are prohibited; these are defined as:
  - any representation regarding abortifacient action; or
  - any representation regarding the treatment, cure or prevention of the following diseases:
    - Neoplastic
    - Sexually transmitted diseases (STD)
    - HIV AIDS and/or HCV; or
    - Mental illness…

    An exception applies to representations:
    - relating to the prevention of skin cancer through the use of sunscreens; and
    - relating to devices used in contraception or in the prevention of transmission of disease between persons.

– "Restricted representations" are also prohibited, unless approval is obtained from the Department of Health; these are representations that refer (whether expressly or by implication) to "**serious forms**" of certain diseases, ailments and conditions set out in the Code such as cardiovascular diseases, endocrine diseases and conditions (including diabetes and prostatic disease), and gastrointestinal diseases or disorders. A "**serious**" form is one which is generally accepted should not be diagnosed or treated without consulting a healthcare professional, and/or one which is generally accepted to be beyond the average consumer to diagnose accurately or treat safely.

– Advertisements may not contain or imply an endorsement by any government agency, hospital (or other facilities providing health care services), health care professionals, including individuals that appear to be health care professionals. Endorsements by consumer associations, bodies that fund or conduct health or associations that represent health care professionals are permitted but only if certain

mandatory information is disclosed and the endorsement based on an objective evaluation of the available scientific data, or otherwise, and if the body has received consideration for the endorsement, the advertisement must acknowledge the consideration.

– Comparative advertising is generally permitted, but needs to be based on substantiation and reflect the full body of evidence at the time of publishing, and in the case of OTC medicines, may not present the competitor product as being broken or defaced, inoperative or ineffective.
– Certain mandatory statements are required, including mandatory statements for particular types of medicines, e.g., analgesics, vitamins and weight-loss products.
– Generic health or disease awareness campaigns (including campaigns in relation to diseases or conditions treatable by pharmacist-only medicines or prescription medicines) are not regulated by the Act or Code, provided that the campaign does not promote one brand of medicine over another, or otherwise evidences an intention by the advertiser to promote the use or supply or a particular medicine. However, there are restrictions imposed by the ASMI Code and MA Code on campaigns relating to diseases treatable by pharmacist-only medicines or prescription medicines.
– Advertisements generally cannot include an offer of a sample; limited exceptions apply, e.g., sunscreen products.
– Only a limited range of medicines may be advertised to minors, including acne preparations, sunscreens SPF 15+, and bandages and dressings.

Note that the Therapeutic Goods Advertising Code, which sets out most of these requirements, will be significantly amended from 1 January 2019.

5. What kinds of promotion programs are allowed?

Consumer competitions are permitted in relation to medicines that can be advertised to consumers (i.e., OTC and complementary medicines), but are subject to the regulations in relation to advertisements.

In addition, the ASMI Code provides that competitions in relation to OTC medicines cannot be conditional on purchase of the medicine (certain limited exceptions apply).

6. Is any prior approval required for marketing activities and promotion programs?

Yes, approval is required for all advertisements in traditional mass media channels, including advertisements published in print magazines and newspapers, broadcast on television and radio broadcasts, or appearing on cinematographic films, billboards, public transport or shopping mall displays; approval is not required for advertisements in media such as internet or email.

Note that pre-approval will not be required after 1 July 2020.

7. Which authority is responsible for approving/certifying marketing activities and promotion programs?

Technically, authority is with the Therapeutic Goods Administration; however, authority has been delegated to the relevant industry bodies, as follows:

– all consumer advertising on broadcast media, (i.e., TV and radio) for both OTC medicines and complementary medicines, is to be approved by ASMI;
– all other consumer advertising in relation to complementary medicines is to be approved by Complementary Medicines Australia.

8. What regulatory authority is responsible for supervising marketing activities to consumers?

The Therapeutic Goods Administration.

The various industry bodies (ASMI in the case of OTC medicines, and Complementary Medicines Australia in the case of complementary medicines) also supervise marketing activities to consumers and have their own self-regulatory complaints processed.

Marketing to healthcare professionals

9. What kinds of marketing activities are permitted in relation to healthcare professionals?

A medicine must be registered or listed on the Australian Register of Therapeutic Goods before it can be advertised. The claims made in advertisements about a medicine must be consistent with the approved indications set out in its registration or listing.

Marketing to healthcare professionals is governed by various industry codes of conduct, depending on the type of medicine, and does not require prior approval:

– Prescription medicines: Medicines Australia Code of Conduct
– OTC medicines: ASMI Code of Practice
– Complementary medicines: CMA Marketing & Supply Code of Practice: Complementary Medicines (additional requirements apply to practitioner-only products: CMA Guideline for the Sale and Supply of Practitioner Products).

In relation to prescription medicines:

– prescription medicines may only be advertised to healthcare professionals;
– advertisements of prescription medicines to healthcare professionals are permitted in print media, electronic and audiovisual media, online media and healthcare professional media subject to requirements in relation to, among other things, mandatory statements and format (e.g., font size);
– advertisements in prescribing software and brand name reminders are not permitted; and
– samples may be provided to healthcare professionals, subject to a number of requirements (e.g., in relation to size, quantity, labelling and record keeping).

In relation to OTC medicines:

– marketing activities to healthcare professionals are generally permitted, subject to various requirements (e.g., mandatory statements);
– the requirements in relation to mandatory statements do not apply to brand name reminder advertisements; and
– samples may be provided to healthcare professionals with their consent.

In relation to complementary medicines:

– marketing activities to healthcare professionals are generally permitted, subject to various requirements (e.g., mandatory statements);
– internet and social media pages designed specifically for healthcare professionals must be log-in and password protected to prevent access by consumers; and
– samples may be distributed provided the distribution is carried out in a reasonable manner and the distribution and record-keeping complies with any applicable legislation.

Additional requirements apply to complementary medicines that are practitioner only products.

10. What kinds of promotion programs are allowed?

In relation to prescription medicines, the following promotion programs are permitted but subject to various requirements:

– quizzes at trade displays and competitions are permitted but prizes must not be offered;
– Product Familiarization Programs (PFPs): requirements include a prohibition on monetary or other rewards being offered to healthcare professionals, their families and/or their employees for taking part in the PFPs;
– holding educational events: requirements deal with, among other things, educational content, venue selection, meals and beverages, travel, accommodation, entertainment, remuneration and partners, family or guests;
– sponsoring educational events: requirements deal with, among other things, sponsorship reporting, educational content, venue selection, hospitality, remuneration, entertainment and partners, family or guests;
– trade displays: requirements deal with, among other things, gifts, samples, prominently displaying the name of the sponsoring company and ensuring any overseas sponsors are aware of and comply with the Medicines Australia Code of Conduct;
– sponsoring healthcare professionals to attend educational events: requirements deal with, among other things, a formal written sponsorship agreement; travel; accommodation; meals and beverages; remuneration; entertainment; guests, family or companions; required disclosure of the existence of a sponsorship; and a prohibition on sponsorships being conditional upon the healthcare professional recommending, prescribing, dispensing or administering a company's products;
– consulting arrangements: requirements deal with, among other things, a legitimate need for the consulting services, the number of consultants, remuneration and subsidies;
– advisory boards: requirements deal with, among other things, a legitimate need for an advisory board, the size of the board, record-keeping and the location of advisory board meetings;
– financial support for medical practice activities: requirements deal with, among other things, permitted purposes, compliance with privacy legislation and a prohibition on making financial support conditional upon the healthcare professional recommending, prescribing, dispensing or administering a company's products;
– grants and financial support: requirements deal with, among other things, a contract outlining the grant or financial support provided, permitted purposes, loaning medical equipment and a prohibition on making financial support conditional upon the healthcare professional recommending, prescribing, dispensing or administering a company's products; and
– market research with healthcare professionals: requirements deal with, among other things, compliance with the Australian Market and Social Research Society Code of Professional Behavior or an equivalent standard; permitted purposes of the research; information that must be disclosed to participants; and payments (and the disclosure of such), vouchers or donations to charities.

Medicines Australia members are also required to report on their respective websites every six months fees payable to healthcare professionals (e.g., in relation to speaking fees, fees for providing consultancy services or for participating in an advisory board or market research) and the sponsorship of healthcare professionals to attend educational events. Members are also required to report to Medicines Australia every six months on their sponsorship of third-party educational events; Medicines Australia consolidates this data across its members and publishes reports on it.

In relation to OTC medicines, the following promotion programs are permitted in relation to healthcare professionals, pharmacy assistants or other non-healthcare professional sales persons but subject to various requirements:

– promotions/competitions: advertisements/promotions must not offer any personal incentive to recommend or supply therapeutic goods;
– hospitality: this must be appropriate to the occasion, reasonable in the circumstances and of modest value;

– entertainment: this must be appropriate to the occasion and reasonable in the circumstances;
– research and educational grants: the provision of financial support for the purposes of research and/or education must not be conditional upon, or provided in the expectation of, the recipient recommending or supplying therapeutic goods, and the publication of research results must identify the researcher and the financial sponsor; and
– sponsorship of third party educational events: financial support for third-party educational events must be declared in a manner appropriate to the circumstances either by the donor or the recipient of the support, and the sponsor is responsible for ensuring this is done appropriately.

In relation to complementary medicines, the following promotion programs are permitted to healthcare professionals but subject to various requirements:

– competitions: competitions must not contain or imply endorsement of a therapeutic good by a healthcare professional, and must not encourage or be likely to encourage inappropriate or excessive use;
– trade displays: samples must not be made available for collection from unattended trade display stands and gifts or offers can be provided to healthcare professionals to visit trade displays provided they comply with the CMA Code of Practice;
– holding educational events: requirements deal with, among other things, permitted purposes, educational content, disclosing the identity of the organizing company, venue choice, remuneration, and meals and beverages;
– sponsoring healthcare professionals to attend educational events: requirements deal with, among other things, travel, accommodation, meals and beverages, and subsidies;
– sponsoring third-party educational conferences: requirements deal with, among other things, permitted recipients of the sponsorship and educational content;
– research and education grants: requirements deal with, among other things, permitted purposes, a restriction on support being conditional upon or provided in the expectation of the healthcare professional recommending or supplying therapeutic goods, and the disclosure of the researcher and financial sponsor in research results;
– market research with healthcare professionals: requirements deal with, among other things, permitted purposes, information that must be disclosed to participants and payment; and
– consulting arrangements with healthcare professionals: requirements deal with, among other things, remuneration, travel, accommodation and hospitality.

11. What sorts of gifts or other incentives, if any, may be provided to healthcare professionals?

For prescription and complementary medicines, gifts, benefits in kind, or pecuniary advantages must not be offered to healthcare professionals or to administrative staff as inducements to recommend, prescribe, dispense or administer a company's product. This prohibition does not apply to gifts and offers that meet the requirements of:

– company-branded items of stationery;
– educational material directed to healthcare professionals or patients;
– sponsorship to attend an educational event; or
– hospitality at an educational event.

For prescription medicines, the Medicines Australia Code of Conduct provides further detail and states that it is not acceptable to provide flowers, confectionery or other gifts that are not related to the practice of medicine or pharmacy to a health professional to mark or acknowledge an occasion such as a family bereavement or special occasion. These gifts may be given only in a personal capacity at the individual company representative's own expense.

In relation to gifts or offers to encourage health professionals to visit a trade display:

– for prescription medicines: they are prohibited unless they meet the requirements of company-branded items of stationery, educational material directed to healthcare professionals or patients, or hospitality at an educational event;
– for OTC medicines: there is no express permission or prohibition of such gifts or offers;
– for complementary medicines: they are permitted provided they comply with the CMA Code of Practice.

12. What regulatory authority is responsible for supervising marketing and promotion activities regarding professionals?

The Therapeutic Goods Administration (TGA) supervises unregistered or unlisted therapeutic goods and off-label claims. Other issues are subject to self-regulation under the relevant industry body, depending on the type of medicine:

– Prescription medicines: Medicines Australia
– OTC medicines: ASMI
– Complementary medicines: CMA.

China

General overview

1. What is the general legal regime for the marketing of drugs?

There is no specific legislation for the marketing of drugs. However, several regulations will apply when marketing drugs, such as the Measures for the Inspection of Drug Advertisements and Criteria for Censoring Pharmaceutical Advertisements, which define the legal requirements for drug advertisements. Additionally, the Anti-Unfair Competition Law will apply if the promotion activities are considered to be an unfair competitive behavior.

2. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organisations)?

There are no such compulsory standards or regulations in China. There are some guidelines which are not compulsory but would apply if the companies agree to abide by them, including the Code of Practice on the Promotion of Pharmaceutical Products issued by the China Association of Enterprises with Foreign Investment R&D-based Pharmaceutical Association Committee and the Ethical Business Practices for Pharmaceutical Enterprises issued by nine pharmaceutical industry associations.

3. What kinds of licenses/registrations must be obtained to engage in marketing or promotion activities?

There is no specific license for marketing or promotion of drugs; however, drug companies that advertise their drugs must obtain a Drug Advertisement License from the local drug administration.

4. Are there any specific requirements for the marketing of drugs online?

The main requirements for online drug marketing concern the content of marketing. The content of marketing materials or advertisements must be scientific and accurate, and comply with the relevant state laws, regulations and provisions regarding the management of medical and health information. Any information referring to superstitions, obscenities, false information or advertisements which have not been examined and approved cannot be published. It is also prohibited to publish advertisements for medical treatment and pharmaceuticals in mass media communications targeted at minors.

5. What kinds of marketing activities are permitted in relation to consumers?

The Chinese legal system does not classify types of marketing activities or even clarify which activities are permitted, restricted or forbidden. In practice, several laws and regulations will be applied to judge whether marketing activities are allowed. Content or forms of the market activity can also influence the activities' legality.

We have summarised some common marketing activities below for reference:

– **Permitted:**
  - OTC drug advertisements for common consumers;
  - Exhibiting drugs at events; and
  - Patient education.

The above activities are generally permitted in China. These practices will be illegal if bribery or other illegal factors are involved, e.g., the content of the OTC drug advertisement is wrong or misleading.

