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Lifesciences

A legal guide to China

Introduction

This CMS Lifesciences Guide (the "Guide") provides an overview of the legal framework governing the lifesciences industry in the PRC, including: regulatory licences, product licences, intellectual property protection, labelling, government pricing policy and product liability.

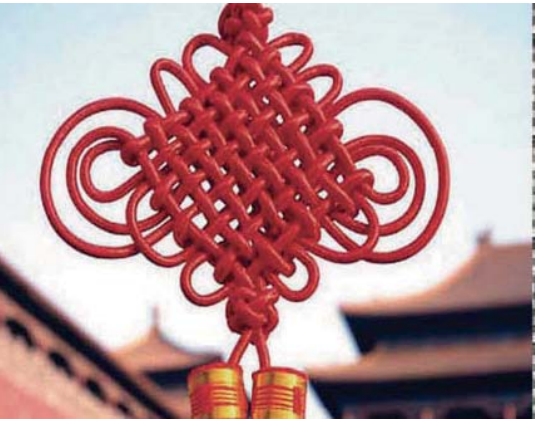
In particular, this Guide focuses on the unique business issues that lifesciences (pharmaceutical, biotechnology and medical device) companies face through their business operations in the PRC.

The Guide is an up-to-date review of the legal issues impacting on the lifesciences industry in the PRC. It provides an essential resource for managers of lifesciences companies to enable them to better understand and manage their operations in the PRC and for company executives to enable them to better understand the regulatory requirements applicable to corporate activities in the PRC.

Disclaimer

This Guide is for general information purposes only and shall not be considered as constituting legal advice in any respect. CMS bears no responsibility for any loss that may arise from acting or refraining from acting on the basis of such information. Formal legal advice for any related issue should be obtained from your legal counsel.

CMS, China



About CMS and China

CMS has been advising clients conducting business in the PRC for almost 30 years. From our Shanghai and Beijing offices, we maintain a close eye on the rapid developments occurring in the PRC, both in the law and industry. The Shanghai office is staffed with over 30 lawyers, mostly PRC qualified, working alongside lawyers from France, Germany, the UK and Switzerland, enabling us to provide an extensive range of legal expertise and services to clients doing business in the PRC. We work hard to be a truly client-focused law firm. This involves understanding the unique needs and challenges of the lifesciences sector, and providing a service that is tailored to the particular concerns and requirements of each client.

CMS consists of 10 major European law firms which have a deep local understanding of legal, tax and business issues and deliver client-focused services through a joint strategy executed locally across 30 jurisdictions. CMS employs over 2,800 lawyers with 55 offices across Europe and the emerging markets.

We are pleased to bring you this Guide and invite you to contact the lawyers listed at the end of the Guide to learn more about the lifesciences industry in the PRC.

Abbreviations and definitions

ADR	Adverse drug reaction
AEFI	Adverse event following immunisation
AIC	Administration for Industry and Commerce
API	Active pharmaceutical ingredient
Catalogue	Catalogue Catalogue of industries for foreign investment dated 2007
CCD	Centre for certification of drugs
CDE	Centre for drug evaluation
CJV	Cooperative joint venture
COFTEC	Commission of Foreign Trade and Economic Cooperation
DRC	Development and Reform Committee
Drug Packaging	Drug packaging materials and containers which are in immediate contact with given drug
EJV	Equity joint venture
FDA	Food and Drug Administration
FIE	Foreign invested enterprise
GCP	Good clinical practice
GLP	Good laboratory practice
GMP	Good manufacturing practice for pharmaceutical products
GSP	Good storage practice for pharmaceutical products
IP	Intellectual property
Licence Number	Drug advertising licence number
MOC	Ministry of Commerce
MOH	Ministry of Health
MOHRSS	Ministry of Human Resources and Social Security
National Catalogue	National catalogue of drugs for basic medical care insurance for which the MOHRSS is responsible
NDRC	National Development and Reform Committee
NICPBP	National Institute for the Control of Pharmaceutical and Biological Products
OTC	Over the counter
PRC	People's Republic of China
Provincial Catalogue	Provincial catalogue of drugs for basic medical care insurance
R&D	Research and development
SAFE	State Administration for Foreign Exchange
SAIC	State Administration for Industry and Commerce
SFDA	State Food and Drug Administration
TCM	Traditional Chinese medicine
TRIPs	Agreement on trade-related aspects of intellectual property rights
VAT	Value Added Tax
WFOE	Wholly foreign owned enterprise
WTO	World Trade Organisation

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Chapter I
INVESTMENT – ESTABLISHING A BUSINESS

1. Investment structure

Lifesciences companies setting up a pharmaceutical business in the PRC, after having decided on the business model and scale, should decide which investment vehicle to use in the light of applicable PRC regulations.

The investor may choose to invest either through an existing Chinese company, or by incorporating a representative office.

1.1 Subsidiary or joint venture

Lifesciences companies wishing to establish a business in PRC can choose between the following forms of company: EJV, WFOE or CJV.

1.1.1 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.

1.1.2 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.

1.1.3 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 al owing 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.

The determination as to which of these three legal entities is most suitable will be influenced by whether the investor wishes to have a partner and, if so, whether the partner will be a Chinese or foreign investor. The desired profit allocation will also be influential.

Engaging a Chinese partner for the intended business may be compulsory.

For instance, in order to manufacture narcotic drugs in the PRC, a foreign lifesciences company is obliged to set up an EJV with a Chinese partner, which must hold the majority of the equity.

Establishment of an entity with another investor may sometimes present risks if the investment is not properly structured and the necessary safeguards are not put into place, particularly in relation to the security of technology transfer and intellectual property.

1.2 Representative office

Establishing a representative is a sensible choice when taking the preliminary steps towards making an investment in the PRC, because it enables the foreign company to develop a better understanding of the Chinese market.

A representative office of a foreign enterprise in the PRC is not a separate legal entity in itself, but rather an extension of its parent company. Representative offices of foreign enterprises are not al owed 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.

2. Greenfield or M&A

2.1 Greenfield investment

Establishing a legal entity in the PRC requires approval and registration with competent local authorities. Generally this means the local bureau of commerce (such as COFTEC) and the AIC. However, under certain circumstances, the MOC and SAIC in Beijing would also need to be involved. In addition, the new entity must be registered with local tax, customs and financial authorities (amongst others) before commencing operations in the PRC.

2.2 Acquisition of existing Chinese companies

In recent years, there has been an influx of foreign investors investing in existing Chinese entities. In 2007, more than 40 such acquisitions were made in the pharmaceutical industry, with a total transaction value of RMB 3.4 billion (approximately EUR 300 million).

The acquisition strategy in the PRC market helps foreign investors to enjoy many benefits, including immediate access to the fast growing Chinese domestic market.

The investor may choose to acquire the equity or assets of an FIE or a domestic company (which, if the equity is purchased, will be converted into an FIE).

Completion of the acquisition of the assets of a lifesciences company may take a substantial amount of time because the compulsory licences and certificates (such as those required for manufacturing, distribution, GMP, GSP or products (drugs or medical devices), are not automatically transferred to the purchaser. In practice, the investor must apply for the name of the licence holder to be altered. Sometimes the local FDA will carry out an on-site inspection, prior to making the alteration, especially where a manufacturing licence is being transferred.

Since such practices vary from one province to another, careful verification of local practice is recommended prior to structuring the transaction.

Every merger or acquisition is subject to the approval of the bureau of commerce. The sale contract will need to be submitted to the bureau of commerce. The transaction must also be registered with the AIC and the tax authorities to enable registration details to be updated and to ensure that all taxes related to the transaction are settled. If the target company is a State-owned company, additional approval by the State Owned Assets Administration Commission is required.

3. Business scope

3.1 Preliminary description of the activities and scope of Chinese companies

The scope of business that can be carried out by a company in the PRC is determined and limited by the type of company it is, for example, whether the focus of the company is manufacturing, trading or consulting. Manufacturing companies may manufacture and sell their own products, provided that they first obtain a Drug Manufacturing Licence, GMP Certificate and/or a Medical Device Manufacturing Licence. To purchase and distribute third parties' products, a lifesciences company must obtain a Drug Trading Licence, GSP Certificate and/or Medical Device Trading Licence. It should be noted that manufacturing companies are permitted to expand their business activities to include the trading of third party products.

3.2 Manufacturing company

In order to establish a manufacturing company, the investor must verify whether there are any specific restrictions which have been imposed by the Chinese government on the products to be manufactured, or the activities to be under taken by the company. In addition, the necessary licences and certificates for the manufacture of drugs and/ or medical devices (as appropriate) should be obtained prior to commencing manufacture.

3.2.1 Permitted business scope

According to the Catalogue, the Chinese government encourages the manufacture of most drugs and medical devices.

However, special attention must be paid to those products which are categorised in the Catalogue as being restricted or prohibited from being manufactured by an FIE.

Restricted activities may, in some cases, only be carried out by an EJV or a CJV with a Chinese majority partner. Restricted activities may also be subject to prior approval by the MOC in Beijing. This will impact on the length of time to be set aside for the approval procedure.

RESTRICTED ACTIVITES

(a) Production of chloramphenicol, penicillin G, lincomycin, gentamicin, dihydrostreptomycin, amikacin, tetracycline hydrochloride, oxytetracycline, medemycin, kitasamycin, ilotyin, ciprofloxacin and offoxacin.

(b) Production of analgin, paracetamol, vitamin B1, vitamin B2, vitamin C, vitamin E, preparations composed of multiple vitamins and oral calcium preparation.

(c) Production of immunity vaccines (excluding the BCG vaccine and poliomyelitis vaccine), bacterins, antitoxins and anatoxins (the DPT vaccine, measles vaccine, Type-B encephalitis, epidemic cerebrospinal meningitis vaccine), which are included in the State's National Immunisation Plan.

(d) Production of API for addiction narcotics and class A psychoactive drugs (a Chinese partner must hold the majority of shares in any FIE intending to produce these products).

(e) Production of non-self-destructible expendable injectors, transfusion systems, blood transfusion systems and blood bags.

(f) Production of low or middle class type-B ultrasonic displays.

PROHIBITED ACTIVITES

(a) Processing of TCM raw materials that belong to "rare and endangered plants" or other protected wild medicinal resources.

(b) Application of preparation technique for preparing elements of TCM in small pieces ready for decoction, through means such as steaming, frying, moxibustion or calcining.

(c) Implementation of secret recipes for patented TCMs.

3.2.2 Drug manufacturing - licence and certificate

In order to manufacture drugs, a drug manufacturer must obtain a Drug Manufacturing Licence and a GMP Certificate.

DRUG MANUFACTURING LICENCE

The establishment of a pharmaceutical manufacturing company must have been approved by the FDA of the province, autonomous region or municipality where the company is located and the company must have been granted a Drug Manufacturing Licence.

A Drug Manufacturing Licence is also required for each branch, factory or any additional workshop established outside the approved factory premises. In addition, the Drug Manufacturing Licence contains details of each of the warehouses used by the manufacturer which are qualified to store drugs.

The Drug Manufacturing Licence will determine the scope of production and each such licence is valid for a term of five years. If the licence is to be renewed, the application must be made no later than six months before its expiration date.

GMP CERTIFICATE

Currently, it is necessary to obtain a GMP Certificate for all drug-manufacturing activities, except for the processing of TCM raw materials and prepared 'slices' of TCM raw materials.

Inspections of drug manufacturing plants are organised by the FDA at the provincial level. Provincial FDAs may then issue a certificate to a manufacturer that complies with the GMP requirement.

For manufacturers producing injections, radioactive drugs or biological products specified by the SFDA, it is the responsibility of the SFDA to conduct the inspection and grant the respective GMP Certificates.

Each GMP Certificate is valid for a period of five years. Applications for renewal must be made six months prior to the expiration date.

3.2.3 Medical Device Manufacturing Licence and GMP requirements

The manufacture of medical devices is administrated by the SFDA in accordance with the following classification levels:

Level	Medical devices description
Level I	Medical devices for which safety and effectiveness can be ensured through routine administration (such as surgical scissors).
Level II	Medical devices for which safety and effectiveness must be controlled but which do not fall within Level III medical devices category (such as blood pressure measuring equipment).
Level III	Medical devices that are implanted into the human body, or used for life support or sustenance, and which pose a potential risk to the human body, as a result of which their safety and effectiveness must be strictly controlled (such as sterilised syringes).

Medical devices of different levels must comply with various supervisory and administrative formalities.

A company that manufactures Level I medical devices is not required to hold a manufacturing licence, but should file a record with the competent FDA at provincial, autonomous region or municipal level.

A company that wishes to manufacture Level II or III medical devices, must be inspected and approved by the competent FDA at provincial, autonomous region or municipal level, which will then issue a Medical Device Manufacturing Licence.

A Medical Device Manufacturing Licence is valid for five years. Any re-inspection and licence renewal application must be undertaken prior to the expiry of the licence.

In December 2009, the SFDA issued the GMP Inspection Measures for sterile medical devices and implantable medical devices and the inspection measures will become effective as of 1 January 2011. This is the first time that the SFDA requires manufacturer of medical devices to be compliant with GMP rules. Although only sterile and implantable medical devices are covered so far, it is expected that the SFDA will extend the GMP scheme to cover most of Class III and Class II products.

3.3 Trading company

Before setting up a trading company in the lifesciences sector, any special restrictions imposed by the Chinese government on the specific products the company intends to distribute must be investigated. Further, depending on whether the company distributes drugs and/or medical devices, different licences and certificates should be obtained prior to the company commencing trading.

3.3.1 Permitted drug trading activities

The wholesale and retail distribution of drugs by FIEs is restricted.

The establishment of an FIE engaging in drug distribution falls under the competence of the MOC rather than the provincial bureau of commerce, and therefore more time may be needed to establish such a company.

A foreign investor wishing to conduct retail trading activities through more than 30 retail outlets for drugs purchased from different manufacturing companies, may only do so through a joint venture with a Chinese majority equity holder.

3.3.2 Drug trading - licence and certificate

The FDA may grant a Drug Trading Licence for the wholesale and retail distribution of drugs. In addition, a GSP Certificate is required for al drug distributors.

TRADING LICENCE

A wholesale distributor should apply for a trading licence to the FDA of the province in which it is located, whilst a retail distributor should apply to the FDA of the city in which it is located.

The trading licence includes details of each of the warehouses belonging to the distributor that are qualified to store drugs and is valid for a term of five years. Applications for renewal must be made six months prior to the expiry of the licence.

GSP CERTIFICATE

A wholesale or retail distributor must undergo a GSP inspection organised by the local provincial FDA to obtain a GSP Certificate. This must be applied for within 30 days of the issue of the Drug Trading Licence.

The GSP Certificate is valid for a term of five years.
Applications for renewal must be made six months prior to the expiry of the Certificate.

3.3.3 Medical Device Trading Licence

The distribution of medical devices must comply with different supervisory and administrative formalities depending on the classification of the particular medical device (Please refer to Paragraph 3.2.3 of this Chapter). Distribution of Level I medical devices does not require a Medical Device Trading Licence, but such activity should be registered with the FDA at the provincial, autonomous region or municipal level.

Distribution of Level II or III medical devices requires inspection and approval by the FDA at the provincial level, which will issue a Medical Device Trading Licence.

Each Medical Device Trading Licence is valid for five years. Applications for renewal must be made at least six months prior to the expiry of the licence.

3.4 R&D off shoring

There has been a recent change in the investment focus of many lifesciences companies doing business in the PRC from manufacturing and/or trading activities to R&D activities. Many foreign companies have moved sections of their R&D capability into the PRC, or have established stand-alone R&D centres that cover country or region specific R&D activities.

The main commercial reasons usually put forward to justify the outsourcing of R&D activity to the PRC are: reduced human resources in the home country; facilities costs in the home country; and access to a large pool of qualified pharmaceutical scientists and patients in the PRC. Further, the Shanghai and Bohai regions are specifically aiming to develop lifesciences clusters, with hundreds of Chinese and FIE establishing partnerships working alongside public institutions.

A foreign established R&D centre may take the form of an EJV, CJV or WFOE.

It may also take the form of an internal department or branch of an FIE.

R&D centres in the PRC benefit from a series of tax incentives, such as an exemption from import duty and import VAT on certain equipment used solely for R&D purposes. These tax incentives are commonly available to companies engaged in "encouraged" industries including FIEs and companies recognised as High and New Technology Enterprises (please refer to Paragraph 7.1 of this Chapter).

3.5 Contractual outsourcing

The PRC is offering an increasingly wide array of contractual manufacturing organisations (CMO), supply organisations (CSO) and research organisations (CRO). The quality and reliability of those organisations is progressively being recognised by FIEs and the number of partnerships is rising rapidly. Further, a number of lifesciences companies also outsource business processes to third-party organisations such as IT and Clinical Data Management. It seems that the major global pharmaceutical companies are adopting a model according to which an increasing part of their activities are performed by a network of contractual partners.

4. Funding the business

4.1 Equity

The registered capital of a limited liability company is the total amount of capital contributions made by all of the registered equity holders.

PRC regulations provide for a minimum amount of registered capital. However, companies engaging in certain restricted activities must be established with a higher amount of registered capital. Local approval and registration authorities sometimes fix their own minimum threshold.

Capital contributions may be made in one lump sum or in several instalments. At least 15% (or 20% in certain municipalities) of the registered capital needs to be paid within three months of the date of issue of the business licence, and the remaining part of the capital must be fully contributed within two years.

In the PRC, a company may use its entire registered capital for commercial use without being required to maintain minimum funds.

4.2 Debt

PRC regulations distinguish a company's registered capital from its total investment. The latter is calculated according to fixed ratios. The difference between the total investment and the registered capital is known as the foreign debt quota of the company. The foreign debt quota is the maximum amount of debt which may be owed by a company to any non-resident in the form of foreign currency, or as guaranteed by overseas collateral. Any loan granted to a FIE in a foreign currency from offshore entities or individuals must be approved and registered with the SAFE in advance.

5. Repatriation of thin capitalization

5.1 Dividends

PRC subsidiaries and joint ventures may repatriate their post-tax profits to overseas parent companies.

Dividends are generally declared and paid after the end of a fiscal year. It is possible, albeit uncommon, to declare and pay interim dividends, which would be subject to special approval from SAFE.

The total amount of the dividends paid is limited to the accumulated after-tax earnings. Furthermore, at least 10% of the net profit of a fiscal year must be paid into a company reserve before dividends can be paid. This reserve must accrue until the balance of the reserve reaches 50% of the company's registered capital.

Dividends paid abroad are subject to a 10% withholding income tax, subject to the provisions of any applicable double tax treaty.

5.2 Interests, royalties and know-how

Interests on loans, royalties and other related fees paid by Chinese companies in the PRC to foreign entities are generally subject to a 5% business tax on the gross income and a 10% withholding income tax on the income after business tax, subject to the provisions of any applicable double tax treaty.

Royalties paid out of the PRC for the transfer and licence of technology use rights may be exempted from tax liability provided the related transfer agreement is registered with the MOC and a technology import and export registration certificate is obtained upon registration.

5.3 Transfer pricing

PRC transfer pricing rules mainly follow OECD standards but currently lack detailed implementation regulations. Existing transfer pricing regulations require annual declarations of transactions between associated and affiliated enterprises to be made along with the establishment of control mechanisms. Local tax regulations provide for detailed measures to prevent tax avoidance in the PRC.

Transfer pricing regulations in the PRC are developing rapidly because transfer pricing adjustments are a major source of tax revenue.

6. Foreign exchange

The PRC implements a strict foreign exchange control system and restricts the full convertibility of the PRC currency (RMB). The RMB official exchange rates against major foreign currencies are issued daily by the People's Bank of the PRC. The RMB is only allowed to float within a narrow band pegged to a fixed basket of foreign currencies mainly composed of the US dollar, the Euro and the Japanese Yen.

The SAFE is the main competent authority responsible for controlling, regulating and supervising the regime of foreign exchange control.

The conversion of registered capital from foreign currencies into RMB should be based on the entity's actual needs under current rules.

If the cumulative amount of the converted amount exceeds USD 50,000, a detailed description of the proposed usage of the converted RMB is required. A request to convert RMB into a foreign currency for trade and daily settlements must be submitted to the bank with relevant supporting documents, including any related tax payment certificate.

Foreign exchange transactions that are categorised as current account items generally no longer require prior approval from the SAFE. Instead, designated banks are responsible, under a delegation of power from the SAFE, to verify and review the company's documents which provide justification for the transactions and to handle the foreign exchange payment out of the PRC.

7. Taxation, accounting and reporting

7.1 Corporate income tax

The corporate income tax system has been dramatically modified with changes effective from 1 January 2008. The two former distinct tax regimes for Chinese domestic enterprises and FIEs have been abandoned. There is now a standardised tax rate of 25% and tax losses can be carried forward for five consecutive years.

The corporate income tax law has seen a shift in tax incentives from being "geography-based" to "predominantly industry-oriented and less geography-based".

Under the new tax incentive program, the most attractive incentive is the High and New Technology Enterprise incentive, which offers a reduced tax rate of 15%. However, the criteria for qualifying as a High and New Technology Enterprise are now much stricter than before. The assessment of High and New Technology Enterprises is jointly governed by three PRC government bodies: the Ministry of Science and Technology; the Ministry of Finance; and the State Administration of Taxation.

Biological and medical technology is one of the industries which qualifies as a High and New Technology Enterprise. The PRC rules define the scope of each qualified industry in detail. For example, companies engaged in biomedical technologies, such as new vaccines, new dosage forms, high and new technology

medical devices as well as the production of new TCM drugs and new chemical drugs, may be designated as High and New Technology Enterprises in the PRC and consequently enjoy a reduced tax rate of 15%.

Before being recognised as a High and New Technology Enterprise, an enterprise must comply with the following four stages:

(i) undertake a self assessment;
(ii) submit required documents in support of the application to a govern mental verification administration institution;
(iii) undergo a review of legal compliance by the governmental verification administration institution; and
(iv) be approved by the governmental verification administration institution, issue a public notice and file relevant documents.

After obtaining a certificate for High and New Technology Enterprise, an enterprise should apply to the competent tax authority for tax exemption or reduction.

7.2 VAT

VAT is a turnover tax levied on the import of goods, the sale of goods (except real estate and unfinished products), and the provision of processing, repair or replacement services in PRC.

VAT payers are qualified either as general taxpayers or small taxpayers. The appropriate category is determined predominantly by business scale or annual sales volume. The standard rate for drugs and medical devices is 17% for general taxpayers. However, anti-HIV products produced by authorised companies are exempted from VAT until 2010. The actual VAT paid by a small taxpayer is output VAT without deduction of input VAT.

The PRC implements a production-based VAT system. Under this system, companies are not usually allowed to claim tax deduction for the purchase of fixed assets such as equipment and machinery. However, the PRC launched an experimental reform in 2004 under which qualified taxpayers in the northeast and central PRC,

which are engaged in designated industries (such as farm product processing), are entitled to claim for a credit for input VAT incurred on fixed assets. The VAT experimental reform is not yet applicable to pharmaceutical industries but is expected to be expanded to include this industry in the future.

VAT refunds are available in the PRC to taxpayers who export goods out of the PRC. The "exemption, credit and refund" method is generally applicable to manufacturing companies, including the manufacturers of drugs and medical devices. Under this method, export sales are generally exempted from VAT, relevant input VAT is credited against output VAT on domestic sales and a specific formula is applied to the remaining VAT input to make it refundable.

7.3 Business tax

Business tax is another turnover tax imposed in the PRC on the transfer of intangible goods, the provision of services which are not subject to VAT, the provision of taxable labour services and the sale of immovable property in the PRC. VAT and business tax are mutually exclusive. Business tax is levied on gross turnover and no input credit is available. Generally the provision of technical services by pharmaceutical manufacturing companies, the assignment of intangible assets and the sale of immovable property in the PRC, are all activities which are subject to business tax at 5%. However, the business tax on technology transfers including licences may be exempted.

7.4 Accounting and reporting

Al FIEs in the PRC are required to prepare annual financial statements, including balance sheets, income statements and cash flow statements. These accounts must be maintained in accordance with the relevant PRC accounting standards, which differ from the International Accounting Standards. A mandatory annual audit by a firm of certified public accountants is required for all FIEs under PRC law.

Chapter II
DRUGS AND MEDICAL DEVICES LICENCES

1. Drug licence

1.1 Scope of approval

Drugs, whether new drugs, imported drugs or generics, must be approved by the SFDA before they are launched on the Chinese market. The definition of drugs in the PRC includes TCM. However, many TCM raw materials and prepared slices of TCM materials are exempted from the approval and Drug Licence requirements, except where specifically designated by the SFDA.

1.2 Responsible authorities

The SFDA is the competent authority responsible for drug approval. The SFDA uses two affiliated organisations, the CDE and the CCD, to conduct technical evaluation and inspection during the approval process.

The testing institutions established by the SFDA and provincial FDAs conduct drug testing during the approval process. Two types of tests are conducted, one for standard verification and one for quality.

The local FDAs are responsible for the preliminary review of drug applications.

1.3 Approval procedures for new drugs

1.3.1 Definition of a new drug

PRC law defines new drugs as those that have never been marketed in the PRC. In addition, the following drugs, which are not new per se, are subject to the same application and approval procedures:

(i) any marketed drugs whose dosage form, or method of administration is altered;
(ii) any marketed drugs to which new applications are added; and
(iii) biological products.

1.3.2 New Drug Certificate and Drug Licence

In addition to the Drug Licence, new drugs shall be granted a "New Drug Certificate". The New Drug Certificate confirms that the SFDA has verified the safety of a drug and its classification as a new drug, but does not grant the certificate holder the right to manufacture it. Only the Drug Licence grants such a right to manufacture.

The New Drug Certificate may be granted to either a manufacturing company or a research institution independently of a Drug Manufacturing Licence while the Drug Licence may only be granted to a qualified drug manufacturing company.

1.3.3 Qualified applicants

Drug manufacturing companies duly registered in the PRC are qualified to become applicants for a New Drug Certificate and Drug Licence.