– **Restricted:**
  - Advertisements of prescription medicines are restricted to the medical or pharmaceutical journals as jointly designated by the public health administrative authority and the NMPA, and cannot be advertised on mass media or promoted in any other manner which targets the public. Prescriptions must not be advertised by distributing medical or pharmaceutical journals to the public for free.

– **Forbidden:**
  - Cash and/or personal gifts; and
  - Advertisements concerning narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs or other specific drugs, pharmaceutical precursor chemicals, as well as drug addiction treatment medicines, medical devices and treatment methods.

6. What kinds of promotion programs are allowed?

Drug promotion programs are generally allowed for both OTC and prescription drugs in China, on the condition that the material benefits to be provided to the consumers shall not be prescription drugs or Type A OTC drugs.

In late 1999, the NMPA issued Regulations on Administration of Distribution of Prescription and Non-prescription Drugs. The regulations prohibited the selling of drugs using some promotion methods, such as lucky draws or the provision of drugs or gifts.

The Measures for the Supervision and Administration of Drug Distribution ('**Measures**'), which came into effect on 1 May 2007, state that the distributor cannot provide the public with prescription drugs or Type A OTC drugs by means of a tie-in sale, or by offering free drugs in association with sales of drug or commodity sale, etc.

Although the NMPA has not clarified whether the Measures have replaced the earlier legislation, under the principle that new regulations shall prevail, the Measures are accepted as the current applicable administration requirements. Therefore, promotion programs are generally allowed if the material benefits provided to the consumers are lucky draws, customer loyalty programs, discounts and Type B OTC drugs. Promotion programs which provide prescription drugs or Type A OTC drugs as material benefits are forbidden.

Promotion programs could be considered to be drug advertisements so are prohibited in some circumstances.

7. Is any prior approval required for marketing activities and promotion programs?

Generally speaking, marketing activities and promotion programs do not require prior approval. However, drug advertisements shall be approved by the authority before being published.

8. Which authority is responsible for approving/certifying marketing activities and promotion programs?

As mentioned above, the NMPA and its local branches will be responsible for approving drug advertisements.

9. What regulatory authority is responsible for supervising marketing activities to consumers?

The NMPA and its branches oversee marketing activities from the regulatory perspective, such as whether the marketing activities constitute advertisements, and whether they have been approved and implemented in the right way, etc.

The SAMR and it local branches will administer the marketing activities from a market supervision perspective, such as whether the activities constitute anti-unfair competition or commercial bribery, etc.

Marketing to healthcare professionals

10. What kinds of marketing activities are permitted in relation to healthcare professionals?

The Chinese legal system does not classify the types of marketing activities or clarify whether such activities are permitted, restricted or forbidden. In practice, several laws and regulations will be applied to judge whether marketing activities are allowed. Content or forms of the market activity can also influence the activities' legality.

The PRC anti-bribery regime and drug advertisement administration regime will apply as the governmental administration level. Additionally, the China Association of Enterprises with Foreign Investment R&D-Based Pharmaceutical Association Committee (RDPAC) Code of Practice, which defines the interactions between pharmaceutical companies and healthcare professionals, will apply for all its member firms as industry guidance.

Based on the government administration and industry association guidance above, we have summarised some common marketing activities below for reference:

– **Permitted**:
  - Provide promotion materials and reasonable promotion aids and gifts;
  - Provide free samples for healthcare professionals;
  - Exhibit the products' information at certain events; and Sales representatives' normal communication activities with healthcare professionals.

The above activities are generally permitted in China, however, if bribery or other illegal factors are involved in such activities, e.g., sales representatives give kickbacks to doctors for the doctors' prescription on certain drugs, then such activities will be forbidden.

– **Restricted**:
  - Holding or sponsoring events and meetings, including continuing medical education and other events which aim to provide scientific or educational information for healthcare professionals;
  - Supporting healthcare professionals with attending events in China, on the condition that the company does not require any unreasonable return from the healthcare professional and only pay reasonable costs.
  - Organisation or sponsorship of exchange-related activities/events outside China, unless it is appropriate and justified to do so from the logistical or security point of view;
  - Engaging healthcare professionals to speak/advise, which is only permitted with a written agreement that clarifies the nature of the service and payment;
  - Reasonable refreshments and/or meals incidental to the primary purpose of the event;
  - Distributing promotional materials (printed and electronic copies), which must:

- Clearly indicate the sponsor company;
- Be consistent with the information approved by the NMPA;
- Be clear, legible, accurate, balanced, fair and sufficiently complete to enable the recipient to form his or her own opinion;
- Not be misleading or ambiguous and all claims shall be validated; and
- Contain certain information, such as the drug name, active ingredients, pharmaceutical company, production dates of the material and abbreviated prescribing information.

– **Forbidden**:
  - Cash, luxury items, personal gifts, entertainment, leisure events; and
  - Advertisement concerning narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs or other specific drugs, pharmaceutical precursor chemicals, as well as drug addiction treatment medicines, medical devices and treatment methods are forbidden.

The above listed items are examples only for reference. There may be further limitations or restrictions when performing marketing activities with healthcare professionals.

– **What kinds of promotion programs are allowed?**

Samples are permitted. However, samples will be subject to any additional requirements of Chinese law. Free samples of a pharmaceutical product may be supplied to healthcare professionals in order to enhance patient care. Samples should clearly be identified as ‘Sample’ or ‘Not for Sale’ and should not be resold or otherwise misused.

– **What sorts of gifts or other incentives, if any, may be provided to healthcare professionals?**
  - Promotional aids: Promotional aids of minimal value that are relevant to the practice of the healthcare professional. Possible examples of appropriate items include: pens, notepads, USB flash drives and laser pens;
  - Items of medical utility: Items of medical utility may be offered or provided free of charge or of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care. Items might include an anatomical model, diagrams for use in an examination room, medical textbooks, journals, magazines or e-journal subscriptions.

11. What is the regulatory authority overseeing marketing to healthcare professionals?

NMPA, SAMR, State Council and their local branches mentioned in question No. 13 have different levels of administrative rights over marketing activities aimed toward healthcare professionals. Meanwhile, the National Health Commission of the People’s Republic of China also oversees marketing from healthcare professional’s administrative perspective.

India

General Overview

1. What is the general legal regime for the marketing of drugs?

– **Marketing of drugs to the public**

Drugs can be marketed only after seeking approval from the CDSCO. Only those drugs which the CDSCO lists as approved drugs for marketing purposes can be marketed. Certain requirements pertaining to the submission of specified kinds of studies via clinical trials can be modified or relaxed in cases in which new drugs have been approved and marketed for several years in other countries and there is adequate published evidence regarding their safety.

– **Marketing of drugs to healthcare professionals**

Doctors and dentists are regulated by the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 ("**Professional Conduct Regulations**") and the Revised Dentists (Code of Ethics) Regulations, 2014 ("**Dentists Code**"), respectively. Amongst other things, these regulations impose restrictions and penalties on healthcare professionals for accepting gifts, etc. from pharmaceutical companies, the allied healthcare industry, or their representatives, inter alia.

The pharmaceutical companies are expected to comply with the Uniform Code of Pharmaceuticals Marketing Practices ("**UCPMP**"), which is a voluntary code in place to regulate pharmaceutical companies and associations with respect to the marketing of drugs. While the UCPMP is currently expected to be voluntarily followed, it does not have the force of law.

2. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organizations)?

Apart from UCPMP, the Dentists Code and the Professional Conduct Regulations mentioned above, associations of healthcare professionals and hospitals have prescribed codes of conduct for their members. For example, the Organisation of Pharmaceutical Producers of India ("**OPPI**") in 2012 issued the Code of Pharmaceutical Marketing Practices to govern their members. Additionally, another voluntary code, the Code of Ethics for Healthcare by the Indian Medical Association and Nathealth, is in place for their members.

3. What kinds of licenses/registrations need to be obtained to engage in marketing or promotion activities?

With respect to marketing/promotion activities to healthcare professionals, no prior licensing/registration requirements have been specified.

4. Are there any specific requirements for the marketing of drugs online?

While there are no specific requirements for online marketing, the rules applicable to offline marketing (specified in answers 16 and 20) have to be complied with to carry out online marketing.

Marketing to consumers

5. What kinds of marketing activities are permitted, restricted and forbidden in relation to consumers?

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 ("**Objectionable Advertisements Act**") bars the advertising of certain specified medicines (for example, those causing miscarriage or prevention of conception among women, etc.), false claims attributed to medicines, etc.

As per the Rules, Schedule H, H1 and X drugs (which can be sold only upon a doctor's prescription) cannot be advertised except with prior Central Government sanction. Non-prescription drugs, however, can be advertised subject to the Objectionable Advertisements Act. While it is not possible to advertise prescription-only medicines to the general public, disease awareness campaigns which encourage persons with certain medical conditions to consult their doctor without advertising the drug are permitted. Further, the Rules specify in Schedule J certain diseases/ailments which a drug may not purport or claim to prevent or cure (e.g. AIDS, cancer, etc.).

Additionally, the Advertising Standards Council of India ("ASCI") is a self-regulatory, voluntary body of the advertising industry in India. Though the ASCI is not a governmental agency, advertisements meant for public exhibition carried by cable services must comply with the ASCI Code, as per the Cable Television Network Rules, 1994. The ASCI, inter alia, promotes advertising in a truthful and honest manner which is not offensive to the public and is against harmful products and unsafe situations, etc.

6. What kinds of promotion programs are allowed?

Promoting the sale of drugs is governed by general laws in place to prevent unfair trade practices. The Consumer Protection Act, 1986 prohibits "unfair trade practices", which are defined as trade practices that, for the purpose of promoting the sale, use or supply of any goods or for the provision of any service, adopt any unfair method or unfair or deceptive practice. An inclusive list of instances which would qualify as unfair trade practices has been provided which, inter alia, include "the conduct of any contest, lottery, game of chance or skill, for the purpose of promoting directly or indirectly, the sale, use or supply of any product or any business interest". However, while such activities are routinely carried out for promotion of products, the legal position around their validity is ambiguous.

7. Is any prior approval required for marketing activities and promotion programs?

No prior approval is required for marketing and promotional activities once the CDSCO approves the drug for marketing. Please refer to answer 20 for restrictions in the general legal regime.

8. Which authority is responsible for approving/certifying marketing activities and promotion programs?

Please see answer 22.

9. What regulatory authority is responsible for supervising marketing activities to consumers?

The CDSCO and state drug control agencies are responsible for supervising marketing activities relating to drugs.

Marketing to healthcare professionals

10. What kinds of marketing activities are permitted in relation to healthcare professionals?

As per the Professional Conduct Regulations, doctors are barred from receiving gifts, travel facilities, hospitality, cash/monetary grants from pharmaceutical and the allied health sector industry. Doctors can receive medical research/study funding only from approved institutions, in a transparent manner and subject to other specified conditions.

The Dentists Code imposes similar restrictions on dentists. However, a penalty is provided in the Professional Conduct Regulations only when the gift value exceeds INR 1,000. Accordingly, one can argue that gifts up to INR 999 may be made and would most likely not qualify as a breach.

The pharmaceutical companies are regulated by the UCPMP, as stated in answer 16. The UCPMP prohibits pharmaceutical companies from giving gifts to doctors to boost the sale of drugs or for their personal benefit. Further, they are prohibited from providing any cash/monetary grants, travel allowances and hospitality services to healthcare professionals and their families, either within the country or outside it, for any conference or for the purpose of continuing medical education.

Similarly, the distribution of free drug samples must be in accordance with the UCPMP. Seminars, conferences or meetings can be organized by pharmaceutical companies for promoting drugs or disseminating information, but the participating practitioner has to pay for his/her own costs.

Further, as per the Professional Conduct Regulations, if the healthcare professional has been appointed as a consultant to the pharmaceutical company, he/she may be compensated for his/her services and, accordingly, his/her participation in a seminar or conference may be funded. The amount payable under such consultancy arrangement must be reasonable and will depend on the location where the services are rendered and the seniority, reputation etc., of the relevant person and the pharmaceutical company. While there is no published guidance from authorities on standards pertaining to this, healthcare professionals are expected at all times to maintain their professional autonomy, not endorse the products of the pharmaceutical company and ensure transparency. In case consultancy fees are paid, records of such payments must be maintained by the pharmaceutical company as well as the healthcare professional to ensure transparency.

Further, all marketing practices which the Professional Conduct Rules prohibit are deemed to be prohibited under the UCPMP.