Entities (such as R&D companies), which are not drug manufacturing companies, can only apply for the New Drug Certificate. Such entities can then transfer the New Drug Certificate to a qualified drug manufacturer which can apply for the Drug Licence with the SFDA.

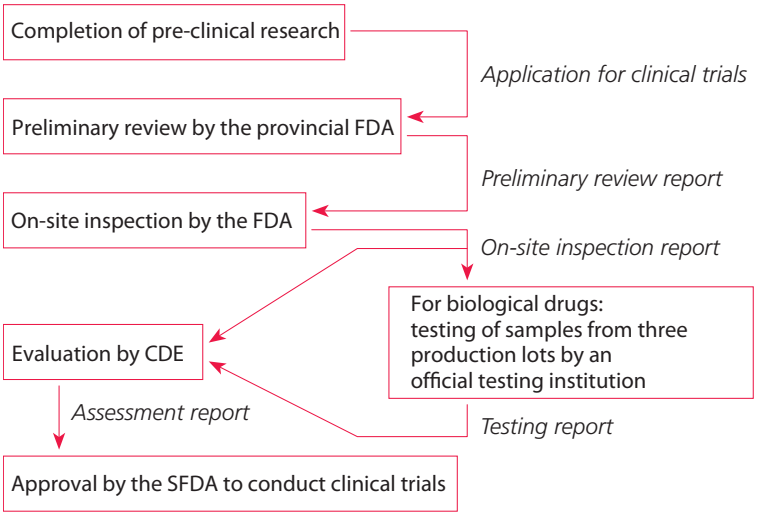
1.3.4 Approval procedure

Pre-clinical research

Pre-clinical research is not subject to approval by the SFDA, but must be carried out in strict compliance with GLP, and by an institution that has been granted a GLP Certificate by the SFDA.

Clinical trials

(A) APPROVAL FOR CONDUCTING CLINICAL TRIALS



(B) CONDUCTING CLINICAL TRIALS

Upon receipt of approval for the conduct of clinical trials, the applicant can appoint a qualified institution that has been approved by the SFDA for a GCP Certificate. Such appointment must take place within three years of the approval date.

Before starting the clinical trials, the applicant must submit to the provincial FDA and the SFDA: the clinical trial protocol; a list of the investigators' names; written consent of the ethics committee organised by an appointed institution (normally a hospital); and samples of the written consents of the human subjects for the clinical trials.

Biological products to be used in the clinical trials must be tested by an official testing institution designated by the SFDA. Other drugs may either be tested by the applicant or by an official testing institution.

(C) INSPECTION BY THE SFDA

The clinical trials must be conducted in strict compliance with GCP.

The SFDA and the provincial FDA have the right to inspect the on-going clinical trials. The SFDA may order the applicant to modify the clinical trial protocol, suspend the clinical trials or even terminate them if any of the following events occur:

(i) the ethics committee fails to fulfil its duties;
(ii) the safety of the human subject cannot be sufficiently guaranteed;
(iii) the applicant fails to report any serious adverse events related to the drugs within the stipulated period of time;
(iv) the drug is found to be ineffective;
(v) the drug is found to have quality problems;
(vi) the applicant or the institution undertaking the trials are found to have cheated or forged data; or
(vii) any other violation of the GCP.

(D) INTERNATIONAL MULTI-CENTRE CLINICAL TRIALS

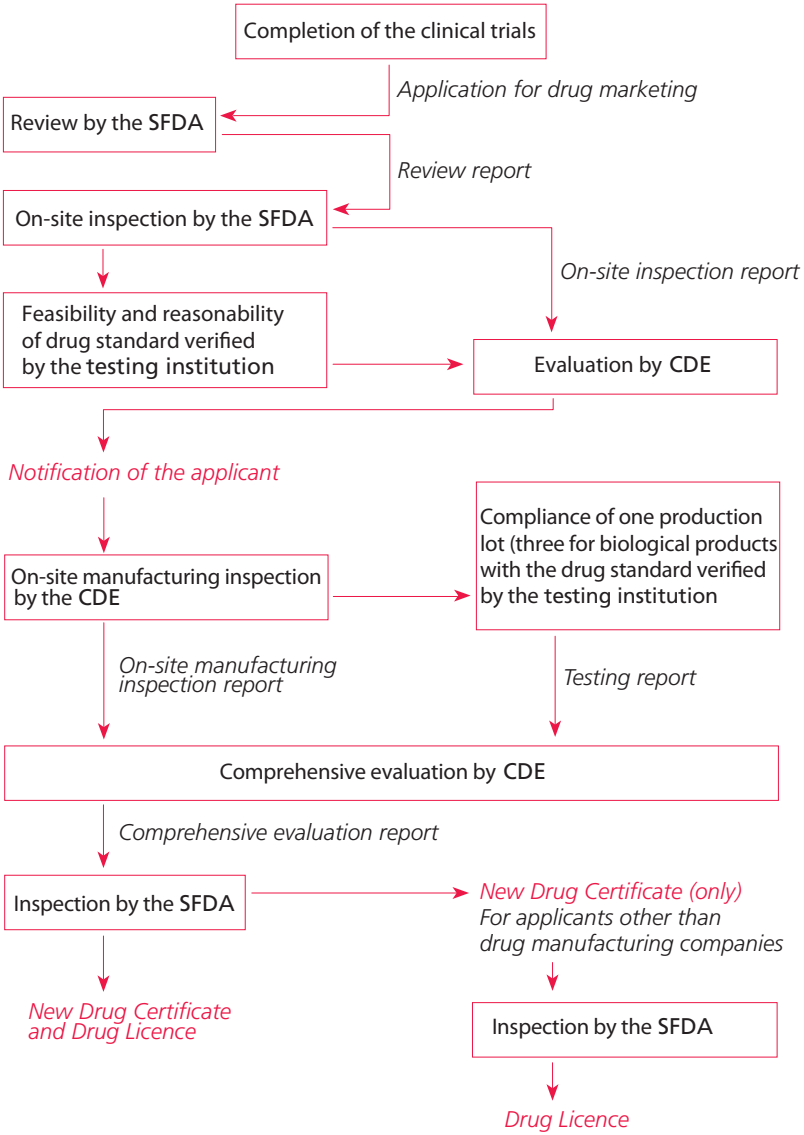
A foreign applicant can submit an application to the SFDA for international multi-centre clinical trials in the PRC.

The drugs used for the international multi-centre clinical trials should be those that have been approved for marketing abroad or, if not yet approved, those that have entered into phase II or III clinical trials. Preventive vaccines to be used in international multi-centre clinical trials must have been approved for marketing abroad.

When conducting international multi-centre clinical trials on any drug in the PRC, any serious adverse reactions and unanticipated adverse reactions relating to such drugs found in any country must be immediately reported by the applicant to the SFDA.

After the clinical trials are completed, the applicant is obliged to submit a complete clinical trials report to the SFDA. The data obtained in the international multi-centre clinical trials, which is used for the drug approval application in PRC, shall meet the relevant requirements, and al related research materials must be submitted to the SFDA.

Market approval



Approval procedure period

In practice, the approval procedure takes approximately 1.5 to two years. However, the timescale for the approval procedure for the following new drugs is generally shortened by three to six months because they are dealt with as a matter of priority:

(i) effective components extracted from plants, animals, minerals and other materials that have not been marketed in the PRC and preparations of the same; newly discovered drug materials and preparations thereof;

(ii) chemical drugs as well as their APIs; and biological products that have not yet been approved for marketing in the PRC or abroad;

(iii) new drugs that are used for the treatment of AIDS, malignant tumours and rare diseases and any other new drugs with an unparalleled advantage in clinical treatment; and

(iv) drugs treating diseases that as yet have no cure.

1.4 Approval procedure for generics

1.4.1 Definition of generics

A generic drug is a drug which is identical to a marketed new drug in terms of active ingredients, dosage form, method of administration and therapeutic effectiveness.

Note that the following drugs are subject to application and approval procedures for new drugs (please refer to Paragraph 1.3.1 of this Chapter):

(i) any marketed drugs whose dosage form, or form of administration has changed; or

(ii) any marketed drugs to which new applications are added.

1.4.2 Qualified applicant

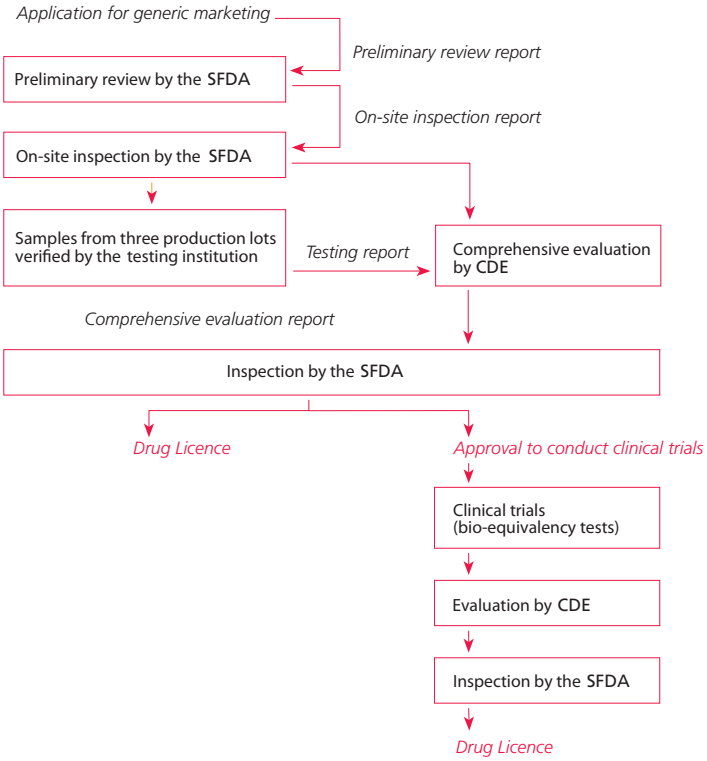
Any PRC drug manufacturer holding a Drug Manufacturing Licence is a qualified applicant for the purposes of approval of generics. Companies that do not manufacture drugs or foreign drug manufacturers are not qualified applicants.

1.4.3 Approval scope

In principle, the generics approval procedure is a simplified version of the new drug approval procedure because no pre-clinical research or clinical trials need to be conducted. However, the FDA may, in practice, require that any generic be subjected to clinical trials.

Clinical trials for generic drugs involve bio-equivalency tests only.

1.4.4 Approval procedure



In practice, the approval procedure takes approximately one year.

1.5 Approval procedure for imported drugs

1.5.1 Scope of approval

An application for a Drug Licence for imported drugs should be made upon conclusion of a licence agreement to import and market the drug in the PRC.

Drugs to be imported and marketed in PRC must comply with the following pre-conditions:

(i) the drugs must have been approved by the drug administration authority of the home country and launched on the home market; and

(ii) the manufacturing process of the drugs must be in strict compliance with the Chinese GMP.

1.5.2 Qualified applicants

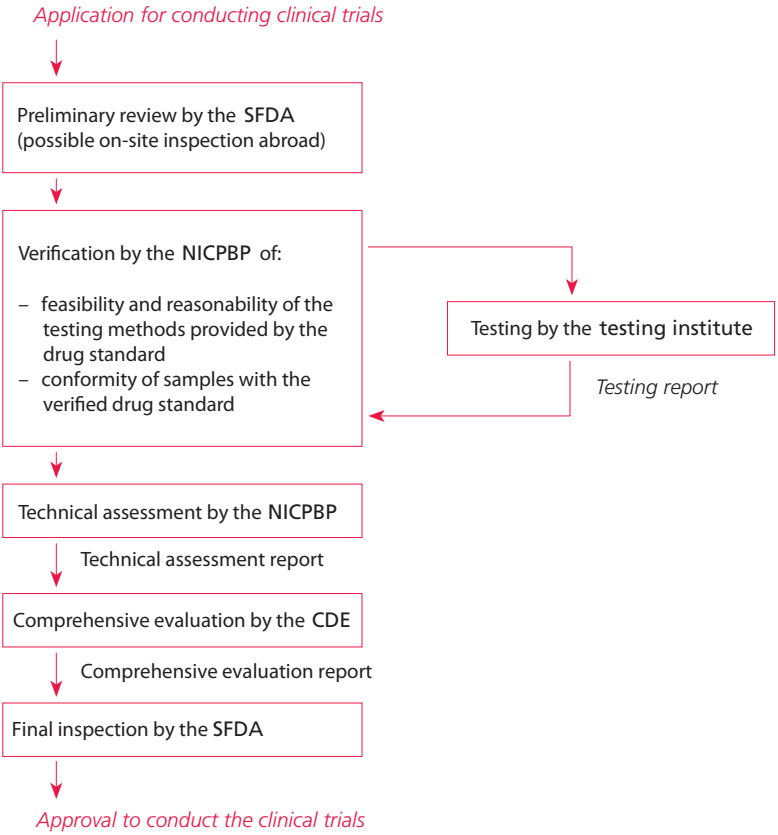
Drug manufacturing companies duly registered in foreign jurisdictions may apply for a Drug Licence for imported drugs. The application should be made through their representative in the PRC or through an appointed domestic agency.

1.5.3 Approval procedure

Imported drugs must undergo clinical trials in order to obtain market approval.

Approval to conduct the clinical trials

Before starting clinical trials, the applicant must apply to the SFDA for approval.



Clinical trials must be conducted in accordance with the Chinese GCP. In general, the requirements for clinical trials for imported drugs are the same as for new drugs.

Market approval

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

If the drug to be imported and marketed in PRC meets the relevant requirements, the SFDA will grant a Drug Licence to the applicant. In practice, the approval procedure takes approximately 1.5 years.

1.6 Application for modification of a Drug Licence

When any indication for which a Drug Licence is approved is intended to be modified, the original applicant must apply for the approval of such modification.

An application for the modification of a Drug Licence as a result of a modified drug standard, excipient or manufacturing process shall be submitted to the FDA at the provincial level for preliminary review and then the SFDA for final approval. The FDA can conduct an on-site inspection, and a testing institution can test the samples selected from three production lots, or verify the modified drug standard that has been submitted, before the application is transferred to the SFDA.

The FDA at the provincial level approves modification of the manufacturer's name and registered address and the drug's validity period. Application for the modification of a Drug Licence of an imported drug should be submitted directly to the SFDA for review and approval.

1.7 fast track approval procedures

The SFDA issued on 7 January 2009 the Measures on Special Approval of New Drugs ("Measures") to create a "Fast Track" for certain new drug applications ("Fast Track Application").

1.7.1 Fast track

The Fast Track essential y means priority for reviewing the accepted application, arranging the on-site inspection, testing and evaluation.

Article 7 of the Measures stipulates that the local drug administrations, testing institutions and centre for drug evaluation ("CDE") shall arrange the on-site inspection, testing and evaluation for Fast Track Application on a priority basis over Normal Application.

Although there is no definite shortened time frame provided by the Measures, the priority for reviewing the submitted application, arrangement of on-site inspection, testing and evaluation is expected to shorten the time-consuming waiting time and expedite the whole approval procedures. However, it is noted that under the Normal Application, the waiting period may last for a couple of months to one year and the approval procedures may take approximately two years.

1.7.2 Qualification Criteria

According to Article 2 of the Measures, to be qualified as a Fast Track Application, the application shall be submitted for any of the following new drugs:

(i) effective components extracted from plants, animals, minerals and other materials that have not been marketed in the PRC and preparations of the same; newly discovered drug materials and preparations thereof;

(ii) chemical drugs as well as their active pharmaceutical ingredients ("APIs"); and biological products that have not yet been approved for marketing in the PRC or abroad;

(iii) new drugs that are used for the treatment of AIDS, malignant tumors and rare diseases and any other new drugs with an unparalleled advantage in clinical treatment; and

(iv) drugs treating diseases that as yet have no cure.

The applicant needs to make a separate request to the SFDA for applying the Fast Track scheme. In addition, the applicant shall meanwhile formulate and submit a risk control plan and a relevant implementation plan to prevent any potential risk likely arising out of the clinical trial or when marketing such drug. The SFDA shall then decide whether or not to accept such application as a Fast Track Application.

The Measures provide that a Fast Track scheme may be terminated

(i) if so required by the applicant;
(ii) if the applicant fails to perform his obligations in due course and meet the requirements contained in the Measures; or
(iii) if the CDE finds and decides that the Fast Track scheme is no longer applicable to the submitted application.

1.7.3 Other preferential treatments

The Measures also grant two additional preferential treatments to Fast Track Applications: i) special communication channel; and ii) dynamic data supplement.

(A) Special communication channel

An applicant may apply for pre-communication with the CDE regarding its eligibility for filing of a Fast Track Application and any important technical issues in the first place, and multi-channel communications with the CDE regarding crucial security issues, clinical trial plan or amendment, major alteration of indication or specification of the new drug during the process of clinical trials.

This special communication channel gives the applicant an opportunity to discuss technical issues with the evaluation panel of the CDE and work out solutions to the concerns raised by the CDE. In contrast, applicants under Normal Applications do not have any channel to effectively communicate with the CDE and can do nothing but wait for the final decision of the CDE.

(B) dynamic data supplement

The applicant is allowed to submit supplementary technical data to the CDE under the following circumstances:

(i) in the event of new discovery of crucial security information;
(ii) if so required by the technical evaluation panel or for communication to the CDE;
(iii) upon receipt of a CDE's notice to supplement data; or
(iv) in the event of any alteration of the clinical trials.

Under the Normal Application procedure, the applicant shall submit all technical data in the first place and are not allowed to supplement any technical data after the application is submitted unless otherwise required by the SFDA or the CDE. If such applicant does want to supplement, it shall withdraw the original application and file a separate application.

1.8 Approval procedures for technology transfer based drug licence application

The SFDA issued on 19 August 2009 the Measures on Technology Transfer Based Drug Registration to introduce a simplified drug approving process for certain applicants whose application are based on acquisition of technologies of approved drugs. Under this new approval scheme, an applicant who has acquired technologies of an approved new drug, generic drug or imported drug, subject to certain restrictions, may be entitled to enjoy a simplified approval procedure which mainly requires sample testing. That said, bioequivalence tests and other clinical trials may be exempted, which will certainly result in considerable saving of time.

To benefit from this simplified approval procedure, an applicant must acquire totally the technology of manufacture of an approved drug and all the registration documents shall be transferred to the applicant by the licence holder of the approved drug. Further, it is required that the applicant, under inspection by the licence holder of the approved drug, must manufacture three consecutive batches of the approved drug and each batch shall successfully pass the quality test.

For generics, it is required that the applicant shall hold more than 50% of the equity interest of the licence holder of the approved drug or more that 50% of its equity interest is held by the licence holder of the approved drug, or both the applicant and the licence holder of the approved drug are subsidiaries of a third party which holds more that 50% of the equity interest of both companies.

For imported drugs, the applicant shall be a domestic drug manufacture company.

It is noted that the SFDA, under this simplified approval scheme, still holds right to request the applicant, for further clarification, to conduct bioequivalence test or other clinical trials, which means, this simplified approval procedure may be converted into the normal procedure at SFDA's discretion.

1.9 Renewal of the Drug Licence

The validity term of a Drug Licence is five years. The applicant shall apply for renewal six months prior to its expiration date.

The Drug Licence renewal (official y known as the "re-registration process") mainly depends upon two factors:

(i) that the drug does not have a severe adverse reaction record and
(ii) that the manufacturer has a good track record.

The renewal process is not a re-evaluation process but if there have been any serious adverse reactions or significant operational non-compliance by the manufacturer, the Drug Licence may not be renewed. The renewal process is carried out with the FDA at provincial level and if the FDA refuses the application, the application is transferred to the SFDA for final decision.

1.10 Revision of rejected applications

The applicant may file an application with the SFDA for the review of any rejected application within 60 days of receipt of the disapproval notice by the FDA or the SFDA. The scope of review of the SFDA is limited to the items described in the original application.

The SFDA shall finally decide on whether to revoke or sustain the disapproval notice within 50 days of receipt ofthe application.

1.11 Liabilities

Applicants shall ensure that all the research data and results submitted are true and lawful, as well as being sufficient and reliable enough to verify security, efficacy and controllability of the quality of the drugs.

If the applicant submits counterfeit application documents and samples either for clinical trials or for market approval, the SFDA may reject the application and impose administrative sanctions (including a refusal to accept any future application from the same applicant within five years, revocation of any clinical trials approval, or revocation of the Drug Licence). Any manufacturer or distributor that markets a drug in the PRC, without obtaining a Drug Licence, may be investigated by the FDA (please refer to Paragraph 1 of Chapter 7).

Criminal prosecution and sanctions may be triggered if a crime is committed.

2. Medical device licence

Manufacture of medical devices must be evaluated for security and efficacy and is subject to inspection and approval by the FDA or the SFDA.

2.1 Definition of medical device

In the PRC, the term medical device refers to any instrument, apparatus, appliance, material or other article which does not achieve its principal action in or on the human body by means of pharmacology, immunology or metabolism, but which may be assisted in its function by such means.

2.2 Authorities in charge

2.2.1 The FDA or SFDA

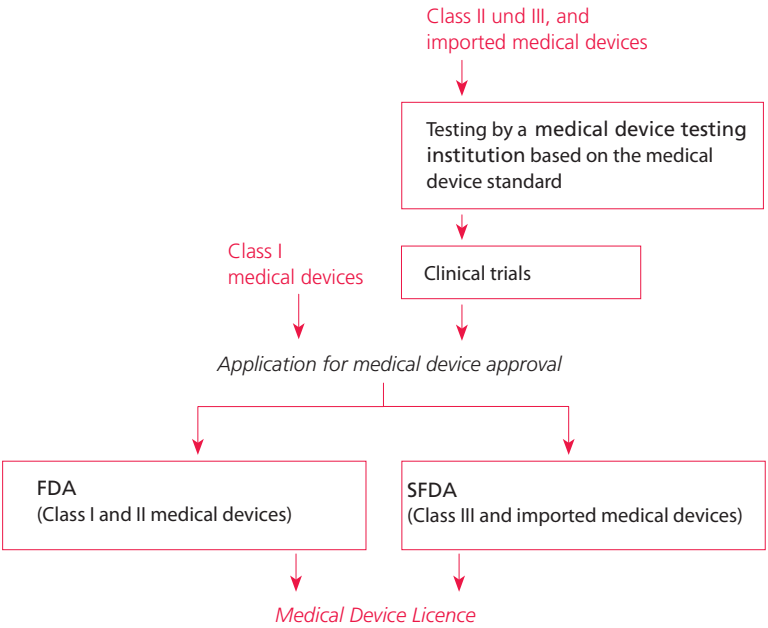
The relevant department of the FDA responsible for approving each medical device depends on the classification of the medical device (please refer to Paragraph 3.2.3 of Chapter 1) and whether it is manufactured in the PRC

Place of manufacture	Type of medical devices	Authority in charge
PRC	Class I	City level FDA
PRC	Class II	Provincial level FDA
PRC	Class III	SFDA
Abroad		SFDA

2.2.2 The medical device testing institution

The medical device testing institution is chosen by the applicant, based on the list jointly put together by the State General Administration of Quality Supervision, Inspection and Quarantine; and the SFDA.

2.3 Approval procedure



Note: For Class I medical devices, a product testing report (either issued by the applicant itself or any outside testing institution) shall be submitted together with the application filed to the FDA.

The timing of the approval process varies depending on which authority is involved.

City level FDAs complete the relevant application procedures within 30 days of receipt of the application.

FDAs at provincial, autonomous regional, or municipal level, directly under the central government, complete the relevant application procedures within 60 days of receipt of the application.

The SFDA complete the relevant application procedures within 90 days of receipt of the application.

2.4 The Medical Device Licence

The Medical Device Licence is valid for a period of four years. Any application for renewal must be made six months before the expiry date, as per the original approval procedure.

2.5 Modification of an approved Medical Device Licence

Details contained in the Medical Device Licence, such as: the specification, manufacturing premises, standards, composition, function or scope of application can be modified. All modifications are subject to approval by the original FDA.

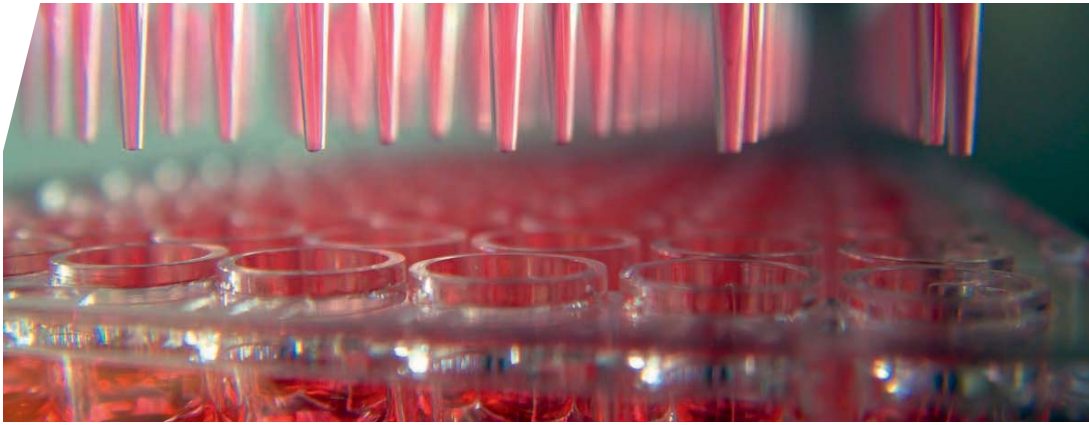
To modify other items such as the company name, local agent (for imported medical devices) or customer service provider, the licence holder must apply for approval to the FDA that granted the original licence.

2.6 Liabilities

If the applicant submits counterfeit application documents and samples for either clinical trials or market approval, the competent FDA may reject the application and impose administrative sanctions (including a refusal to accept any future application from the same applicant within two years, revocation of the clinical trials approval and revocation of the Medical Device Licence).

Any manufacturer or distributor that markets a medical device in the PRC without a valid Medical Device Licence will be answerable to the FDA (please see Paragraph 1 of Chapter 7).

Criminal prosecution and sanctions may be imposed if a crime is committed.