11. What kinds of promotion programs are allowed?

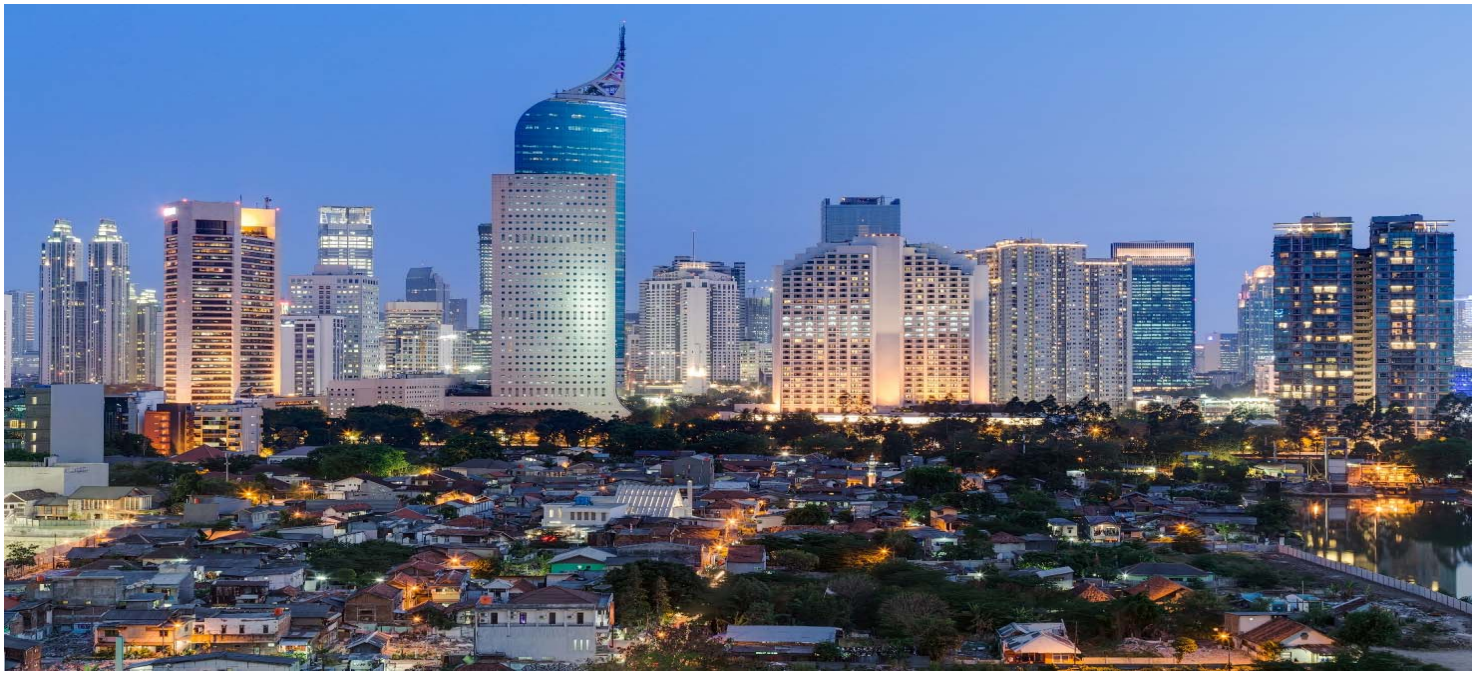
No promotion activities in terms of providing “material benefits” to healthcare persons in return for boosting sales of products are allowed. Please see answer 25 for permitted marketing activities. Free sample drugs can be given subject to the Code and it requires, inter alia, that such samples are provided only on an exceptional basis and for the purposes of acquiring experience in dealing with such product.

12. What sorts of gifts or other incentives, if any, may be provided to healthcare professionals?

No gifts or other incentives, such as domestic/foreign conferences sponsored by pharmaceutical companies, can be given to healthcare professionals apart from the ones specified in answer 25.

13. What regulatory authority is responsible for supervising marketing and promotion activities regarding professionals?

As stated above, healthcare professionals, i.e., doctors and dentists, are governed by the Professional Conduct Regulations and the Dentists Code, respectively, while the pharmaceutical companies are governed by the voluntary UCPMP. The Medical Council of India and the Dental Council of India monitor the compliance with the above Codes. The responsibility of regulating pharmaceutical companies under the UCPMP lies with associations of pharmaceutical companies like the Indian Drug Manufacturer Associations, Indian Pharmaceutical Association, etc. Similarly, the OPPI, Nathealth and other associations of healthcare professionals and institutions regulate their members' marketing activities, as per their Codes.



Indonesia

General overview

1. What is the general legal regime for the marketing of drugs?

– **Legal Regime**

The marketing of drugs is regulated in the Decree of the Head of BPOM No. HK.00.05.3.02706 of 2002 on Drug Promotion. However, general legislation applicable to marketing must be considered when conducting marketing activities. For example:

– The Consumer Protection Law must be observed when targeting consumers;
– The Anti-Monopoly Law must be taken into consideration when marketing activities are targeted to businesses.

– **Limits to Marketing Activities**

Pursuant to the Decree of the Head of BPOM No. HK.00.05.3.02706 of 2002 on Drug Promotion, the limits to marketing activities are as follows:

– Drugs promotions in the form of sponsorship are only allowed for scientific purposes;
– Provision of drugs to an institution (but not to professionals) as donations must not come with an obligation for the recipient to prescribe the drugs;
– Pharmaceutical producers/distributors must not:
  - i. Enter into cooperation with pharmacies or drugs prescribers (such as doctors);
  - ii. Organize a group specifically to increase the use of certain drugs for marketing purposes; and
  - iii. Promote certain drugs by using prizes as the reward (e.g., quizzes).

In addition, all promotional activities must be done on a transparent basis, and the drugs must come provided with written product information that is objective, complete and correct. The product information must contain the following minimum information:

– Name of the product;
– Name of the producer/importer;
– Components or main ingredients of the product;
– Directions for use;
– Warnings and side effects; and
– Expiry date.

2. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organizations)?

The Association of Indonesian Pharmaceutical Companies/Gabungan Perusahaan Farmasi Indonesia and the Association of International Pharmaceutical Manufacturer Group/*Perkumpulan International Pharmaceutical Manufacturers Group* have their own code of ethics, namely:

– Code of Ethics on Marketing in the Indonesian Pharmaceutical Industry/*Kode Etik Pemasaran Usaha Farmasi di Indonesia*; and

– Code of Ethics on Pharmaceutical Product Marketing Practices/*Kode Etik Praktek Pemasaran Produk Farmasi*

All relevant parties have an obligation to comply with the codes, and the codes may be considered as constituting customary regulations of the industry and complementing the prevailing regulations.

3. What kinds of licenses/registrations must be obtained to engage in marketing or promotion activities?

Please see our response to question No. 6.

4. Are there any specific requirements for the marketing of drugs online?

Please see our response to question No. 14 on online transactions and question No. 1 on the limitations of marketing activities.

Marketing to consumers

5. What kinds of marketing activities are permitted in relation to consumers?

Indonesian laws and regulations are silent about the permitted marketing activities. However, the limitations provided in question No. 1 above must be considered when conducting marketing activities.

6. What kinds of promotion programs are allowed?

There is no specific law or regulation that governs promotion programs that are allowed with respect to consumers. Nevertheless, it should be noted that any narration of the promotion program regarding claims of efficacy of the drugs must be in accordance with the claims that have been approved by the BPOM in the MA/*Izin* Edar.

7. Is any prior approval required for marketing activities and promotion programs?

– **Marketing Activities:**

Yes, any drugs to be distributed and/or marketed within Indonesian territory must first be registered in order to obtain an MA/Izin Edar from the BPOM.

– **Promotion Programs:**

No. However, the narration of the promotion program regarding claims of efficacy of the drugs must be in accordance with the claims that have been approved by the BPOM in the MA/Izin Edar.

8. Which authority is responsible for approving/certifying marketing activities and promotion programs?

BPOM has the authority to approve the marketing activities by issuing the MA/*Izin* Edar.

As for promotion programs, no approval is required.

9. What regulatory authority is responsible for supervising marketing activities to consumers?

BPOM is authorized to supervise marketing activities. In order to conduct the supervision over marketing and promotional activities, the head of BPOM may establish an independent commission made up of members from healthcare professional organizations.

Marketing to healthcare professionals

10. What kinds of marketing activities are permitted in relation to healthcare professionals?

Indonesian laws and regulations are silent about the permitted marketing activities in relation to healthcare professionals. However, the limitations provided in question No. 14 above must be considered when conducting marketing activities.

11. What kinds of promotion programs are allowed?

As we explained in question No. 1, the following kinds of promotions are allowed for healthcare professionals:

– Drug promotions in the form of sponsorship to provide information about such drugs are only allowed for scientific purposes; and
– Drugs promotions in the form of donations may only be provided to an institution (not to professional) and must not come with an obligation for the recipient to prescribe the drugs.

12. What sorts of gifts or other incentives, if any, may be provided to healthcare professionals?

Any gifts in form of money (cash, loan, voucher, ticket, etc.) provided by the pharmaceutical industry or large pharmaceutical distributors/*pedagang besar farmasi* to healthcare professionals who prescribe their drugs are not allowed.

13. What regulatory authority is responsible for supervising marketing and promotion activities regarding professionals?

Please see our response to question No. 7.

Japan

General Overview

1. What is the general legal regime for the marketing of drugs?

The Pharmaceutical and Medical Devices Law forbids false or exaggerated advertising,35 as well as advertising toward the general public for specified pharmaceuticals or regenerative medicine products intended for use in the cure of cancer or other designated diseases36 or advertisement of pharmaceuticals, etc., which have not yet been approved.37

In addition, the MHLW has issued “Standards on Appropriate Advertising of Pharmaceuticals” and “Interpretations and Notes regarding Standards on Appropriate Advertising of Pharmaceuticals”, and, in practice, the advertising of pharmaceuticals is governed by these guidelines.

Further, at present, the MHLW is currently drafting guidelines regarding activities to provide sales information regarding the sale of prescription pharmaceuticals (these guidelines were opened to public comment from July 12 until August 13 of 2018), and it will be required that information provided regarding prescription pharmaceuticals follow these guidelines in the future.

2. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organizations)?

The following industry organizations for prescription pharmaceuticals, OTC pharmaceuticals, and medical devices have issued guidelines which should be followed with regard to advertising.

– **Japan Pharmaceutical Manufacturers Association**: Guidelines for creation of advertising for prescription pharmaceuticals
– **Japan Self-Medication Industry**: OTC pharmaceuticals Proper Advertising Guidelines
– **Japan Federation of Medical Devices Associations**: Collected Guidelines for Proper Advertising of Medical Devices

3. What kinds of licenses/registrations need to be obtained to engage in marketing or promotion activities?

For marketing/promotion activities, no prior licensing/registration requirements have been specified.

[35] Article 66 of the Pharmaceutical and Medical Devices Law
[36] Article 67 of the Pharmaceutical and Medical Devices Law
[37] Article 68 of the Pharmaceutical and Medical Devices Law

Marketing to consumers

4. What kinds of marketing activities are permitted, restricted and forbidden in relation to consumers?

– **For approved pharmaceuticals and medical devices:**

For prescription pharmaceuticals and medical devices, etc. for physicians, etc., it is not permitted to advertise to the general public. Also, even for other pharmaceutical products, conforming to proper advertising standards is required. The list of behaviors or actions that are not permitted under the Standards on Appropriate Advertising of Pharmaceuticals is as follows:

- Using a name other than the name that has received approval.
- Expressions that risk giving an impression that is contrary to fact regarding the excellence of a product, such as “Leading edge manufacturing methods.”
- For a pharmaceutical that has obtained approval as an “analgesic”, to advertise an effect/efficacy which exceeds the scope of the effect or efficacy for which it received approval, for example, as “antihypertensive”.
- Use of expressions exceeding the scope of approval, or inaccurate expressions regarding the method of use or quantity to be used, such as “no matter how much you take, there are no side effects” or “it is safe no matter how you use it.”
- With regard to the effect/efficacy or the safety, it is not permitted to advertise that statements such as “complete recovery, powerful medicine, excellent effectiveness, without (or minimal) side effects, confirmed safety, gentle, can be used with confidence” are guaranteed to be true. Also it is not permitted to use clinical data, experimental cases, or user experiences in advertising.
- Use of superlatives or similar expressions with regard to effect/efficacy or safety, such as “ACE Gastrointestinal Medicine, No. 1 Seller, Mighty, Totally Safe.”
- Expressions exceeding the medically or pharmaceutically approved range with regarding to the level of effect/efficacy, for example: “quick-acting, works for three days in a row, fast acting”, or, for headache medicines, for example, statements in advertising like “pass the entrance exam.”
- Advertising in which a child holds the medicine in its hands or other advertisements which risk promoting excessive consumption or abuse.
- Advertising related to diseases which cannot be expected to be cured, etc., unless therapy is offered by physicians, etc. For example, advertisements may not use the names of diseases such as “gastric ulcer”, “diabetes”, “hypertension”, “heart disease”, etc.
- Advertising that defames the products of other companies.
- Advertising with endorsements (“blurbs”) from medical professionals.
- Advertising which confers pharmaceuticals as goods or prizes (but samples are acceptable).
- Advertising which risks causing distasteful feelings, trouble, anxiety, or fear. For example, a phrase may be repeated no more than five times, and strange voices are not permitted. Also, expressions that cause anxiety such as “You already have XX disease” are not permitted.

– **For pharmaceuticals and medical devices that are not yet approved:**

Advertising of unapproved pharmaceuticals and medical devices is forbidden, and violators may be punished by up to 2 years in prison with labor, a fine of up to JPY 2 million, or both.

5. What kinds of promotion programs are allowed?

Promotion programs of any sort are allowed, provided that they do not violate the Proper Advertising Standards for Pharmaceuticals, etc.

6. Is any prior approval required for marketing activities and promotion programs?

No prior approval for marketing activities or promotion programs is required.

7. Which authority is responsible for approving/certifying marketing activities and promotion programs?

For marketing activities and promotion programs for pharmaceuticals and medical devices, the MHLW as well as each prefecture, cities with public health centers, and special wards have this authority.

Most of the actual enforcement of the relevant laws is carried out by prefectures or the public health centers.

8. What regulatory authority is responsible for supervising marketing activities to consumers?

With regard to marketing activities aimed at consumers for pharmaceuticals and medical devices, the Compliance and Narcotics Division of the Pharmaceutical Safety and Environmental Health Bureau, which is in the MHLW, would have this authority, and each prefecture, cities with public health centers, and special wards also have departments in charge of pharmaceutical affairs, which have authority.

Also, most of the actual enforcement of the relevant laws is carried out by prefecture or the public health centers.

Marketing to healthcare professionals

9. What kinds of marketing activities are permitted in relation to healthcare professionals?

Please see our response to No. 4 above.

Just as with marketing activities aimed at consumers, the Standards for Proper Advertising of Pharmaceuticals, etc., apply. However, due to the provision of improper information by pharmaceutical marketing authorization holders becoming a problem (such as advertisements claiming an effect/efficacy outside the scope of approval), the MHLW is currently studying how to respond to these problems.

There is a plan to issue guidelines for marketing activities for prescription pharmaceuticals in the future, and business operators will be required to provide information in compliance with such guidelines.

10. What kinds of promotion programs are allowed?

Please see our response to question No.4 above.