Chapter III
ADVERTISING, LABELLING AND PACKAGING

1. Advertising, labelling and packaging of drugs

1.1 Advertising

SCOPE OF APPROVAL

1.1.1 Scope of drug advertising

According to PRC law, a "drug advertisement" is defined as any published advertisement which contains drug names, details of the application of drugs or TCMs to diseases or other drug-related content.

Advertisements made other than through ublications such as on-site promotions, oral communications or sponsorship does not fall within the scope of the applicable regulations. Therefore, such advertisements are not subject to the following rules.

1.1.2 Exemptions

The following types of drug advertisements are expressly exempted from the drug advertising regime:
(i) advertisements for OTC drugs which only advertise the name of the drug and (ii) advertisements for prescribed drugs which only advertise the name of the drug in designated professional medical or pharmaceutical publications. Such drug advertisements do not need prior approval from the authorities.

1.1.3 Drugs which are not permitted to be advertised

The advertisement of anaesthetics, psychotropic drugs, toxic drugs and radioactive drugs is strictly forbidden. In addition, preparations confected by medical institutions, drugs that do not have a Drug Licence and drugs specifically required by the army may not be advertised.

REQUIREMENTS FOR ADVERTISING CONTENT

1.1.4 Required information

All drug advertisements must include certain information; including the drug specification, name, validity period, form (such as pill , liquid or powder), instructions, for administration and dosing, details of the manufacturing or trading company, the Drug Advertising Licence Number ("Licence Number") and the Drug Manufacturing Licence or Drug Trading Licence number.

In addition, if the company wishes to include details of the drug's uses, applicable disease indications, functions, applications and pharmaceutical effects, such information should be included in accordance with instructions approved by the FDA.

An advertisement for prescription drugs should advise that the drugs are only on offer to doctors and pharmacists. An advertisement for OTC drugs should advise that the drug should only be purchased and used in accordance with the instructions provided, or following the guidance of a pharmacist.

If an advertisement refers to any patent protection covering the drug, the patent number and category of the patent should be clearly mentioned as well. Only drugs with patents which have been registered and are effective in the PRC may refer to patent status in their advertisements.

Any advertisement for therapeutic medicines that should only be used under medical supervision should include advice to seek medical advice before purchasing and administering.

1.1.5 Characteristics of the information

There is an underlying general principle that all information provided in a drug advertisement should be true and in accordance with the law. The drug advertisement must not contain any information that is false, unscientific, or a categorical assertion or warranty of any described function.

The regulations strictly prohibit the inclusion of the PRC flag, national emblem, national anthem, or the names or images of any government organisation, department or official, in all drug advertisements.

In addition, drug advertisements must not contain anything to suggest that the safety of the drug is guaranteed in the absence of sufficient supporting scientific evidence. Drug advertisement must also not include any statistics regarding the efficiency of the treatment offered or the curative rate. The use of superlative terms to describe the drug is prohibited. An advertiser must not exaggerate, deceive, or provide misleading information to the consumer.

In addition, there is a prohibition on any comparison of the efficiency or safety of the advertised drug with other drugs.

Drug advertisements should not refer to or include information about any medical or pharmaceutical research institutions, academic institutions, experts, scholars, physicians or patients.

In addition, OTC drug advertisements should not contain medical or pharmaceutical terms that are difficult for the general public to understand or are confusing.

Advertisements should not contain anything which would have an adverse effect on underage or handicapped persons. Children must not feature in any way in drug advertisements.

ADVERTISING FORM

1.1.6 Targeted public

While OTC drugs may be freely advertised to the general public, advertisements for prescribed drugs must only be addressed to medical or pharmaceutical professionals. It is strictly forbidden for such advertisements to be aimed at the general public.

1.1.7 Advertising support

Advertisements for prescribed drugs can only be published in medical or pharmaceutical professional publications, as designated by the SFDA or by the MOH. The SFDA releases a list of such publications on its official website. As mass media cannot be used to advertise such drugs, it should be noted that indirect concealed advertising such as through news reports is also prohibited.

Conversely, advertisements for OTC drugs may be released as television broadcasts.

APPLICATION PROCEDURE FOR THE LICENCE NUMBER

1.1.8 Authorities

All proposed drug advertisements should be submitted to the FDA at the provincial level for review and approval under the guidance and supervision of the SFDA.

1.1.9 Qualified Applicant

An application for the Licence Number is only accepted if the drug advertiser is a qualified applicant. A drug manufacturer holding a Drug Manufacturing Licence is also a qualified applicant. A distributor holding a Drug Trading Licence is a qualified applicant, provided that he has obtained the manufacturer's prior consent to the drug advertisement.

1.1.10 Application procedure

Once the applicant has provided all of the completed application documents, the FDA shall issue a notice of drug advertising in acceptance.

If the FDA believes that the application documents are incomplete, it shall notify the applicant of the required corrections within five working days of receipt of the application. Failure to issue such notification shall be deemed as acceptance of the application by the FDA, as of the date of receipt of the application.

Within ten days of the acceptance date of the application by the FDA, the FDA shall decide whether to issue the Licence Number. If the FDA decides not to issue the Licence Number, the FDA shall notify the applicant of its decision, its reasoning and the applicant's right to initiate an administrative appeal.

Upon issuing of the Licence Number, the FDA shall report to the SFDA and the relevant AIC responsible for registering the Licence Number and publishing the approved drug advertisement.

If the content of the advertisement is modified, after the issue of the Licence Number, a new Licence Number must be applied for to cover the revised content.

1.1.11 Validity of the Licence Number

The Licence Number is valid for a period of one year.

If the advertisement is intended to be published outside the geographic jurisdiction of the original approval authority, an application should be made to the FDA where the extended publication is to take place. The FDA will then report to the AIC, within five working days of the acceptance of the application.

PENALTIES

Drug advertisements are supervised and administered by the AIC. In general, any violation of the drug advertisement rules results in the advertiser facing administrative penalties (including revocation of the Licence Number or the Drug Licence or rejection of any further applications for advertisements for that drug within a certain period). In addition to its administrative responsibility, any drug manufacturer, distributor or medical institution which causes harm or loss to consumers may be liable to compensate the consumers. Criminal procedures and sanctions may be imposed in very serious cases.

1.2 Instructions and labelling

Drug labels are legally defined as including any information printed or affixed to the packaging of the drugs, including the interior and the exterior labels. The interior labels are those on the packages that are in immediate contact with the drugs, while the exterior labels refer any other labels not in immediate contact with the drugs.

Generally, drug packages to be sold to consumers are required to include labels and have instructions attached.

1.2.1 Required information

The information to be included in the instructions and labels must conform to the following requirements:

(A) Instructions

The instructions must contain important scientific data and information regarding the safety and effectiveness of the drugs, which can be relied on by the users (including doctors) as guidance for the safe and reasonable use of the drugs.

Drug instructions should also list all the active ingredients or Chinese herbs (as appropriate) contained in the composite prescriptions and all ingredients or supplementary materials (the additives used for drug manufacturing and prescription making) which might cause a serious adverse reaction, as well as information on the possible adverse reactions to the drug.

In addition, instructions for drugs to be administered by injection and OTC drugs should also list all the other materials contained in the drug.

(B) Labelling of drugs

Interior labels must at least contain the following information: the drug name, applications or functions of the drug, specifications, usage and dosage, production date, product batch number, use-by date and manufacturing enterprise. If the package is too small to include all the required information, the general name of the drug, specifications, product batch number and the use-by date at least must be mentioned on the interior labelling.

In addition to the information required for interior labelling exterior labels must include, the following information: details of possible adverse reactions, contraindications, precautions, storage recommendations and the approval number of the drug. If the package is too small to include the required information, this information must be included in an insert sheet instead and the wording "see instructions for details" or equivalent must be included on the exterior label.

Labels for packages used for transport and storage of raw material drugs must include, in addition to the above information, the quantity of the drugs included in the package and any precautions that should be taken during transportation.

1.2.2 Symbols

Instructions and labels for narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs, drugs for external use, OTC drugs or prepared slices of a TCM material must include the relevant symbols identifying them as such.

1.2.3 Characteristics of the information

In order to protect public health and ensure the correct use of drugs, any expression used in drug instructions and labelling must be scientific, standardised and accurate. In addition, any expressions used for OTC drugs must be drafted in plain and simple language that can be understood by consumers to enable them to select and use OTC drugs without seeking medical guidance.

The wording included in labels and instructions must be clear and easy to understand and any symbols must be conspicuous and easy to identify.

There should be no missing print and all attached stickers must be properly affixed. The contents of labels and instructions should not be obscured by means of affixation, cutting or alteration.

Standardised Chinese characters must be used in all drug labels and instructions. Where more than one language is used, the Chinese wording shall prevail.

1.2.4 Forbidden information

Any wording or symbols which indicate the curative effect of a drug and mislead the consumer as to the correct use of the drug or inappropriately advertise the drug are strictly forbidden and should not be included in either the instructions or the labels.

In addition, except for the purpose of meeting the requirements for instructions and labelling, the packaging may not introduce or advertise the drugs or the drug manufacturer in any form (whether through wording, audio, video or any other medium), without approval from the SFDA.

1.2.5 Special contents for TCM materials and prepared slices of TCM materials

Labels for TCM materials must include: the name of the TCM materials, place of production, date and name of the consignor, and quality certification mark.

Prepared slices of TCM materials must be printed or affixed with a label which indicates the name of the TCM material, specifications, place of production, manufacturer, product batch number, production date and drug approval number if required.

Patented drugs are not subject to any special requirements for labelling and should follow the general rules applicable to all drugs.

1.2.6 Labelling and instructions

The labelling shall be drafted in accordance with the instructions and shall not exceed the scope of the instructions.

1.2.7 Labelling, instructions and trade mark

Drug labelling and instructions may not make reference to any trade mark that is not registered in the PRC.

Any registered trade mark indicated on the labelling must be printed in a corner of the label. The font size of any words included in the trade mark must not exceed one quarter of the size of the font used for the name of the drug in that label.

1.2.8 Approval procedure

There is no specific approval procedure for drug labelling. Content of labels are approved during the drug approval procedure.

Conversely, any instructions to be included with the drugs are subject to approval by the SFDA. This approval procedure is carried out in conjunction with the Drug Licence approval procedure.

Following approval, all amendments to instructions and labels must be sent to the SFDA for examination and approval.

1.2.9 Penalties

A drug manufacturer that attaches a drug label without adhering to the requirements faces administrative penalties, which in the most serious cases, can result in revocation of the Drug Licence.

In addition, a drug manufacturer that fails to amend in a timely manner, instructions or labelling as to the safety and effectiveness of a drug, or detailing possible adverse reactions, will be liable for any claim or compensation arising thereof. Criminal procedures and sanctions may be imposed in very serious cases.

1.3 Packaging

1.3.1 Requirements for Drug Packaging

All Drug Packaging must be suitable for the drug included in the package and convenient for storage, transportation and medical use.

Drug Packaging must conform to the common standards of human health and safety, as well as strictly complying with the national standards for Drug Packaging.

Drug manufacturers must only use Drug Packaging approved by the SFDA. Such packaging must be submitted together with the application, for drug approval.

1.3.2 Approval of the packaging: the "Drug Packaging Licence"

Scope of approval

Drug Packaging is subject to approval by the FDA, which shall verify that the Drug Packaging is suitable for the drug it contains.

Application procedures

Different procedures apply depending on whether the application is for Drug Packaging manufactured in the PRC, Drug Packaging imported into the PRC or for modification of approved Drug Packaging.

(A) Application for Drug Packaging manufactured in the PRC

(a) Qualified applicant

The qualified applicant is the manufacturer of the Drug Packaging, being a company incorporated in the PRC.

(b) Application procedure

The applicant must submit an application for a preliminary review of the Drug Packaging to the FDA, together with a sample of the Drug Packaging. The FDA will carry out an on-site inspection and instruct a testing institution to conduct tests on selected samples. The testing institution will issue a testing report, which the FDA will submit to the SFDA for final review, along with its own preliminary review report and on-site inspection report.

The SFDA will organise a technical evaluation of the sample. Upon receipt of the technical evaluation report, the SFDA shall decide whether the Drug Packaging Licence should be granted. The approval procedure takes approximately five to six months in total from the application date.

(B) Application for Drug Packaging imported into the PRC

(a) Qualified Applicant

A qualified applicant includes any foreign packaging manufacturer, which applies through its representative office or an appointed domestic agent.

(b) General procedures of such application

The applicant must submit an application for Drug Packaging approval to the SFDA for preliminary review, together with a sample of the Drug Packaging. After reviewing the documents submitted, the SFDA will issue an acceptance and testing notice to the applicant. The applicant should then submit three sample batches to a testing institution, which will issue a testing report.

Upon receipt of the testing report, the SFDA will organise a technical evaluation of the sample. Meanwhile, the SFDA will decide, at its sole discretion, whether to carry out an on-site inspection at the foreign manufacturing facilities to check and or select a sample from the foreign manufacturer's premises in order to check the manufacturing process.

Upon receipt of the technical evaluation report, the SFDA will make a final decision on whether to grant the applicant an "Imported Drug Packaging Licence".

In total, the approval procedure takes approximately five to six months.

(C) Application for modification of approved Drug Packaging

When the Drug Packaging or its manufacturing process is modified, the original applicant must apply to the original approval authority for further approval of the modified Drug Packaging.

In the event that an on-site inspection is required, an application for the modification of approved Drug Packaging manufactured in the PRC follows the same procedure as the original approval procedure. If an on-site inspection is not required, the FDA will submit the related application documents and a sample, together with its preliminary review report to the SFDA for final review.

Application for modification of approved Drug Packaging imported into the PRC should be submitted to the SFDA. The SFDA will take between 20 days and 60 days to issue an approval, depending on whether a technical evaluation is required.

(D) Drug Packaging licence

(a) Validity of the Drug Packaging Licence
Both the Drug Packaging Licence and the Imported Drug Packaging Licence are valid for a period of five years. The applicant must apply for any renewals at least six months before the relevant expiration date.

(b) Renewal procedure for the Drug Packaging Licence
Renewal procedures for both the Drug Packaging Licence and Imported Drug Packaging Licence follow the same course as the initial approval application procedures, with the exception that the technical evaluation organised by the SFDA will be completed within 40 days for the Drug Packaging Licence or 50 days for the Imported Drug Packaging Licence.

(E) Revision procedure of rejected applications
The applicant may file an application for review of any rejected application to the SFDA within ten days of receipt of the rejection notice from the FDA or SFDA. The SFDA may only review the items described in the original application, the originally submitted documents and the original sample provided.

The SFDA will then make a final decision on whether to revoke or sustain the rejection notice. If the rejection notice is revoked, the SFDA shall grant the applicant a Drug Packaging Licence or Imported Drug Packaging Licence as appropriate.

1.3.3 Penalties

In the event that any Drug Packaging is used without prior approval, the drug may be confiscated, together with all revenues generated from the sale of such drugs.

The packaging manufacturer and/or the drug distributor may also face a fine, and in more serious cases, be ordered to suspend business operations pending rectification; have the Drug Licence, Drug Manufacturing Licence or Drug Trading Licence revoked; and have any other application to the SFDA or FDA made in the following three years by that party rejected. Criminal procedures and sanctions may also be triggered in very serious cases.

2. Advertising, labelling and packaging of medical devices

2.1 Advertisement of medical devices

The regulations specifically applicable to medical device advertising are currently being redrafted. However, in general the regulations applicable to the advertisement of medical devices are similar to those applicable for the advertisement of drugs and should be considered. Reference is made to Paragraph 1.1 of this Chapter.

2.1.1 Definition of medical device advertisement

While the current regulations do not expressly define the term 'a medical device advertisement', the draft regulations define this as any published advertisement, which contains the name of the medical device, its applicable scope, features, structure, composition function, mechanism, and any other related characteristics. As with the drug advertisement regulations, the draft regulations only seem to cover published advertisements and therefore any advertising through other means (such as on-site promotion, oral communication or sponsoring) is not covered.

2.1.2 Exempted medical device advertisement

According to the draft regulations, advertisements including the name of a medical device do not need to be approved by the relevant drug authorities, provided that the licence number of the medical device is indicated on the advertisement.

2.1.3 Prohibited medical device advertisement

There is a strict prohibition on the advertisement of the following medical devices:

(i) medical devices distributed in the PRC which have not been approved by the FDA;

(ii) imported medical devices entering into the Chinese market without approval by the relevant authorities in the territory in which the devices are manufactured;

(iii) medical devices manufactured without a Medical Device Manufacturing Licence;

(iv) medical devices manufactured for the purpose of clinical trials or those in the trial phase for the medical device manufacture; and

(v) medical devices for HIV treatment or sexual dysfunction improvement and treatment.

2.2 Labelling of and instructions for medical devices

A medical device label is specifically defined as any written description, and/or any graphics or symbols attached to either medical devices or their packaging. Medical device instructions are defined as the technical documents produced by the medical device manufacturer for the customers' reference which include basic information about the product's safety and validity and can be used for guidance for their installation, adjustment, operation, use, repair and maintenance.

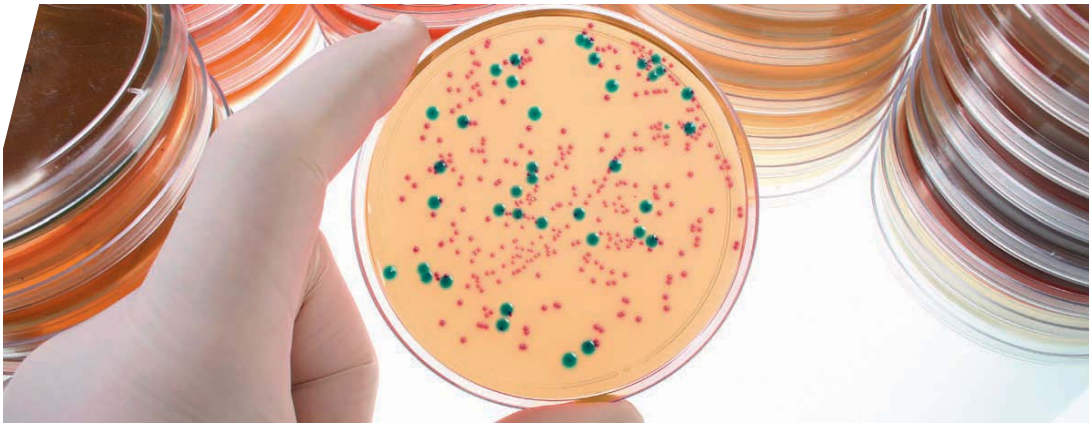
Generally, the legal rules applicable to labels and instructions for medical devices are similar to those applicable to labels and instructions for drugs (please see Paragraph 1.2 of this Chapter).

All medical devices are required to have labels, instructions and packaging marks attached or included with them. It is however possible to attach only one or two of these items, if expressly approved by the SFDA.

Specific requirements also apply to labelling and instructions for sterilised or disposable medical devices. These must include wording or marks of precaution, such as "sterilised" or "disposable use". They must also indicate the sterilisation method and the method by which any damaged sterilisation package should be disposed. In addition, they should indicate the appropriate method of disinfection or sterilisation that should be adhered to prior to the use of the medical device.

2.3 Rules for packaging of medical devices

To date, there are no specific rules regulating the packaging of medical devices.



Chapter IV
IP AND OTHER PROTECTIVE RIGHTS

1. IP rights: IP rights protection

1.1 Trade mark protection

1.1.1 Trade mark registration

The name of a company, drug or medical device may be protected if it is registered as a trade mark.

Please note that there is no specific company name protection regime in the PRC. If a company name is identical or similar to a registered trade mark and this leads the public to be confused, the trade mark rights holder has the right to claim for the cancellation or modification of the company name in the PRC.

The trade mark for a drug does not have to be formally registered to be used for the distribution of the drug. However, if a trade mark appears on the accompanying instructions, labelling or advertising materials, that trade mark must be registered in the PRC.

There are two ways to register trade marks in the PRC.

(A) National registration

Drug manufacturers can apply for trade mark registration directly to the State Trade Mark Office.

Applicants can apply to register words, letters, characters, logos and any combination of these. In addition, it is also possible to register three-dimensional trade marks.

Lifesciences companies can enhance the breadth of protection of their trade marks by registering in both Western characters and Chinese (whether as a phonetic and/or semantic transliteration).

The adopted name for a drug (the name used to describe the drug itself, as opposed to the brand name) cannot be registered as a trade mark.

The period of protection for a trade mark is ten years from the date of issue of the certificate of registration. This can be renewed indefinitely.

Because the PRC is a member of the Paris Convention, a foreign citizen or company can benefit from a priority right of six months from the date of application of its trade mark in its own country, provided that its nation State or place of incorporation (as applicable) is also a member of the Paris Convention.

In practice, the registration of a trade mark in the PRC will take at least two to three years. The State Trade Mark Office is currently making efforts to improve the efficiency of the trade mark examination process and is hoping to handle all pending trade marks within the next three years. It intends to reduce the application procedure to one year from 2010.

(B) International registration (Madrid System)

Drug manufacturers can also apply for trade mark registration in their home State and seek an extension of protection to the PRC through the Madrid System with the International Bureau of Intellectual Property. The protection period for a trade mark is either ten or 20 years, and this can be renewed.

National registration within the PRC has traditionally been preferred to international registration because the Madrid System is prone to a centralised attack, under which the cancellation of an initial trade mark registration within five years from its registration date, may automatically cancel its subsequent registration abroad.

In practice, the trade mark right holder may instead ask the trade mark authorities to consider the later registration of a trade mark independently from its initial registration.

1.1.2 Recognition of unregistered trade marks

Unregistered trade marks may be protected through administrative recognition or judicial recognition, by the provincial or municipal government if they are "well-known" trade marks, or as "famous" trade marks.

(A) Administrative recognition of a well-known trade mark

Administrative recognition of a well-known trade mark was initially used as a concept in 1987 to recognise the trade mark "Pizza Hut".

The legal framework followed in 1996.

As at March 2008, for the year 2008, six of the 228 trade marks that were recognised as well-known were for drugs. As at April 2009, for the year 2009, 17 of the 390 trade marks that were recognised as well-known were for drugs. Applications for the administrative recognition of a well-known trade mark must be filed with the AIC, which will examine and submit the application to the State Trade Mark Office.

Administrative recognition may only be filed if one of the following circumstances applies:

(i) an infringer has registered a trade mark which is identical or similar to the applicant's trade mark which can be considered as well-known in the PRC;
(ii) the State Trade Mark Office has published the application for registration of a third-party trade mark which is identical or similar to the applicant's trade mark, which is well-known in the PRC; or
(iii) the applicant considers that a third party has infringed its well-known trade mark.

(B) Judicial recognition of well-known trade marks

In comparison to administrative recognition, judicial recognition is very limited.

Judicial recognition is applied on a strictly case-by-case basis. If the well-known trade mark is infringed again following a finding of infringement, the applicant must request that the court decides on the well-known status of the trade mark again, unless the defendant does not challenge previous case law recognising the trade mark as well-known. This practice inevitably results in different trade marks being treated differently by different courts.

The trade mark holder may not use a well-known trade mark recognised as such by a court of law in any advertisement. Courts at intermediate level or above have the right to judicially recognise well-known trade marks in the PRC.

(C) Provincial or municipal government recognition of famous trade marks

A trade mark can be recognised as a regionally famous trade mark by a provincial or municipal government for a period of up to three years.

The AIC's practice is to reject any application for the registration of a company name that is identical or similar to a famous trade mark in the same industry.

In practice, a famous trade mark, by its very nature, enjoys more favourable protection, especially against counterfeit trade marks appearing on a product's packaging.

Recognition of a trade mark as a famous trade mark contributes to the recognition of it as being a well-known trade mark.

1.2 Patent protection

PRC patent regulations provide for design and invention (product and process) patent protection for drugs and medical devices. Prior to 1992, in order to protect the PRC local pharmaceutical industry, only the drug manufacture process could be patented. Patents for the drugs themselves were permitted from 1992.

1.2.1 Patent registration

There are two ways to register a patent in the PRC.

(A) National registration

Lifesciences companies can apply directly to the State Intellectual Property Office for patent registration. The period of protection is 20 years for an invention patent and ten years for a design. Protection commences from the application date.

The law does not provide for any validity extension of a drug patent to accommodate a drug approval process.

Since the PRC is a member of the Paris Convention, a foreign citizen or company can benefit from a priority right of 12 months (for an invention) or six months (for a design) from the date of application for the patent design in their own country, provided that the nation State, residence or place of incorporation (as appropriate) is also a member of the Paris Convention.

(B) International registration (Patent Cooperation Treaty)
Patent proprietors with rights that are registered in countries that are contracting parties of the Paris Convention can also apply for patent registration (with the PRC being the designated country of protection) under the Patent Cooperation Treaty with the International Bureau of Intellectual Property.

1.2.2 Compulsory licence

Where a national emergency or any extraordinary state of affairs occurs, or where the public interest (including the prevention and control of occurrence, dissemination and treatment of epidemics) so requires, the State Intellectual Property Office may force a drug manufacturer to grant a compulsory licence to allow exploitation of a patent in return for reasonable compensation.

Apart from domestic compulsory licences, the State Intellectual Property Office may also grant compulsory licences to foreign licensees to import drugs and to Chinese licensees to export drugs in these circumstances. According to the relevant law, parallel imports into the PRC of drugs for epidemics, which are covered by granted Chinese patents, do not need compulsory licences.

1.2.3 Parallel imports

The new Patent Law effective as of 1 October 2009 explicitly confirms that parallel imports are not considered to be a patent infringement.

Moreover, it remains to be seen how an international exhaustion system can be effectively implemented in practice as long as the authorities require an original copy of an import product licence in China before issuing customs clearance. Currently, such document is only granted to foreign manufacturing entities and not to any middleman or entity such as wholesalers. Finally, in many jurisdictions, export of patented products constitutes a breach.

1.2.4 Bolar exception

The Bolar provision has also been incorporated into the new Patent Law. Unlike the EU Bolar exception clause that limits the purpose of the Bolar exception to a reduced application process for generics, the Chinese Bolar provision applies to obtaining administrative approvals for new drugs and medical devices. Further, the provision does not seem to apply exclusively in the case of a market authorization in China unlike in the EU.