11. What sorts of gifts or other incentives, if any, may be provided to healthcare professionals?

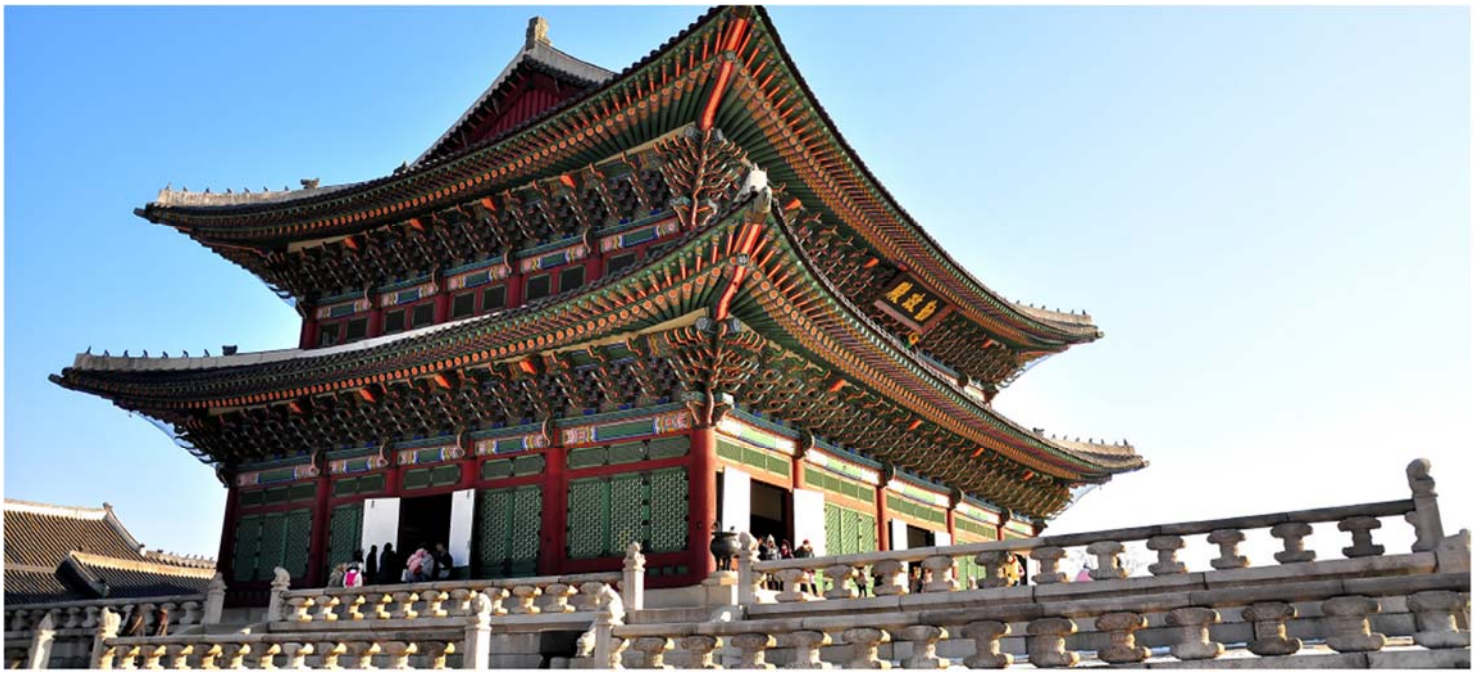
Under the Fair Competition Code concerning Restriction on Premium Offers in the Prescription Pharmaceuticals Marketing Industry (issued by the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry) as a measure against improper inducements involving prescription pharmaceuticals, it is not permitted to offer premiums. Exceptions to this restriction are as follows:

– In the case of providing goods or services that are necessary when using prescription pharmaceuticals, etc., of one's own company at a medical facility, etc., or providing goods or services which improve the utility or convenience thereof.
– In the case of providing materials, or explanatory materials, related to medical or pharmaceutical information and the like, on prescription pharmaceuticals, which relate to one's own prescription pharmaceuticals.
– In the case of providing pharmaceuticals for test use.

– In the case that a request has been made to a medical facility, etc., and payment of compensation and costs has been made for medical or pharmacological investigation or research for post-marketing investigation, testing, or clinical trial, etc. of the prescription pharmaceuticals.
– In the case that goods or services are provided, or the pharmaceutical company assumes the burdens of the costs of attendance, when providing a lecture on one's own pharmaceuticals for a medical facility, etc., so long as the relevant costs are not extravagant or excessive.

12. What regulatory authority is responsible for supervising marketing and promotion activities regarding professionals?

With regard to overseeing marketing to healthcare professionals, in addition to the MHLW, each prefecture, cities with public health centers, and special wards also have this authority.



Korea

General overview

1. What is the general legal regime for the marketing of drugs?

Only approved or reported drugs are allowed to be marketed. Marketing unapproved or unreported drugs can subject the marketing company to criminal and administrative sanctions.

2. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organizations)?

The Korea Fair Trade Commission regulates drug advertising that is false, misleading, exaggerated or makes use of unfair comparisons under the Act on Fair Labelling and Advertising.

In addition, the Korean Research-based Pharma Industry Association ('**KRPIA**'), an association for global pharmaceutical companies in Korea, has internally set up the KRPIA Fair Competition Code and Working Guideline in order to provide its member companies with detailed guidelines to comply with the Monopoly Regulation and Fair Trade Act that prohibits unfair solicitation of customers.

3. What kinds of licenses/registrations need to be obtained to engage in marketing or promotion activities?

Nobody other than a licensed manufacturer, importer, distributor or pharmacy can engage in marketing or promotion of drugs. However, a simple service provider for such marketing or promotional activities does not need to obtain approval or license from the MFDS.

Marketing to consumers

4. What kinds of marketing activities are permitted, restricted and forbidden in relation to consumers?

Over-the-counter drugs can be advertised through media such as print, broadcast and Internet. However, such direct-to-consumer mass advertising generally cannot be used for the purpose of marketing prescription drugs.

5. What kinds of promotion programs are allowed?

Other than advertising, the Pharmaceutical Affairs Act does not specifically mention what types of promotion programs are allowed for consumers.

6. Is any prior approval required for marketing activities and promotion programs?

In general, advertisements for over-the-counter drugs must be reviewed and approved by the MFDS.

7. Which authority is responsible for approving/certifying marketing activities and promotion programs?

MFDS.

8. What regulatory authority is responsible for supervising marketing activities to consumers?

MFDS.

Marketing to healthcare professionals

9. What kinds of marketing activities are permitted in relation to healthcare professionals?

In general, other than the activities that are specifically listed as exceptions, any provision of an economic benefit to healthcare professionals is prohibited. The exceptions are as follows:

– provision of samples;
– donations for medical, pharmaceutical, educational and charitable purposes;
– support of participation, hosting or operation of academic conferences;
– product presentations;
– provision of drugs for clinical trials;
– market survey;
– post-market surveillance study and other clinical activities; and
– exhibition and advertisement.

Please note, however, that each of the exceptions has detailed requirements, procedures and limitations.

10. What kinds of promotion programs are allowed?

Please see question No. 9 above.

11. What sorts of gifts or other incentives, if any, may be provided to healthcare professionals?

No gifts or incentives may be provided to HCPs unless they fall under one of the exceptions listed in question No. 9 above.

12. What regulatory authority is responsible for supervising marketing and promotion activities regarding professionals?

– MOHW
– MFDS
– Korea Fair Trade Commission
– Anti-Corruption and Civil Rights Commission

Singapore

General overview

1. What is the general legal regime for the marketing of drugs?

The marketing of drugs is governed by the Medicines Act and the Medicines (Medical Advertisements) Regulations.

2. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organizations)?

In addition to the requirements imposed by the Medicines Act and the Medicines (Medical Advertisements) Regulations, all medical advertisements must also comply with the Singapore Code of Advertising Practice drawn up by the Advertising Standards Authority of Singapore.

3. What kinds of licenses/registrations need to be obtained to engage in marketing or promotion activities?

Under the Medicines Act and the Medicines (Medical Advertisements) Regulations, no person shall issue or cause to be issued any medical advertisement or conduct any sales promotion without first obtaining a permit from the HSA.

'**Medical advertisement**' is defined under the Medicines Act as an advertisement relating to, or likely to cause any person to believe that it relates to, any medicinal product or any device, instrument, apparatus or contrivance used or represented to be used for a medicinal purpose.

'**Sales promotion**' is defined under the Medicines (Medical Advertisements) Regulations as any sales campaign (including door-to-door sales), exhibition, competition or any other activity for the purposes of introducing, publicizing 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.

4. Are there any specific requirements for the marketing of drugs online?

Internet advertising of medicinal products is subject to the same rules as advertising in other mediums.

Marketing to consumers

5. What kinds of marketing activities are permitted, restricted and forbidden in relation to consumers?

– **Permitted marketing activities**

In general, medical advertisements and sales promotions are permitted as long as the requisite permits are validly obtained from the HSA prior to the carrying out of such medical advertising.

Before a medical advertisement is published or a sales promotion is conducted, it is mandatory for the company initiating the advertisement and the publisher, media owner or the organizer(s) of the sales promotion to ensure that:

– The advertisement or sales promotion has a valid permit from the HSA;
– The permit number is printed legibly on the advertisement and promotional materials; and
– The advertisement has not been amended without prior written permission from the HSA.

In addition, the following types of advertisements relating to medicinal products do not require a permit from the HSA:

– Package inserts accompanying the product;
– Announcements and warnings on imitation of medicinal products with no intent to advertise the product;
– Announcements on the name and address of a new distributor;
– Display cards on product shelves printed with only the name of the medicinal product and the price (not the special or discounted price);
– Packaging with a protruding display flap, containing a single unit of a medicinal product;
– Reference advertisements: product information pertaining to the safe and correct use of a medicinal product, published by a person or company with no commercial interest in the product, for dissemination to practitioners and pharmacists; and
– Trade advertisements: defined as a document for the purpose of a sale by way of wholesale dealing which does not contain any recommendations on product use.

– **Restricted marketing activities**

The following product names are not allowed for advertising:

– Names with sexual implications;
– Names that are exaggerated or misleading; and
– Names which specify substances that are not found in the product.

There are also additional guidelines and restrictions in relation to specific products; for instance, among other products, medicines sold in pharmacies only, red yeast rice products and slimming products.

– Forbidden marketing activities

No advertisements are allowed for any product or article with any direct or indirect reference to the list of 19 diseases and conditions listed in the First Schedule to the Medicines Act. In addition, no advertisements referring to any skill or service relating to the treatment of any disease or condition affecting the human body are allowed.

False or misleading advertisements relating to medicinal products are also forbidden under the Medicines Act. Any person who carries out any such false or misleading advertisements will be guilty of an offense and shall be liable on conviction to a fine not exceeding S$5,000 or to imprisonment of a term not exceeding two years, or to both.

Medicines that require a doctor's prescription may not be advertised or subject to sales promotions.

6. What kinds of promotion programs are allowed?

Please see our response to question No. 5 above.

In addition, under the Medicines (Medical Advertisements) Regulations, no person shall, in conducting any sales promotion, offer any gift or prize to promote the sale of any medicinal product.

7. Is any prior approval required for marketing activities and promotion programs?

Yes, please see our response to question No. 5 above.

8. Which authority is responsible for approving/certifying marketing activities and promotion programs?

The Ministry of Health and HSA approve/certify marketing activities and promotion programs.

9. What regulatory authority is responsible for supervising marketing activities to consumers??

The Ministry of Health and HSA oversee marketing to consumers.

Marketing to healthcare professionals

10. What kinds of marketing activities are permitted in relation to healthcare professionals?

– **Permitted marketing activities**

Only promotional materials meant for dissemination to healthcare professionals may be distributed without a permit from the HSA. It should be stated clearly on the materials that they are for healthcare professionals only and not for general circulation. Nonetheless, the HSA may, when it deems necessary in the interest of public safety, subject such medical advertising to regulatory control.

In addition, under the Medicines (Advertisements by Healthcare Institutions) (Exemption) Order 2004, any private hospital, medical clinic, clinical laboratory or healthcare establishment licensed under the Private Hospitals and Medical Clinics Act may publish or cause to be published any advertisement referring to any skill or service relating to the treatment of any disease or condition affecting the human body.

11. What kinds of promotion programs are allowed?

Distribution of samples or bonus offers to drug stores, pharmacies, wholesalers and clinics – provided there is no sales promotion to the general public – do not require a permit from the HSA. Nonetheless, the HSA may, when it deems necessary in the interest of public safety, subject such sales promotion to regulatory control.

12. What sorts of gifts or other incentives, if any, may be provided to healthcare professionals?

– **Doctors**

The Medical Registration Regulations 2010 provides that every registered medical practitioner must observe the pronouncements on professional matters and professional ethics issued from time to time by the Singapore Medical Council.

Under the Ethical Code and Ethical Guidelines promulgated by the Singapore Medical Council, a doctor can receive small, insubstantial gifts which cannot be regarded as inducement. However, a doctor cannot ask for gifts, hospitality or other inducements that may affect or be seen to affect his or her judgment in making decisions about patients' treatment. A breach of the Ethical Code and Ethical Guidelines could

lead to doctors being asked to defend their actions and ultimately to face disciplinary proceedings for professional misconduct.

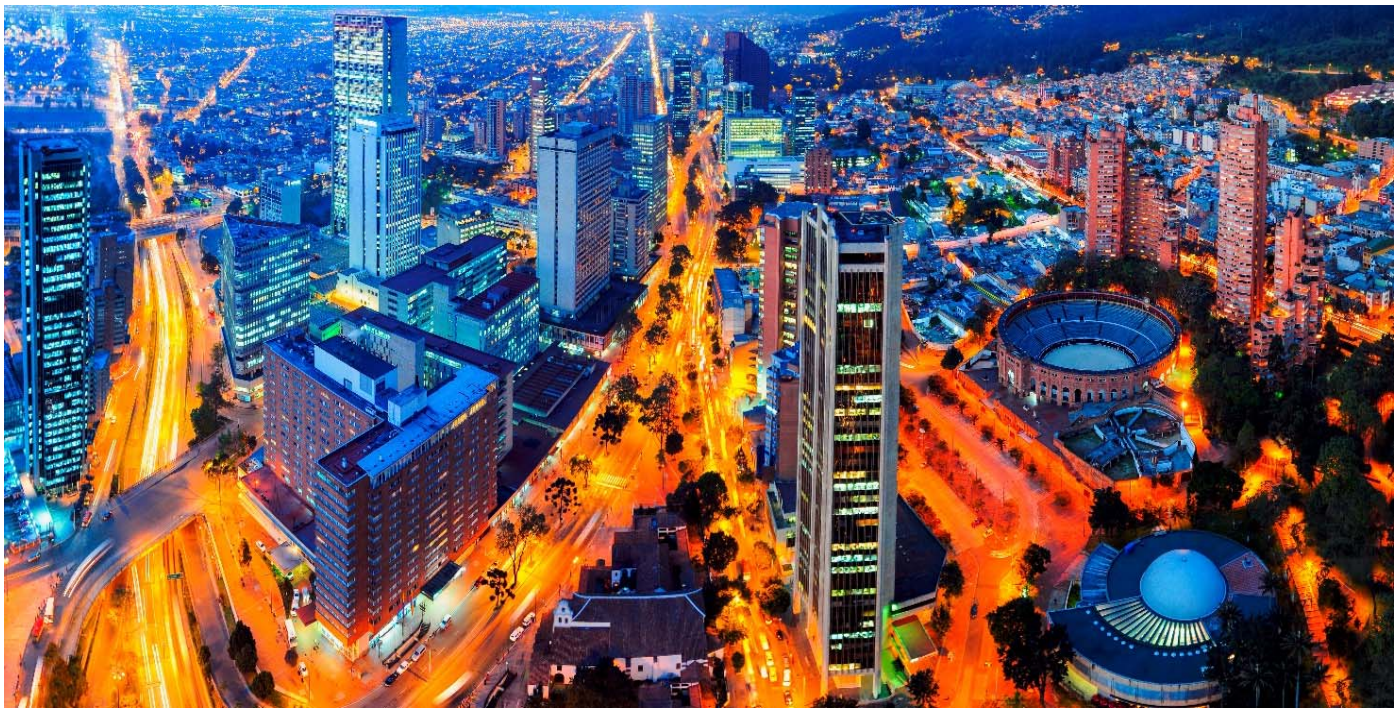
– **Members of the Singapore Association for Pharmaceutical Industries**

Under the Singapore Association for Pharmaceutical Industries ('**SAPI**') Code of Marketing Practices, promotional items of insignificant value of not more than S$20 provided free of charge are permissible as long as they are related to the healthcare professional's work and/or entail a benefit to patients. Gifts as a token of appreciation for services rendered by healthcare professionals should be limited to S$50 or less. Congratulatory flowers limited to promotions, conferment of awards or clinic opening should be limited to S$150 per occasion.

Congratulatory messages in any form of media on behalf of a healthcare professional or a center are strictly prohibited. Exceptional gifts during various festive seasons should be symbolic and modest, with a value of up to S$50, such as cakes, cookies and mandarin oranges. Each healthcare professional should only be offered a maximum of two such gifts per year.

13. What is the regulatory authority overseeing marketing to healthcare professionals?

The Ministry of Health and HSA oversee marketing to healthcare professionals.



Taiwan

General Overview

1. What is the general legal regime for the marketing of drugs?

Medicament advertisements are closely related to the marketing of drugs, and those regulations have been formulated in the Pharmaceutical Affairs Act and its enforcement rules. The TFDA has issued "**Medicament Advertisements Application Guidelines**" and "**Principles for the Handling of Online Medicament Advertisements**" for examination and inspection of medicament advertisements.

In addition, the Fair Trade Act, which is the main legislation of competition law in Taiwan, has also been applied to the administration of medicament advertisements. While the most common violation of the Fair Trade Act is publishing misleading/exaggerated advertisements that are categorized into "unfair competition", pharmaceutical companies would be regulated by the regulations of "restraint on competition" as well, such as not imposing restrictions of the resale prices on their trading counterparts.

2. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organizations)?

The industrial organization International Research-based Pharmaceutical Manufacturers Association ("**IRPMA**") has issued the "IRPMA Code of Practice" based on the IRPMA Guiding Principles on Ethical Conduct and Promotion, and the applicable scope covers the relationship between pharmaceutical companies and healthcare professionals, medical institutions, and patient organizations. Though in general the code of practice does not cover OTC drugs, OTC drugs used under physician prescriptions or in hospitals would still be regulated under IRPMA Code of Practice.

3. What kinds of licenses/registrations must be obtained to engage in marketing or promotion activities?

Medicament advertisements need prior approvals before publishing and broadcasting and are under the supervision and examination of the TFDA or the municipal competent authority. The qualified applicant of publishing or broadcasting medicament advertisements must be a pharmaceutical company, who shall submit all texts, drawings or pictures constituting an advertisement, and the approval is valid for one year.

4. Are there any specific requirements for the marketing of drugs online?

"**Medicament advertisements**" defined under the Pharmaceutical Affairs Act is any advertising of medical efficacy by means of communications aiming at the promotion of drugs. Any conduct consisting of interviews, news reports or propaganda containing information implying or suggesting medical efficacy would be deemed as medicament advertisements as well.

According to the Handling of Online Medicament Advertisements issued by the TFDA, online medicament advertisements could be divided into several types:

– Pharmaceutical companies only publishing the contents of their own products on their websites are not obligated to file applications for medicament advertisements, while the contents of products posted online must include all the information indicated in the approved package inserts and the pictures of the packaging.
– Pharmaceutical companies publishing medicament advertisements of OTC drugs online must file applications, and the advertisements are available to the public.
– Pharmaceutical companies publishing medicament advertisements of prescription drugs online must file applications, and the advertisements are only available to medical professionals.

Marketing to consumers

5. What kinds of marketing activities are permitted in relation to consumers?

The regulations of marketing activities under the Pharmaceutical Affairs Act mainly focus on medicament advertisements; pharmaceutical companies must comply with the following rules:

– **Prescription drugs**

Advertisements containing drugs required to have the prescriptions of physicians or to have been specifically designated by the TFDA shall be published only in academic medical journals.

– **Improper means**

Improper means mentioned in the Pharmaceutical Affairs Act include making use of the name of another person, warranting the efficacy or functions of the medicament by means of book or publication materials, or release in an interview or news report.

– **Improper contents**

Improper contents prohibited from being published or granted the license involve: (a) sexual efficacy; (b) the use of methods likely to encourage drug abuse, such as exchanges of drug containers for prizes or the provision of incentives; (c) any promotion stating that the use of drugs will cure a particular disease or improve health, or create any false or misleading scenario; and (d) exaggeration of a drug's efficacy or safety.

6. What kinds of promotion programs are allowed?

The IRPMA Code of Practice provides several industry guidelines for promotional information, in which the core spirit of promotion is clear, legible, accurate, balanced, fair, sufficiently complete and without any ambiguity. Interactions with patient organizations are included in IRPMA Code of Practice as well.

– **Promotional information**

Promotional information must contain the name of the drug, the approved active ingredients, the name and address of the pharmaceutical company or its agent responsible for marketing, the date of the advertisement, and abbreviated prescribing information. As for electronic materials such as posts on websites, the contents and their presentation must be clear and apparent to the intended audience.

– **Interactions with patient organizations**

Pharmaceutical companies must ensure that interaction with patient organizations is ethical. If pharmaceutical companies are involved in providing financial support or contribution to patient

organizations, they would have to prepare written documentation indicating the nature of support and the purpose and funding of all activities.

Please note that the IRPMA Code of Practice is not applied to advertisements of OTC drugs.

7. Is any prior approval required for marketing activities and promotion programs?

Only medicament advertisements require a prior approval by the TFDA or the department of health of the municipal government, depending on where the pharmaceutical company is located.

Any medicament advertisement must contain the name of pharmaceutical company, the number of market approval and the number of licensed advertisement documentation. Texts and images used in a medicament advertisement are limited to the name of the drug, dosage form, prescription content, usage quantity, usage method, efficacy, guidelines, packaging, and the name and address of the pharmaceutical company, as initially approved by the TFDA.

8. Which authority is responsible for approving/certifying marketing activities and promotion programs?

The competent authority responsible for approving medicament advertisements depends on where the pharmaceutical company is located.

– Located in a special municipal city, containing Taipei, New Taipei, Taoyuan, Taichung, Tainan, and Kaohsiung: the department of health of the municipal government.
– Located in a non-special municipal city: The TFDA.

9. What regulatory authority is responsible for supervising marketing activities to consumers?

The TFDA and the department of health of the municipal government will be in charge of examining and supervising medicament advertisements. The Fair Trade Commission (FTC) is also responsible for supervision of medicament advertisements, yet the FTC would focus more on maintaining market order to prohibit any misconduct relating to misleading or exaggerated advertisements.

Marketing to healthcare professionals

10. What kinds of marketing activities are permitted in relation to healthcare professionals?

The IRPMA Code of Practice provides several industry guidelines:

– **Events and meetings**

Events (including promotional, scientific or professional conferences for healthcare professionals) held or sponsored by pharmaceutical companies shall be for the purpose of providing scientific, educational, or product information. Refreshments shall be limited to meals incidental to those events and only provided to the participant himself/herself. Entertainment or other social activities for healthcare professionals are prohibited.

– **Sponsorship and fees for services**

Pharmaceutical companies can sponsor healthcare professionals to attend the aforementioned events or meetings, but conditional obligations to prescribe, recommend, purchase, supply, or promote any drug are forbidden.

Healthcare professionals can provide consulting services to pharmaceutical companies and receive appropriate remuneration. The scope of services includes giving lectures, hosting a conference, participating in medical or scientific research, conducting clinical trials, and attending training programs or market research. Hiring a healthcare professional for those events must not be an incentive to influence his or her discretion to prescribe, recommend, purchase, or supply any drug.

– **Restrictions on gifts**

Cash, cash equivalents (such as gift certificates), promotional freebies or any personal item are prohibited to be presented to healthcare professionals, while gifts for charity use are permitted under relevant regulations of the Pharmaceutical Affairs Act.

11. What kinds of promotion programs are allowed?

Samples and gifts of drugs presented to healthcare professionals for specified purposes are allowed while applications for approvals are still required. Approved samples or gifts may not be sold, assigned, or provided for other unauthorized use, and the packaging must be marked with “sample” or “gifts” in an obvious way.

– **Sample**

Pharmaceutical companies can file applications for samples for the following purposes:

- Use for the purpose of applying for registrations or improving manufacturing approach.
- Exclusively used for the purpose of research or trials in need of business.
- Use for the purpose of educational information of approved drugs.
- Use for the purpose of public security, public health or catastrophe.

– **Gifts**

Pharmaceutical companies can file applications for gifts only for a charitable purpose to present approved drugs to healthcare institutions, clinics or hospitals, or relief agencies.

12. What sorts of gifts or other incentives, if any, may be provided to healthcare professionals?

Other than the gifts of drugs applied for charitable purpose and approved by the TFDA, medical journals or textbooks for academic use can be presented to individual hospital departments under the IRPMA Code of Practice. Other items of medical utility could be presented to hospitals or clinics depending on whether the items are of modest value and are beneficial to enhancing medical services or for patient care, and not used for offsetting routine business practices, yet they must not be provided to individuals for personal interest.

13. What is the regulatory authority overseeing marketing to healthcare professionals?

Generally, samples and gifts approved in accordance with the Pharmaceutical Affairs Act and the relevant regulations would be supervised by the TFDA.

In addition, if healthcare professionals are deemed to be civil servants under relevant regulations, they would be obligated to conform to “Integrity and Ethics Directions for Civil Servants” and be supervised by the employee ethics competent authority.

Thailand

General overview

1. What is the general legal regime for the marketing of drugs?

– **Legal regime**

Sections 88 to 90 of the Drug Act regulate the promotion of medicinal products, and the law is enforced by the FDA. The general requirements are that any advertisement must be truthful, must not be exaggerated and advertisements must be approved by the FDA before dissemination.

– **Limits on marketing activities**

Section 88 of the Drug Act provides that advertisements must not:

– Boast that a medicine can miraculously or absolutely treat, cure or prevent a disease or illness;
– Exaggerate or falsely declare properties of the medicine;
– Give the impression that the drug has a substance as its chief or component ingredient that it:
  - Does not have; or
  - Has in a lower quantity than is believed to be present;
– Give the impression that it is an abortifacient or a strong emmenagogue;
– Give the impression that it is an aphrodisiac or a birth control drug;
– Advertise specially controlled drugs or dangerous drugs;
– Contain certification or endorsement of its therapeutic properties by any other person;
– Show its therapeutic properties as being capable of curing, mitigating, treating or preventing diseases (or symptoms of them) as notified by the Minister of Public Health under section 77 of the Drug Act:
  - Such Ministerial Regulation includes several diseases, which are diabetes, cancer, paralysis, tuberculosis, leprosy and disease, or health conditions regarding brain, heart, lung, liver, spleen and kidney; or
– Advertise impolitely, by means of singing and dancing, or by showing the distress or suffering of a patient. (Section 89 of the Drug Act.)

Furthermore, according to the FDA Internal Rules 2002, advertisements must not:

– Be contrary to tradition, such as local beliefs, norms and morals;
– Persuade patients to consume the product more than necessary or create a misunderstanding that the product should be used regularly;
– Make a comparison that would defame other products;

– Cause consumers to misunderstand that the drug is equivalent to other products, such as food or cosmetics; or
– Encourage acts or activities contrary to law.

In addition, advertisements must meet the FDA information requirements (for example, they must contain the drug name, ingredients and manufacturing source).

2. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organizations)?

Pharmaceutical companies that are members of the Pharmaceutical Research and Manufacturers Association ('**PReMA**') must comply with the PReMA Code of Sales and Marketing Practice 8th edition – 2008 ('**PReMA Code**'). The PReMA Code provides the standards for the industry's practice of promotional activities, including organizing conferences for healthcare professionals.

Many pharmaceutical companies, including non-members of PReMA, tend to follow the same standards as a courtesy and to ensure fair competition within the industry.