In addition, it should be noted that SFDA currently requires that the application for a generic of a patented drug can only be accepted two years prior to the expiration of the patent.

1.3 Actions against IP right infringements

Infringements of IP rights related to drugs and medical devices can first be brought before the FDA since such infringements are normally caused by counterfeit drugs or medical devices (please refer to Paragraph 1 of Chapter 7). If this course of action fails, the right holder can then initiate a process with the AIC. However, if the infringer removes the trademarks from the products or packages, the AIC may only order that the infringers cease using the packages or labels, without actually destroying the infringer's drug/medical device production capabilities.

1.3.1 Civil protection against infringements

(A) Pre-trial actions

A trade mark right holder, a patent rightholder or an interested party can apply for pre-trial measures, before a procedure on merit, to freeze the alleged infringer's assets.

Pre-trial measures include freezing assets and/or bank accounts of the defendant provided all of the following cumulative conditions are met:

(i) because of the urgency of the circumstances, the rights and interests of the claimant would suffer irremediable harm if such pre-trial action were not immediately granted;
(ii) the claimant must provide the court with a security bond of no less than the estimated value of the property to be frozen; and
(iii) the claimant must file an action on the merits within 15 days of the pre-trial action being executed by the court.

Such measures shall be limited to the scope of the claim or to the property relevant to the case.

The Court may also order the State Trade mark Office or the State Intellectual Property Office to freeze any transfer, licence, cancellation or pledge of any trade marks or patents belonging to the defendant.

The defendant may cancel the pre-trial measures by providing a counter-security bond.

(B) Interim injunction

The court may order the cessation of the trade mark or patent infringement, the freezing of the production capacities of the alleged infringer, and the preservation of the infringement evidence, before commencing the proceedings.

The applicant must submit a security bond to the competent court in exchange for the issue of an interim injunction. This cannot be cancelled by the provision of a counter-security bond by the alleged infringer.

A full claim should be filed with the court within 15 days of the issue of the interim injunction, after which the court may decide to cancel the injunction.

(C) Procedure on merit

A successful claim for trade mark or patent infringement, allows the court to impose a wide range of remedies (including cessation of infringement, compensation for losses, payment for breach of contract damages and formal expression of apology).

In addition, the court may also impose a penalty and confiscate the infringing products, infringing trade mark labels and materials, and the tools and equipment used for the manufacture of goods with infringing trade marks.

Furthermore, for patent infringement only, the court may force the infringer to apologise in writing and confiscate any property used for illegal activities and / or the gain of illegal income. In principle, the compensation payable shall be equal to the illegal gains or the losses suffered by the claimant as a result of the infringing activity (reasonable expenses incurred in stopping the infringing acts may be claimed for trade mark infringement, but not for patent infringement).

If such gains or losses are difficult to quantify, compensation may be calculated as a multiple of royalty payments under any existing licences granted by the trade mark or patent right holder to third parties or based on a standard or reasonable royalty sum widely used in the pharmaceutical industry.

The court may also determine at its discretion statutory damages up to a maximum of RMB 1,000,000 (patent) and RMB 500,000 (trade mark).

1.3.2 Administrative protection

Administrative protection against the infringement of IP rights is generally preferred to civil protection, especially when the infringement is not ambiguous. Administrative protection is often chosen as a preliminary step to gather sufficient evidence to commence a civil action.

The administrative protection process is much faster than the process required for civil protection which can involve a long period of trial and possible scope for appeal. In addition, administrative protection is cost effective since no fee is charged by the administrative authorities.

Therefore, of the available remedies, administrative protection can provide a quick practical end to the trade mark infringement.

(A) Trade mark and patent counterfeit procedures

In addition to civil protection measures, the trade mark holder, patent holder or any interested party may directly ask the AIC (in the case of trade mark counterfeits) or the patent bureau (in the case of patent counterfeits) to take the necessary measures to prevent the continuation of the counterfeit. It was confirmed in 2004 that the AIC has the jurisdiction to handle trade mark counterfeiting issues involving drugs.

The AIC can impose a fine, order the cessation of infringing acts, confiscate and destroy infringing goods and any materials and tools used for the manufacture of infringing goods and infringing trade mark labels. The patent bureau may order the counterfeiter to rectify its actions and can publish details of the act and the consequent sanctions. It can also order the counterfeiter to pay a penalty and confiscate the illegal gains obtained.

However, neither the AIC nor the patent bureau can order the counterfeiter to pay damages to the rights holder.

(B) Trade mark cancellation procedure and patent invalidation procedure

TRADE MARK CANCELLATION PROCEDURE

An application for cancellation of a trade mark must be filed with the trade mark re-examination committee, once the trade mark has been registered.

If a registered trade mark includes the name of a drug or it has been registered illegally or by deceptive means, any interested party can ask the trade mark re-examination committee to cancel that trade mark registration.

In addition, if a registered trade mark infringes other parties´ prior rights or has already been used by a third party with certain impact before its registration, the trade mark re-examination committee may cancel the registration of that trade mark within five years of its registration. If a trade mark has been registered which is identical or similar to a well-known trade mark which has not yet been registered in the PRC and the use of that trade mark gives rise to confusion amongst the public, trade mark re-examination committee can cancel the registration of the trade mark within five years of its registration. Once the five year period has expired, it must be proved that the trade mark was registered in bad faith in order to cancel the registration.

If any party is not satisfied by the decision of the trade mark re-examination committee, they may file an action before the Beijing intermediate civil court within 30 days of the decision.

PATENT INVALIDATION PROCEDURE

A patent invalidation application should be submitted to the patent re-examination committee in Beijing. If a party does not agree with the decision of the patent re-examination committee, it can bring an action against the decision before the Beijing intermediate civil court within three months of the decision.

(C) Border measures

Border measures were first established in 1995 and are a key tool in detecting the existence of counterfeit products.

In 2008, infringing products found in coastal cities (Guangzhou, Beijing, Hangzhou, Fuzhou, Shanghai, Shenzhen, Gongbei, Nanjing, Qingdao and Xiamen) represented 90% of the total infringing products located in the PRC.

A trade mark or patent holder with a registered trade mark or patent in the PRC may ask customs authorities to carry out border measures, including the detention of suspected and actual infringing goods (for a maximum 50 days, except if for an interim injunction or pre-trial measures). They may also impose punishments on consigners and consignees and transfer the matter to the police security bureau for further investigation.

Customs may act on tip-offs from applicants or on its own initiative.

In order for customs to respond to individual applicants, the applicant must first file trade mark and patent archives with the customs authorities in Beijing. This filing will be distributed to all PRC custom authorities around the country. The filing is valid for ten years and can be renewed.

In order to apply for border measures, the applicant must pay a bond to customs. The bond must equal the value of the goods to be detained which is calculated according to the value of the genuine goods. If, however, customs detain the goods on the basis of a trade mark and patent archive filing on their own initiative the guarantee will be capped at RMB 100,000 per trade mark or patent (as appropriate).

Customs may release the detained goods if the party accused of infringing IP rights provides a guarantee equivalent to the value of the detained goods, calculated according to the value of the genuine goods. They may also release the goods if they consider that no trade mark or patent infringement has occurred.

Border measures are still the predominant measures taken by customs. In 2008, 642,801,664 products infringing trademarks amounting to RMB 277,175,492 were seized, representing 99.63% of all border measures.

In 2008, 99.96% of the measures were related to export.

1.3.3 Criminal prosecution against IP rights infringements

The AIC may refer to the police any case which it considers constitutes criminal activity. In addition, any person may report infringing activities to the police and the police can initiate criminal actions if appropriate. The police will then decide whether to transfer the case to the public prosecutor, who in turn decides whether to transfer the case to the competent criminal court.

If the police consider that the infringement does not constitute criminal activity, the individual may then report the infringing activities to the public prosecutor. If the latter also refuses to proceed with criminal prosecution, only the alleged victim of the infringing activities is entitled to refer the case directly to the competent criminal court.

Any individual trade mark infringer which has been found to have committed a crime faces criminal sanctions (including fines and imprisonment for a maximum of seven years).

Any patent counterfeiter which has been found to have committed a crime faces criminal sanctions (including fines and imprisonment for a maximum of three years).

1. IP rights: Drug related IP rights protection

1.4 Data exclusivity period

An applicant for a Drug Licence shall benefit from a data exclusivity period which protects the otherwise undisclosed data provided to the SFDA as part of the drug approval process.

Both of the following conditions must be fulfilled in order for the applicant to benefit from this exclusivity period:

(i) the drug must be a new drug containing a "new chemical entity"; and
(ii) the data must be undisclosed and developed by the applicant itself.

The data exclusivity period is six years, starting on the date of market approval of the drug.

During the data exclusivity period, the SFDA shall not grant approval to other applicants based on the undisclosed drug research data, unless the research is acquired independently or with the permission of the original applicant.

When an applicant wishes its drug to benefit from the data exclusivity protection, it must, during the application for the drug's market approval, specifically request the protection and provide supporting evidence that the drug qualifies for such protection. At the time of the examination of the drug's market approval by the SFDA, the SFDA should review and decide on the ability of the drug to qualify for data exclusivity protection. In practice, the SFDA has not yet granted a period of data exclusivity protection to any drug, because it seems to lack the internal operational procedures to examine data exclusivity requests.

1.5 Data protection

Data protection is provided to prevent the unfair commercial use of any undisclosed drug research data which is independently acquired and submitted by an applicant to the SFDA. The conditions to be fulfilled in order to obtain data protection are the same as those required for obtaining the data exclusivity period. However, the period of data protection will start on the date that the documents containing the data are submitted to the SFDA.

Any claim for protection shall be made to the SFDA. The SFDA has the ability to suspend any application by a competitor if the claimant succeeds in proving unfair commercial use of the data by the competitor.

The SFDA can disclose the data for public interest purposes. If the data is to be disclosed for other purposes, the SFDA must take necessary measures to prevent unfair commercial use of such data.

1.6 Trade secret protection

There are sanctions under PRC law for infringement of trade secrets which have been illegitimately acquired by a third party.

The owner of the trade secret whose rights are infringed may ask the AIC to impose administrative sanctions (such as fines). In addition, the AIC may order the infringer to withdraw the infringing application with the SFDA.

The owner may also bring a separate action before a civil court for compensation. In addition, criminal remedies may also be pursued.

2. Market exclusivity protection

2.1 Monitoring period

A monitoring period of five years shall be granted for a new drug that has never been distributed in the PRC. Drugs which are considered "new" only for reasons based on new dosage forms or new applications (unless they are targeted preparations, slow-release or controlled-release drugs), do not qualify for this monitoring period.

The monitoring period starts from the date of the market approval of the drug by the SFDA. During the monitoring period, the SFDA shall not approve any other applications for this drug.

Note however that the monitoring period only applies to drugs manufactured in the PRC, and not to imported drugs.

2.2 TCM protection

Significantly effective TCMs may benefit from special manufacturing protection if agreed by the SFDA. In principle, only the right holders of the TCM protection as designated by the SFDA are entitled to manufacture protected TCM for a renewable period of between seven to 30 years (determined by the SFDA). Protection for the same TCM may be granted to several right holders.

A TCM protection rights holder may authorise a third party to manufacture the TCM under protection, in the name of the rights holder. In this case, the rights holder will maintain control over the distribution of the protected TCM.

A third party which manufactures the protected TCM without the prior consent of the rights holder shall be treated as an illegitimate manufacturer and as such could face administrative sanctions from the FDA, and may even be subject to criminal penalties. All applications for TCM protection will be rejected during the monitoring period for new drugs. An applicant may only apply for TCM protection after the expiration of the monitoring period. A patented TCM may not be granted TCM protection.

If the application is granted TCM protection, the company will receive a "Certificate of TCM Protection".

2.3 Special pharmaceutical administrative protection system

Prior to 1993, it was not possible to obtain patent protection for drugs in the PRC. In order to address this lack of protection, the PRC developed a type of substitute patent protection for qualified applicants whose drugs were granted patent protection in their own jurisdictions in the period from 1986 to 1992.

This administrative protection for drugs was initially meant to be a transitional measure offered to foreign patent right holders of drugs that could not be protected as patents in the PRC. However, it is still applied today.

Protection is granted upon the issue of a "Certificate of Administrative Protection" which grants an exclusivity right for a term of 7.5 years starting from the issue date.