Although the PReMA Code is not considered to be law, and the FDA does not have the authority to enforce it, a violation of the PReMA Code may be reviewed by the PReMA Committee, which has the power to sanction its members.

3. What kinds of licenses/registrations need to be obtained to engage in marketing or promotion activities?

See No. 1 above.

4. Are there any specific requirements for the marketing of drugs online?

There are no particular rules or codes of practice on the use of the Internet or social media for drug advertising. Information distributed on the Internet which is intended for customers in Thailand must meet the same requirement as other media. According to the FDA, most advertisements (more than 85%) on the Internet are being run without permission, and the FDA has made it a priority to focus on this problem.

Marketing to consumers

5. What kinds of marketing activities are permitted, restricted and forbidden in relation to consumers?

For a non-household remedy drug, marketing activities to consumers are limited to activities that help create disease awareness, patient education and basic healthcare education.

With respect to the household remedy category which may be advertised directly to consumers and the general public, the law does not limit the types of activities. However, advertisements selling drugs through radio, TV, motion pictures or printed material must: (1) receive prior permission for the text, sound or picture used in the advertisement from the FDA, and (2) follow the conditions (if any) set by the FDA (section 88 bis). The law further provides that drugs shall not be advertised impolitely, or by means of singing and dancing, or by showing the distress or suffering of a patient (section 89).

Although the Drug Act is silent about the restriction on patient education, the general public should have access to information on medical conditions and the treatments which may be prescribed by their doctors. The PReMA Code gives a guideline that patient education material should be distributed for educational purposes and should encourage patients to seek further information or explanation from the appropriate healthcare professional.

In addition, the following criteria must be satisfied:

– The educational material must be current, accurate and balanced.

– The educational material may not focus on a particular product, unless the material is intended to be given to the patient by a healthcare professional after the decision to prescribe that product has been made.
– The educational material may include descriptions of the therapeutic category, medical condition, and a discussion of the relevant clinical parameters in general.
– The educational material must include the advice 'Please consult your physician' and the contact address and telephone number of the supplier of the material.

The educational material must also include a statement directing the patient to seek further information about the condition or treatment from his or her doctor. Such statements must never be designed or made for the purpose of encouraging members of the public to ask their doctor to prescribe a product.

The tone of the message must not be presented in a way which unnecessarily causes alarm or misunderstanding in the community.

On all occasions, the information, whether written or communicated by other means, must be presented in a balanced way so as to avoid the risk of raising unfounded hopes with regard to a particular product.

Patient aids, which are solely intended to provide information for the patient once a decision to prescribe that product has been made, may be product specific.

The content of such material must be designed to promote patient compliance by providing information which clarifies the method of administration, precautions, special instructions and similar information. It must not make comparisons or include promotional claims.

A hotline, website or other similar information service may be set up to provide general information useful to the public (e.g., deworming, travel, smoking cessation, etc.). Such services must be general and may not include any product promotional information or personal medical advice.

Drug companies may set up or participate in programs that support patients already prescribed a prescription-only medicine to improve positive health outcomes. To ensure that such activities are not considered as promotional programs, drug companies must ensure that any statements made or material provided to members of the general public are not promotional and cannot be considered as having the intention to promote a prescription medicine to members of the general public.

6. What kinds of promotion programs are allowed?

Section 90 of the Drug Act provides that no sale of drugs shall be advertised by means of a gift or lottery drawing. The FDA has adopted a broad interpretation of this section and has determined that the giving of free samples or buy-one, get-one-free offers is equivalent to advertising by giving a gift.

7. Is any prior approval required for marketing activities and promotion programs?

– **Legal regime**

Only drugs in the household remedy category may be advertised directly to consumers and the general public, and that advertising is subject to FDA review and approval before dissemination.

– **Products**

Drugs that may be advertised directly to consumers and the general public must not be classified as dangerous drugs. However, most drugs are classified as dangerous drugs under Thai law. Also, drugs that are classified as dangerous must be dispensed by a pharmacist or doctor.

Drugs which are not classified as dangerous drugs would be traditional drugs or household remedies that are specifically listed by the Ministry of Public Health as drugs that patients may buy without having a pharmacist dispense them. Traditional drugs or household remedies may be advertised to the consumers, but the advertisement and marketing activities must receive prior approval from the FDA.

8. Which authority is responsible for approving/certifying marketing activities and promotion programs?

The FDA is responsible.

9. What regulatory authority is responsible for supervising marketing activities to consumers??

– **Regulatory authority**

The responsible agency is the FDA under the Ministry of Public Health, subsection Food and Drug Law.

– **Supervision**

The FDA randomly visits hospitals and drug stores, and monitors advertisements on TV, radio and the Internet. The FDA will also conduct an investigation when it receives complaints from consumers or competitors. When the FDA finds that an advertiser has violated the advertising/marketing regulations, a notice will be sent to the advertiser with a deadline to provide explanations or defend its case.

– **Rights of appeal**

– An appeal against the final decision can be filed with the Office of the Secretary General of the FDA.

Marketing to healthcare professionals

10. What kinds of marketing activities are permitted in relation to healthcare professionals?

Advertisements for prescriptions or pharmacy-dispensed medicines may only be targeted to professionals. As a result, marketing activities in the pharmaceutical industry in Thailand are mainly focused on the professional sector. The types of marketing activities to professionals are more open than those to consumers. However, only products that are registered in Thailand may be promoted to healthcare professionals. When promoting products, the information must be accurate, fair and objective and it must be presented in such a way as to conform not only to the legal requirements, but also to high ethical standards. The information should also be in good taste. Claims may not be stronger than scientific evidence warrants, and every effort should be made to avoid ambiguity and making off-label product claims. No pharmaceutical product shall be promoted for use until the requisite approval for marketing for such use has been obtained (PReMA Code).

Advertisements of marketing activities may not:

– Exaggerate or falsely declare properties of the medicine;
– Give the impression that the drug has a substance as its chief or component ingredient that it:
  - Does not have; or
  - Has in a lower quantity than is believed to be present; or
– Be advertised impolitely, or by means of singing and dancing, or by showing the distress or suffering of a patient.

11. What kinds of promotion programs are allowed?

The PReMA Code provides broad guidelines for promotional activities to ensure the transparency of such promotion. Clinical assessments, post-marketing surveillance and experience programs, and post-authorization studies must not be disguised as promotion. Such assessments, programs and studies must be conducted with a primary scientific or educational purpose. Material relating to pharmaceutical products and their uses, regardless of whether it is promotional in nature, that is sponsored by a company must clearly indicate who sponsored it. Product information furnished to healthcare professionals must be current, accurate, balanced and may not be misleading, either directly or by implication, omission or addition. Scientific data to support the claims and recommendations for use must be made available, on request, to healthcare providers.

12. What sorts of gifts or other incentives, if any, may be provided to healthcare professionals?

Payment in cash or cash equivalents (such as a gift voucher) must not be offered to healthcare professionals, and gifts for the personal benefits of healthcare professionals are prohibited. However, gifts to healthcare professionals and institutions for customary and acceptable local occasions are allowed on an infrequent basis. The value of such gifts, the nature and type of which are related to the particular customary occasion, shall not exceed THB3,000 per healthcare professional per occasion (PReMA Code).

– **Frequency**

The restriction under the PReMA Code is that medical representatives must not employ any inducement or subterfuge to gain a call; neither should any fee be paid for that purpose.

– **Provision of hospitality**

There are no explicit restrictions. However, the PReMA Code provides the guideline that the medical representatives should ensure that the frequency, timing and duration of appointments, together with the manner in which they are made, are such so as not to cause inconvenience to the doctors, pharmacists or nurses, especially in the out-patient department.

– **Discounts**

Giving discounts and rebates is acceptable in Thailand. Such discounts or rebates associated with the sales of pharmaceutical products shall be made by account payee check, bank transfer to a bank account associated with the respective hospital or by invoice only (PReMA Code).

– **Free samples**

The Drug Act does not address the issue of free samples for professionals. However, the PReMA Code provides that samples of products may only be supplied to a healthcare professional upon their consent. The size and quantity of the sample supplied should be appropriate for the following:

– Familiarizing with presentation and appearance of a product;

– Providing to patients for initiation of therapy; or

– Conducting an agreed-upon clinical evaluation of the product.

All samples delivered by sole distributors or medical representatives, or via mail or courier, should be securely packed and must be signed for by the receiver when received.

Under the PReMA Code, the term ‘drug sample’ means a unit of a drug which is not intended to be sold and is intended for the reasons stated above. No person may sell or trade, or offer to sell or trade, any drug samples.

– **Sponsorship of professionals**

It is acceptable/permissible to sponsor healthcare professionals to attend an international congress, and to invite them to a satellite symposium at a congress they are already attending.

It is prohibited and not acceptable or appropriate to run an overseas standalone company-sponsored meeting for healthcare professionals where all (or nearly all) of the attendees and/or speaker(s) are from Thailand.

Furthermore, the PReMA Code contains the guideline that symposia/congresses (local and international) which are initiated by the company (locally only), the regional office, or corporate headquarters, must devote a minimum of 75% of the total time to scientific sessions, outside of reasonable travel time. Any hospitality/entertainment/gimmick provided by drug companies, either directly or by sponsorship or assistance to the meeting organizers of educational meetings, must be secondary to the educational purpose and not capable of being seen as extravagant by local standards.

Invitations to attend medical and scientific meetings must only be given to healthcare professionals. Sponsorship shall be limited to the payment of travel, meals, accommodation and registration fees. Guests may not be invited, nor expenses of persons accompanying the attendee paid for.

Companies should not provide direct sponsorship for healthcare professionals to attend sporting or other entertainment events, as this can be seen as inducement.

Donations may be made directly to the institution (not individuals) upon the institution’s request to support activities for healthcare professionals, as long as it can be demonstrated that there is a link to scientific

education, patient benefit or charitable contribution that would benefit the improvement of healthcare services.

– **Other indirect incentives**

Indirect incentives are not allowed.

13. What is the regulatory authority overseeing marketing to healthcare professionals?

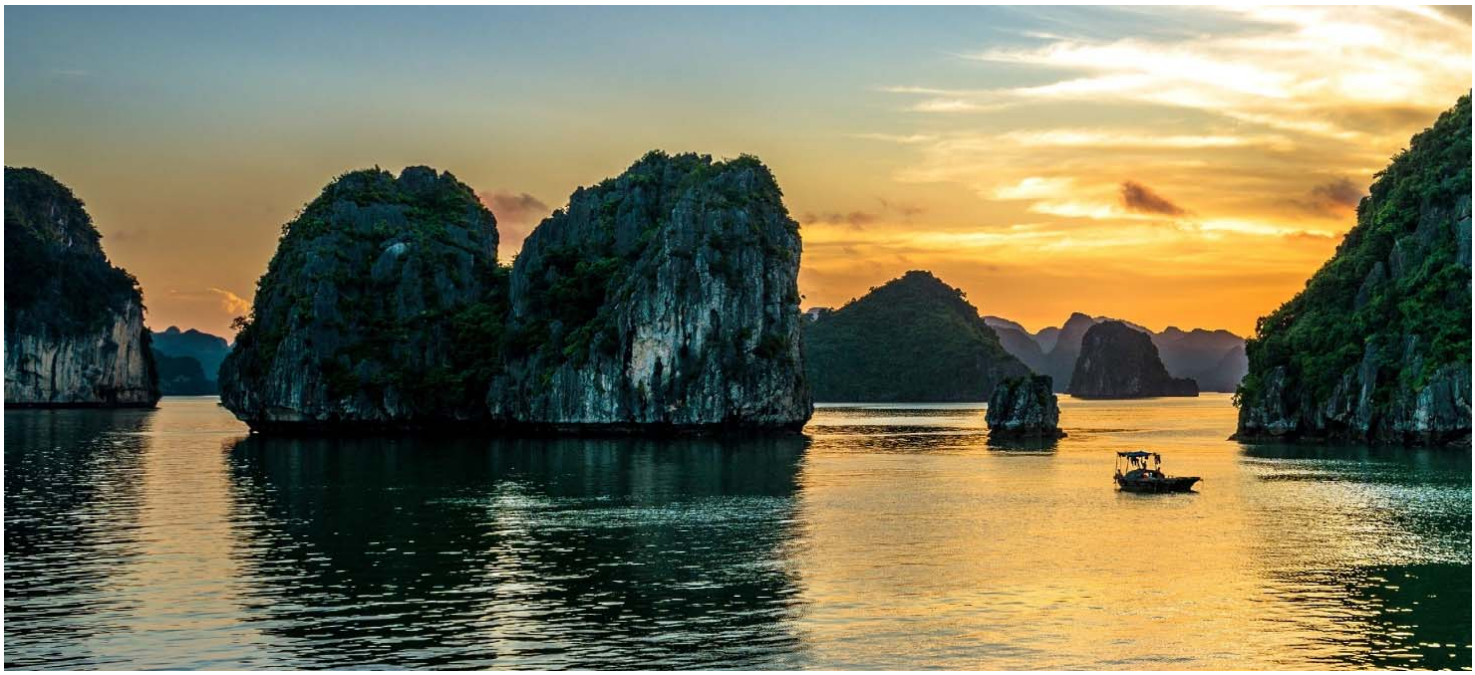
– **Regulatory authority**

The responsible agency is the FDA under the Ministry of Public Health, subsection Food and Drug Law.

– **Supervision**

PReMA takes an important role in supervising marketing activities that violate the PReMA Code. The Sales & Marketing Ethics Committee (SME) will carry out a review of the provisions of the PReMA Code after seeking input from interested parties at least every three years. In addition to regular reviews of the PReMA Code, the SME will perform activities to create awareness of the PReMA Code.

If a complaint regarding a breach of the PReMA Code is filed by one of the members, the complaint will be administered by the PReMA Chief Executive Officer and the Code of Conduct Committee.



Vietnam

General overview

1. What is the general legal regime for the marketing of drugs?

Legal regime

The main laws and regulations governing marketing activities of drugs in Vietnam are as follows:

- Vietnam's Commitments to the World Trade Organization;
- Law on Commerce No. 36/2005/QH11 passed by the National Assembly on 14 June 2005;
- Decree No. 37/2006/ND-CP of the Government dated 4 April 2006 on trade promotion activities as amended on 6 August 2009;
- Law on Advertising No. 16/2012/QH13 passed by the National Assembly on 21 June 2012 and effective from 1 January 2013 ("**Law on Advertising**");
- Decree No. 181/2013/ND-CP of the Government dated 14 November 2013 regulating the implementation of a number of articles of the Law on Advertising;
- Law on Pharmacy;
- Decree 54;
- Circular No. 07/2018/TT-BYT of the Ministry of Health dated 12 April 2018 on guidelines for some articles on pharmacy business of the Law on Pharmacy and Decree 54; and
- Circular No. 09/2015/TT-BYT of the Ministry of Health dated 25 May 2015 stipulating the approval of contents of advertisements for special products, commodities and services under the authority of the Ministry of Health.

Limits on marketing and promotional activities

Marketing activities for drugs which are subject to registration with or approval by the competent authorities include the following:

- Sales promotion;
- Drug introduction seminars;
- Provision of drug information material to healthcare professionals;
- Trade fairs and exhibitions; and
- Advertising.

Sales promotion of drugs (such as giving drugs as gifts, offering discounts, royalty programs, lucky draws, etc.) to end users is strictly prohibited in Vietnam. Promotion to drug traders/distributors is permitted. However, the promotion must be registered with and/or have a notification delivered to the competent trade authorities prior to implementation.

Drugs can be displayed and introduced in a drug introduction seminar to healthcare professionals (HCPs), provided that such seminar is duly registered with the competent health authorities. Drugs which have been issued an MA number by the MOH can be displayed at trade fairs and exhibitions, except for addictive drugs, psychotropic drugs, pre-substances used to manufacture drugs, and radioactive drugs. If any entity wishes to display or introduce any drug which has not yet been issued an MA number, such entity must be issued a license for the import of drugs by the DAV in order to display such drugs at the trade fair or exhibition.

Only OTC drugs granted MA numbers may be advertised to the public. Prescription drugs are prohibited from advertising but can be introduced to HCPs via drug introducers, drug information introduction materials for HCPs, and drug introduction seminars. All advertisements and drug information introduction materials must be approved by competent authorities prior to dissemination.

2. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organizations)?

The Foreign Research-Based Pharmaceutical Manufacturers Association in Vietnam, commonly known as Pharma Group, is a sector committee under the European Chamber of Commerce in Vietnam. The members of Pharma Group, representing more than 20 international pharmaceutical companies, are required to adhere to the association's Code of Pharmaceutical Marketing Practices, which includes provisions related to the marketing of drugs in Vietnam. Pharma Group members must comply with regulations in the Code of Pharmaceutical Marketing Practices or those found in the legislation of Vietnam, whichever are stricter.

3. What kinds of licenses/registrations must be obtained to engage in marketing or promotion activities?

Generally, an approval or registration needs to be obtained or conducted before conducting any marketing or promotional activity. For advertisement of non-prescription drugs or provision of drug information material to HCPs, advance approval from the DAV should be obtained. With regard to the organization of a drug introduction seminar to HCPs, a registration with the provincial Department of Health needs to be conducted. A sales promotion program needs to be registered with/have a notification delivered to the provincial Department of Industry and Trade.

It is advised that specific advice be obtained for each case.

4. Are there any specific requirements for the marketing of drugs online?

Drug trading establishments are only permitted to advertise drugs that such establishments themselves trade, and they can only advertise on their lawful websites.

Drug trading establishments can authorize another entity to advertise drugs on their website, provided that the entity is an advertising service provider which possesses a license for internet content provision issued by the Ministry of Information and Communications and a business registration certificate for advertising services as stipulated by law.

All drug advertisements are required to be approved by the MOH in advance, including advertising drugs online.

Notably, a drug advertisement containing sound on a website must comply with the same regulations as those for the advertising of drugs on radio or television, including having an audible caution of "Read package insert carefully before administration." Non-sound advertisement for a drug on a website must comply with the same regulations as advertisements aired on books, newspapers, magazines and flyers.

If there are many advertising pages/shots, these pages/shots should be in steady motion, or paused deliberately in order for viewers to read all information conveyed on that page. Pages or shots displaying product information should be unanimated without any movement to allow viewers to carefully read such information.

Marketing to consumers

5. What kinds of marketing activities are permitted, restricted and forbidden in relation to consumers?

Permitted marketing activities in relation to consumers include drug advertising and displaying drugs at trade fairs and exhibitions. The advertising of drugs can be in the following forms:

– Advertisements in books, newspapers, magazines, leaflets, and posters;
– Advertisements on billboards, placards, panels, banners, objects which are illuminated or appear in the air or underwater, means of transportation, and other mobile objects;
– Advertisements on radio and television;
– Advertisements in electronic newspapers, company websites, and websites of advertising service providers; and
– Advertisements on other means of advertising as permitted by law.

Only non-prescription drugs can be advertised to consumers. However, non-prescription drugs whose use should be restricted or subject to the supervision of a doctor, according to the recommendations of the competent state body, also cannot be advertised.

It is strictly prohibited to use any material or financial benefits in any form to influence doctors or drug users in order to motivate the prescription and use of drugs. Accordingly, providing consumers with free samples or any special offers is prohibited.

6. What kinds of promotion programs are allowed?

No sales promotion program is allowed for consumers. Only certain marketing activities, as discussed in question No. 4 above, are permitted for consumers.

7. Is any prior approval required for marketing activities and promotion programs?

As discussed in question No. 1 above, drug marketing activities and promotion programs are subject to the prior approval by or registration with the competent authorities.

8. Which authority is responsible for approving/certifying marketing activities and promotion programs?

The Drug Administration of Vietnam (DAV) is responsible for approval of drug information materials and advertisements, while the provincial Department of Health is responsible for registration of drug introduction seminars to HCPs. Sales promotion activities are subject to registration with or notification to the relevant trade authorities.

9. What regulatory authority is responsible for supervising marketing activities to consumers?

The Inspection Department under the DAV is the main authority responsible for supervising all activities related to drugs nationwide, including the activities of marketing to consumers. In addition, the Market Surveillance Agency under the Ministry of Industry and Trade and its provincial branches may also supervise marketing activities to consumers related to drugs.

Marketing to healthcare professionals

10. What kinds of marketing activities are permitted in relation to healthcare professionals?

Drugs can generally be introduced to HCPs through one of the following:

– Via medical representatives (drug introducers) with valid drug introduction cards issued by the provincial Department of Health;
– Provision of drug introduction materials which were approved by the DAV in advance;
– Drug introduction seminars to HCPs which were duly registered with the provincial Department of Health; or
– Displays at specialized health conferences and seminars.

11. What kinds of promotion programs are allowed?

Under the Law on Commerce, the term "promotion" includes (i) sales promotion; (ii) advertisement (of the company's image, services and/or products) and (iii) display and exhibition of goods and services, and trade fairs and exhibitions.

A sales promotion program may be conducted through different ways, such as offering discounts, giving gifts, giving goods samples, giving coupons, lucky draws, etc.

Drugs are highly regulated in Vietnam with certain restrictions such as the prohibition of giving drug samples, using material benefits to influence drug prescription or use, advertisement of prescription drugs, etc. Therefore, it is advised that specific advice be obtained for each case.

12. What sorts of gifts or other incentives, if any, may be provided to healthcare professionals?

Local regulations prohibit the use of material or financial benefits in any form to influence HCPs and drug users in order to promote the prescription and use of drugs. Therefore, using any gifts – whether in the form of money, loans, vouchers, tickets, etc. – to influence HCPs' drug prescription is not allowed, regardless of the gift's value.

13. What is the regulatory authority overseeing marketing to healthcare professionals?

The Inspection Department under the DAV is the main authority responsible for supervising marketing and promotional activities to healthcare professionals. In addition, the pharmacy department of the provincial Department of Health also may supervise all activities related to pharmaceuticals in its territory, including marketing and promotional activities to healthcare professionals.

How can LAN help?

Together, we can provide you with the best industry focused legal advice available in the APAC region. This is because we have:

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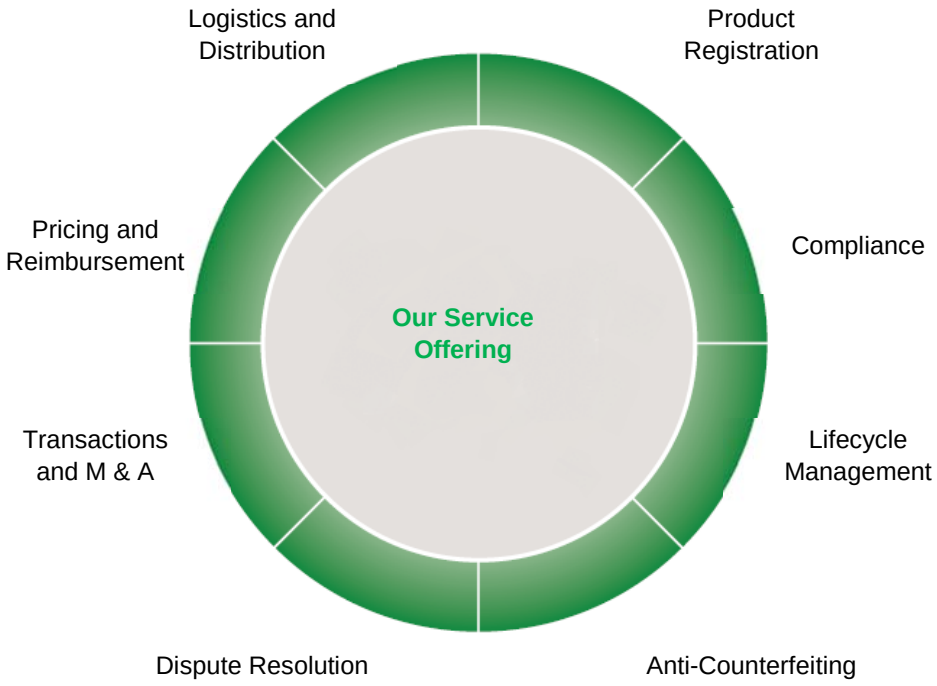

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Kate has worked on a number of high profile patent cases including the Australian case that clarified the law relating to patentability of methods of medical treatment. In addition to acting for pharmaceutical companies she has acted for many international clients in relation to medical devices including drug eluting stents, catheters and braces.

She has particular expertise in multi-jurisdictional litigation – recently she acted for Samsung in the smartphone litigation which was unprecedented in scale (23 patents were in suit).

Although Kate is foremost a litigator, she also has extensive experience in advertising and regulatory approvals and trade mark and contractual disputes in the pharmaceutical sector.

Kate was awarded the prestigious Euromoney Australasian Women in Business – 'IP rising star' award in 2013. She was also listed as a Best Lawyer for IP in the Best Lawyers Peer Reviews (2013–2016), as an IP star for trade mark and patent litigation in Managing Intellectual Property (2014–2016) and individually in the World Trade Mark Review.

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Nick is the Managing Partner of the Beijing Office, Global Co-Head of CMS Lifesciences & Healthcare Sector Group and Head of Asia-Pacific IP. Nick has extensive experience in advising on all aspects of intellectual property, regulatory and commercial matters affecting Lifesciences & Healthcare clients internationally and his practice spans both contentious and non-contentious issues.

Nick has substantial experience in coordinating complex multi-jurisdictional matters, regularly working with colleagues throughout CMS and around the world. His work in the areas of commercial and corporate transactions and disputes, parallel trade, anti-counterfeiting, trade mark and patent opinions and IP infringement particularly spans international borders.

Nick is recommended as a prominent practitioner in his field in Chambers & Partners, Legal 500, the PLC Lifesciences Handbook, Super Lawyers London, Who's Who Legal Trademarks and Lifesciences (Patent Litigation and Transactional) and the Guide to the World's Leading Trade Mark Law Practitioners. Nick was awarded 'Lifesciences Law – Lawyer of the Year in China' 2017 by Corporate Intl Magazine Global and Corporate LiveWire.

Nick is described as providing "heavyweight IP, parallel trade and patent litigation capability for an impressive roster of clients" and 'Dynamic' practice head Nick Beckett 'has an unparalleled ability to bring international teams together to deliver the precise expertise that his clients require'" in Legal 500. Nick is also described in Chambers & Partners for Lifesciences, "He has a really sophisticated understanding of lifesciences in the Asia-Pacific region. He's very comfortable and savvy talking through the differences in

jurisdictions and he has great commercial, regulatory and litigation expertise. He's just a delightful person, really generous and very inspired." Nick has also been recognised as a 'Top 15 IP Lawyer in China' by Asian Legal Business 2017.

Nick led the team on Takeda's €9.6bn acquisition of Swiss drug company, Nycomed A/S, which won the FT & Mergermarket Private Equity's Deal of the Year. In China, Nick's team has been ranked in the Asian Legal Business Asia's Top 50 Largest Law Firms (2014-2017) and been highly commended at the FT Innovative Lawyers for Asia-Pacific (2014-2017). In addition, the IP team in Asia is recognised in the Asian Legal Business IP Rankings.

Nick is a Solicitor-Advocate of the English Courts and a listed Arbitrator at the Beijing International Arbitration Centre (BIAC) and Beijing Arbitration Commission (BAC).

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Eko holds an LL.M. in banking and financial law from Boston University and has more than 15 years' experience as a legal practitioner. His focus extends across the corporate, banking & finance, and FDI practices, and he has amassed extensive experience in a range of rapidly expanding sectors, including Lifesciences, the creative industries and TMT.

He has advised a number of multinational companies on their FDI ventures in Indonesia, and is an Asialaw Profiles 'Recommended Lawyer.' His expertise was one of the contributing factors to Assegaf Hamzah being named an Asian-Mena Counsel 2014 'In-house Community Firm of the Year' in Indonesia for Lifesciences.

Prior to joining Assegaf Hamzah, Eko served as legal counsel with the Indonesian Bank Restructuring Agency (IBRA) during a tumultuous period that saw the agency rebuild the country's decimated financial services sector from the ruins of the 1997/98 Asian financial crisis. Eko speaks Indonesian and English.

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Chie, a Japanese-qualified attorney (Bengoshi) of some 15 years' standing, leads the IP/IT & Healthcare team. She is an IP/IT & Healthcare practitioner with deep knowledge of legal issues relevant to the lifesciences field, and highly experienced in patent and regulatory/compliance matters. She represents biotechnology, medical device and other pharmaceutical companies in patent protection and litigation both domestic and cross-border. She also advises her clients on licensing, transfer, development and collaboration agreements.

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Ki Young is a co-chair of Yulchon's Healthcare Practice Team and a partner in the Corporate & Finance Group. After joining Yulchon in 1998, he successfully advised a number of international and Korean pharma/medical device companies on general corporate matters, including mergers and acquisitions, joint ventures and other strategic alliances, drug/medical device sales and distribution agreements, R&D related matters, and licensing and related disputes. Ki Young also specializes in government regulation and policy issues, including issues related to product approvals, market access, pricing, labeling, advertisement, healthcare insurance and regulation by the MOHW and the MFDS. Ki Young also provides extensive compliance and anti-corruption advice related to marketing activities to numerous international and Korean pharma/medical device companies.

Ki Young's experience includes a secondment with Allen & Overy, Hong Kong from 2003 to 2004 and service as an outside director of Ildong Pharmaceutical Co., Ltd. from 2010 to 2014. Currently, he serves as a legal adviser to the Korean Cosmetics Association, Korea Pharmaceutical Traders Association and Korea Medical Devices Industry Association, and he is an IRB member of St. Mary Hospital in Seoul.

Ki Young speaks English and Korean.

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Wee Hann Lim
Partner
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Wee Hann has over 23 years of experience in advising companies on cross-border investments, private mergers & acquisitions, sale & purchase of companies and businesses and other corporate transactions. Wee Hann also specialises in labour law and employee benefits.

Wee Hann's expertise includes advising numerous biotechnology, health and pharmaceutical global leaders on cross-border acquisitions and divestments. He is a recommended lawyer in the PLC Lifesciences Handbook for his work in the Lifesciences industry and is also listed by the International Who's Who of Lifesciences Lawyers as one of the world's leading practitioners in the field of Lifesciences.

Wee Hann speaks English, Bahasa Malaysia, Mandarin, Vietnamese and is learning Japanese.

Taiwan

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Jennifer is the partner of Chen & Lin Attorneys-at-Law since 2008. Jennifer and Chen & Lin team have extensive experiences in serving clients in the sector of pharmaceuticals, biotech, medical device, nutritious food as well as cosmetics, including both domestic and international companies, hospitals, laboratories, associations and individuals.

Jennifer's specialised legal areas include foreign (PRC) investment, legal compliance, corporate, M&A, securities and anti-trust related issues. Jennifer, together with the team, provides holistic legal services to Lifesciences clients, ranging from administrative application, local legal compliance, fundraising, M&A, IPO, licensing, daily operation related agreements, patent litigation, maltreatment litigation and criminal procedures about health insurance fraud.

Jennifer is one of the ranked lawyers in Taiwan in Chambers & Partners Asia-Pacific 2018 in the fields of corporate/M& and capital market.

Jennifer speaks Mandarin and English.

Thailand/Cambodia/Laos/Myanmar

Alan Adcock
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Tilleke & Gibbins

Alan is a partner and the deputy director of Tilleke & Gibbins' intellectual property and regulatory affairs groups, helping to oversee the firm's client work in these areas across ASEAN. He also co-heads the firm's regional lifesciences practice with Thomas Treutler.

Alan has over 20 years' experience in Asia, during which time he has devoted much of his work to IP acquisitions, strategic structuring, technology transfer, and IP licensing and securitisation agreements, mainly in the pharmaceutical, agrochemical, and material science sectors. He handles various IP infringement and regulatory infraction cases involving labelling, advertising, clinical trials, product handling/warehousing, product registration, taxation, and import/export violations in the Asia-Pacific region. He also deals with local pre-litigation strategy and litigation management for infringement and invalidation matters in the region.

Since 2005, Alan has been recognized by Asialaw Leading Lawyers as one of Asia's leading business lawyers in the area of intellectual property, and he has been named a top IP lawyer in Thailand by The Legal 500 Asia Pacific and WTR 1000. Alan is also recognized as a leading IP strategist by IAM Strategy 300, an expert on patents in IAM Patent 1000, one of the world's foremost lifesciences practitioners by IAM Lifesciences 250, and a leading lifesciences regulatory lawyer by Who's Who Legal.

Alan is licensed to practice in New York and New Jersey and is admitted in the U.S. District Courts of Southern and Eastern New York. He speaks English and Mandarin.

Vietnam

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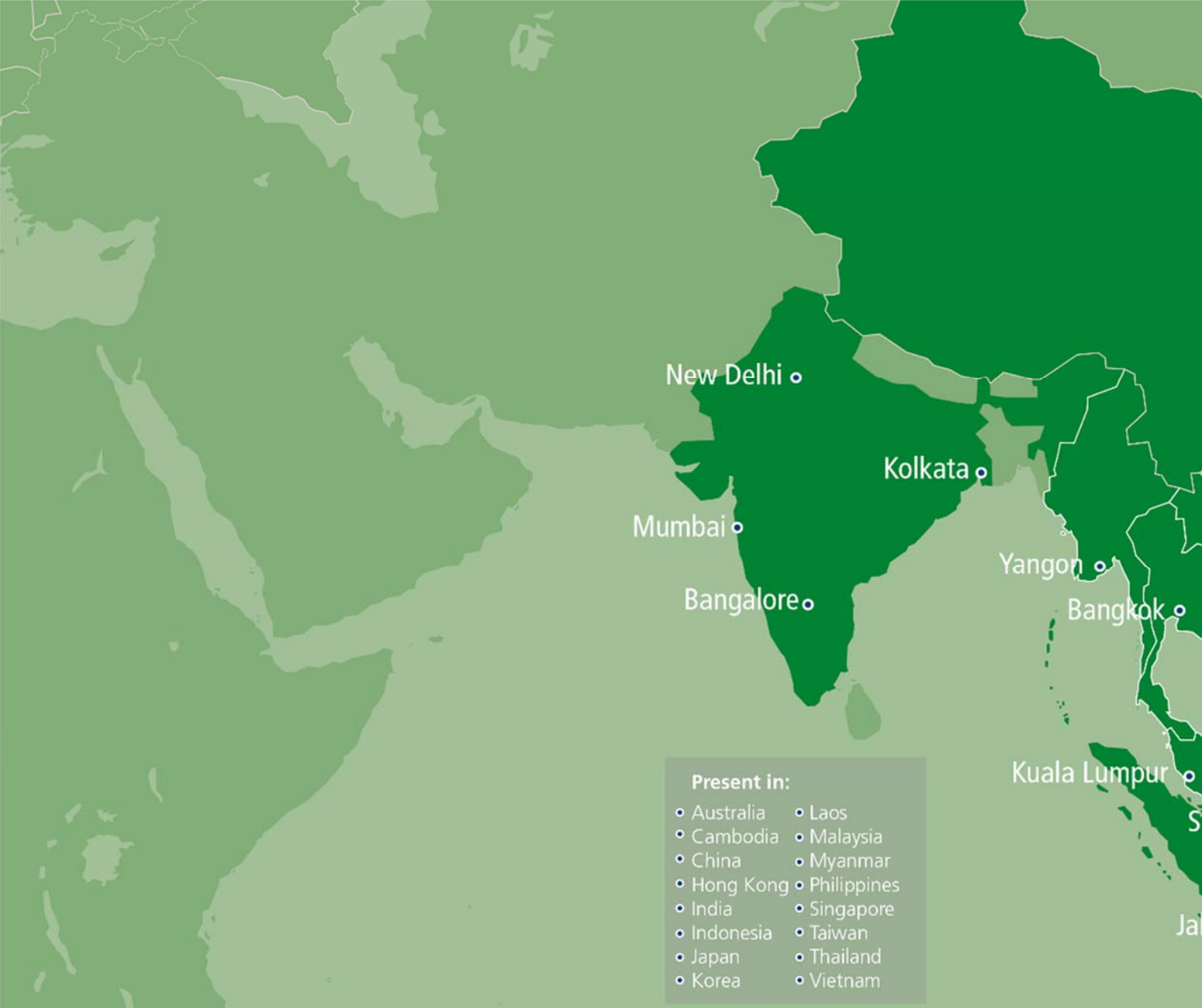
Tilleke & Gibbins

Tom is the Managing Director of Tilleke & Gibbins' Vietnam offices. He is an attorney licensed by the State Bar of California and is registered to practice as a foreign lawyer in Vietnam and before the USPTO and the U.S. Court of International Trade.

Tom has worked in the legal services field in Vietnam since 1994, specializing in corporate and commercial law as well as IP. He co-heads Tilleke & Gibbins' regional lifesciences practice with Alan Adcock. Recognized as a leading lawyer by *Chambers, The Legal 500*, and *Managing IP*, Tom has extensive experience in IP enforcement and has secured a number of landmark victories for foreign investors operating in the lifesciences and technology sectors.

Tom is a former Chair of the East Asia and Pacific Subcommittee of INTA's Famous and Well-Known Marks Committee, is a member of the INTA Asia-Pacific Global Advisory Council, and currently sits on the INTA Copyright Committee. He has advised EuroCham Vietnam's Pharma Group (an industry group of major pharmaceutical innovators), and has assisted with drafting position papers on compulsory licensing and a roadmap for Vietnam's compliance with the EU-Vietnam Free Trade Agreement and TRIPS. Tom also serves as a local expert for Vietnam for the European Commission's ASEAN IPR SME Helpdesk.

Tom earned his JD, *magna cum laude*, from Indiana University Bloomington's Maurer School of Law, where he now serves as a member of the Dean's Global Advisory Board. He speaks English and Vietnamese.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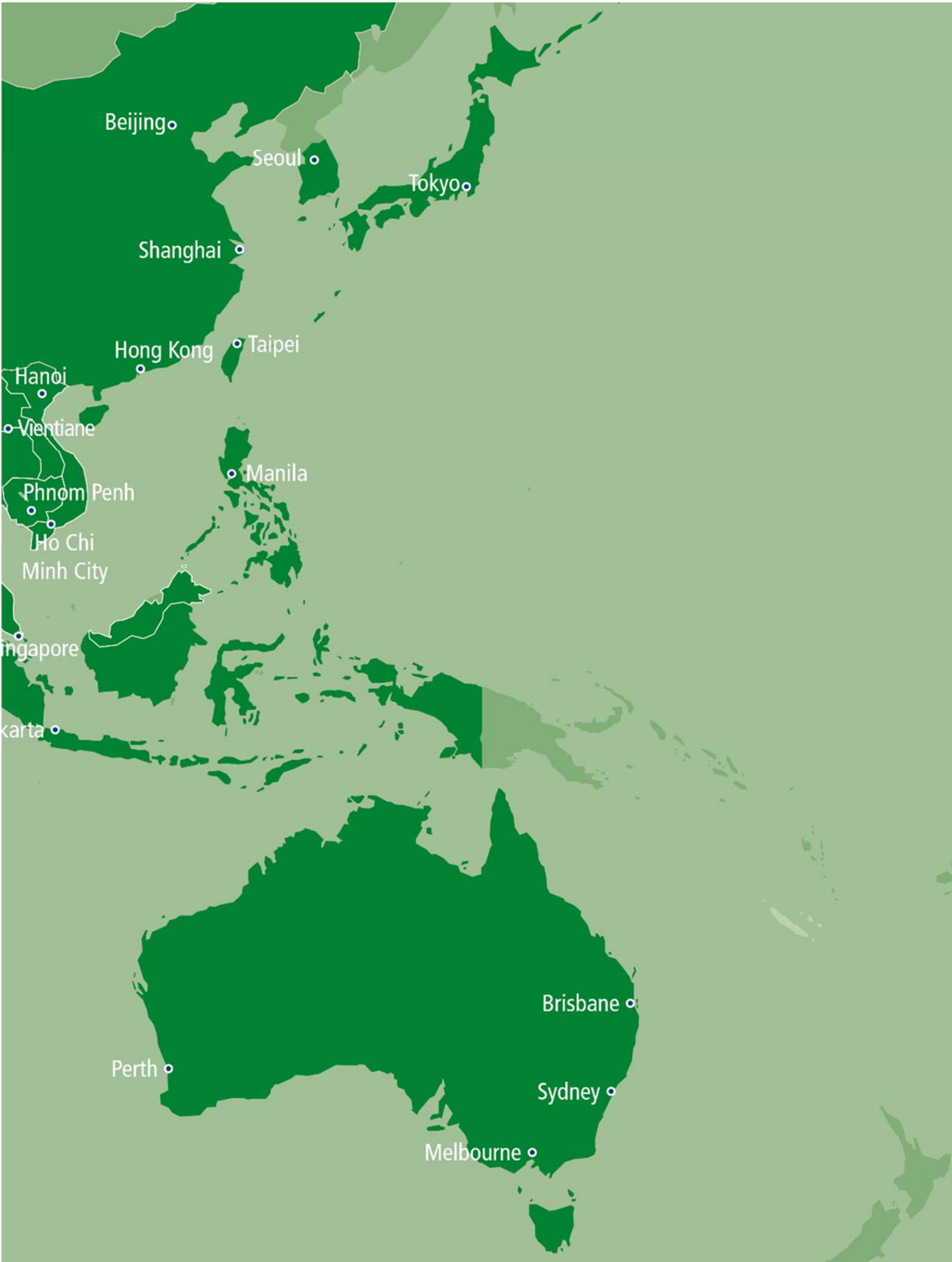
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Further information about each firm can be found respectively at www.ahp.co.id, www.aplaw.jp/en/, www.chenandlin.com, cms.law, www.corrs.com.au, www.rajahtann.com, www.tilleke.com, www.yulchon.com