To obtain the protection, the following conditions must be satisfied:

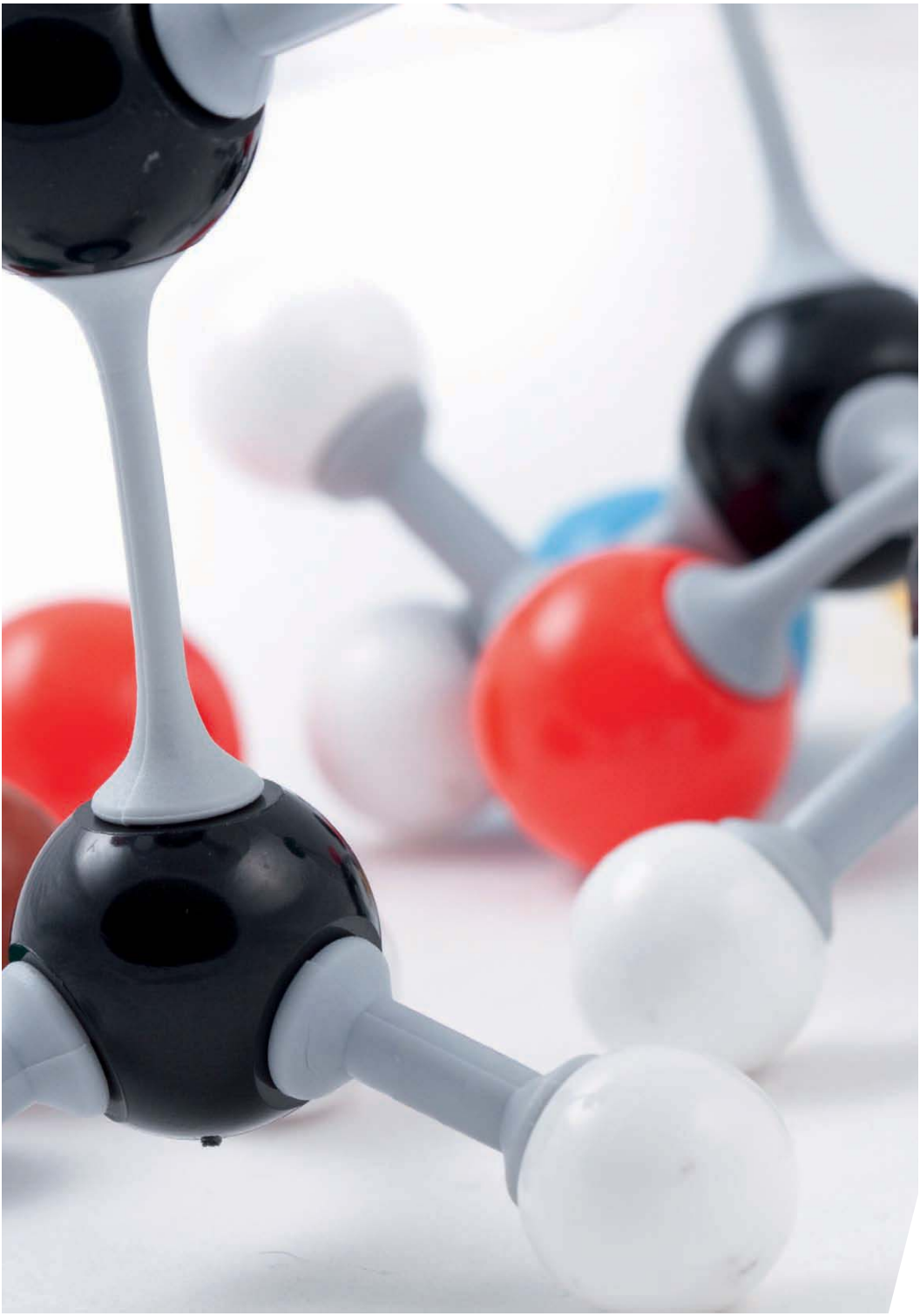
(i) the drug must be developed for use by human beings;

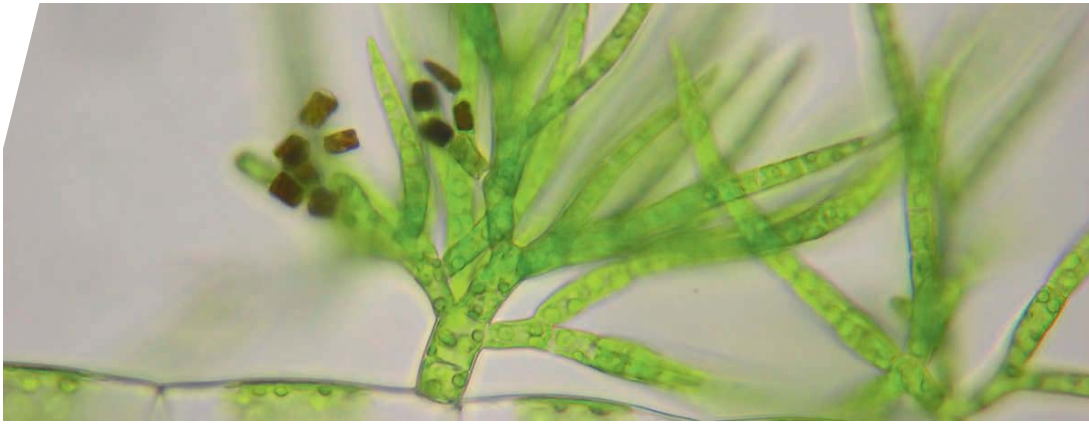
(ii) the drug must not have been patented in the PRC before 1 January 1993;

(iii) the foreign patent must have been registered in the applicant's home country in the period between 1 January 1986 and 1 January 1993, and the applicant must have exclusive rights to that drug in that country; and

(iv) the drug must not have been marketed in the PRC prior to the date of filing the application for administrative protection.

The administrative protection is often considered as a quasi-patent protection. If a drug has administrative protection, the FDA and SFDA shall not approve any other entity to manufacture or sell the same without a prior licence having been granted by the exclusive rights holder. If this exclusive right is infringed, the certificate holder can request the SFDA to prevent the infringing party from manufacturing and/or selling the infringing drugs. The certificate holder can also claim damages against the infringer in the civil court.





Chapter V
REIMBURSEMENT AND PRICING POLICY

1. Reimbursement policy

1.1 Scope of drug reimbursement

Drugs for which reimbursement may be sought from the state are listed in the National and Provincial Catalogues of drugs. The National Catalogue is issued by the MOHRSS. Each provincial bureau for human resources and social security may adjust the National Catalogue when issuing the Provincial Catalogue.

1.2 Selection of reimbursable drugs

1.2.1 Authorities in charge

The authority which selects drugs to be added to the catalogue is the MOHRSS with the assistance of its provincial counterparts. They must also consult with the NDRC, Ministry of Finance, MOH, SFDA and the State Traditional Chinese Medicines Administration and their respective provincial counterparts.

1.2.2 Drugs qualifications

To be included in the National Catalogue a drug must be safe, effective, reasonably priced, convenient to use and available in sufficient supply.

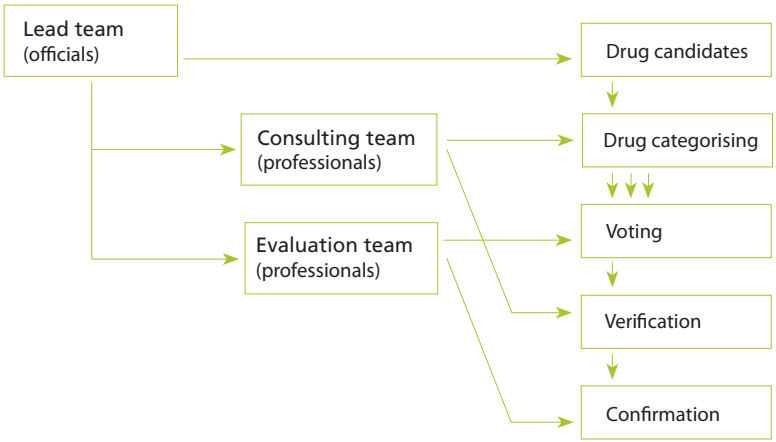
The MOHRSS has forbidden reimbursement for the following drugs:

(i) drugs whose dominant function concerns nutrition;
(ii) medicinal animal organs and nuts;
(iii) medicinal liquor made by steeping TCM materials;
(iv) oral effervescence preparations and preparations with fruit flavour; and
(v) blood and protein products (excluding those for emergency medical treatment).

The MOHRSS may add additional drugs to this list at its discretion.

1.2.3 Selection procedures

The procedure for the selection of drugs to be included in the National Catalogue is as follows:



The lead team is composed of officials from MOHRSS, NDRC, MOH, SFDA and the State Traditional Chinese Medicines Administration.

Drug manufacturers themselves are not entitled to apply for their drug to be selected. However many manufacturers have become active in lobbying activities to achieve this end.

The procedures for selection of a drug to be included in a Provincial Catalogue are established by each provincial level authority and are generally similar to the procedure described in the diagram above.

1.3 Classification of reimbursable drugs

The National Catalogue is divided into two price-dependent categories: Category I and Category II reimbursed drugs. Category I drugs are cheaper than those in the Category II. The provincial authorities may change the list of Category II drugs appearing in the National Catalogue by adding or removing up to 15% of the total number of Category II drugs. As a result, the Provincial Catalogue is essentially changeable with regard to Category II drugs. The drugs in Category I may not be adjusted locally.

Drugs in Category I are fully reimbursed from the basic medical care insurance fund. Category II drugs are only partially reimbursed by the fund. The amount of partial reimbursement for Category II drugs varies from one province to another.

2. Pricing

2.1 Government pricing principles

In general, the following principles are taken into account when government authorities decide how drugs should be priced: production cost and reasonable profit, market demand, differentiation between drugs of varying quality and effectiveness, encouragement for new drug development, reasonable price difference between different concentrations and dosage forms of the same drug.

2.2 Scope of government pricing

Drugs included in the National Catalogue (please refer to Paragraph 1.2.3 of this Chapter), patented drugs and drugs (such as narcotic drugs) which may be exclusively manufactured or distributed only by companies with recognised permissions from the SFDA, are subject to government pricing regulation.

The NDRC publishes and keeps updated a catalogue of drugs that are subject to government pricing regulations. The latest version of this catalogue was published in 2005 and provides that the following drugs categories fall within the scope of government pricing.

Drug category	Responsible authority
Prescription drugs included in the National Catalogue	NDRC
Narcotic drugs, certain psychotropic drugs, government purchased birth control drugs and devices and vaccines for compulsory inoculation, which are not included in the National Catalogue	NDRC
Drugs patented in the PRC within the protection period	NDRC
Blood products not included in the National Catalogue	NDRC, together with MOH
OTC drugs included in the National Catalogue	Provincial DRC
Drugs in the Provincial Catalogue	Provincial DRC

Generally, it is the responsibility of the DRC at provincial level to conduct the review of the price of a drug proposed by the manufacturers. The NDRC will then make the final decision on price. However, certain drugs are solely regulated by the DRC at the provincial level, acting under instructions from the NDRC.

2.3 Government pricing approaches

Currently, the NDRC and the DRCs take two approaches to regulate the price of a drug: (i) ex-factory or ex-port pricing, and (ii) retail pricing.

2.3.1 Sales price upon exit from the factory or port

Calculation basis

The formula to define the ex-factory price is:

(A) Ex-factory price = manufacturing cost and expenses
(1 – profit margin) × (1 + VAT rate)

For imported drugs, the formula used to define the ex-port price is:

Ex-port price = CIF price × (1 + tariff rate) × (1 + VAT rate) + clearance charges

(B) Scope of drugs

The ex-factory and ex-port pricing approach applies to narcotic drugs, psychotropic drugs, government purchased birth control drugs and vaccines for compulsory inoculation, which are included in the National Catalogue.

All other drugs in the Provincial Catalogue are subject to the retail pricing approach.

2.3.2 Retail pricing approach

The retail pricing approach involves the competent authorities setting a price cap for drug retailers.

The retail price cap is calculated based on the sum of the cost of ex-factory or ex-port drugs, tax, reasonable sales expenses, and reasonable profit margin.

The NDRC sets different standards for maximum rates of sales expenses and profit margins for different drugs as per the following table:

Drug category	Rate of sales expenses	Profit margin
Class I new drug: New drug never marketed in domestic or overseas market	30%	45%
Class II new drug: New drug never marketed in domestic market but marketed overseas which includes a new administration path (oral, injection, etc.) never marketed in either domestic and overseas markets	20%	25%
Class III new drug: New combination of chemical substances	18%	18%
Class IV new drug: Domestically marketed drug with a new administration path or a new dosage form	15%	15%
Class V new drug: Drug marketed in domestic market with new applications	12%	12%
Generics	10%	10%

Note that since October 2007, marketed drugs with new dosage forms and new applications are not treated as new drugs unless they comprise target preparations, slow-release preparations or controlled-release preparations.

2.3.3 Cost and expenses used for the calculation of retail price

The authority uses the figure for average costs or expenses of all manufacturers in the industry to calculate the government retail price. However, a company can apply for "independent pricing" treatment, under which the authority uses the cost or expenses suggested by a manufacturer, rather than the average costs or expenses, to determine the government retail price.

(A) Qualifications

A product must meet one of the following requirements to qualify for independent pricing:

(i) the product has clear safety and efficiency advantages over the drugs of the same category manufactured by other companies; or

(ii) the cycle of therapy of the product is significantly shorter than for drugs of the same category manufactured by other companies.

(B) Disqualifications

An application for independent pricing will be rejected if any of the following circumstances applies:

(i) the manufacturer is unable to provide at least one article about the drug published in a national academic journal;
(ii) the manufacturer is unable to prove that it has already established a pharmacovigilance system; or
(iii) where imported drugs are concerned, the manufacturer is unable to provide reliable information on the comparable price (or constant price) in the home country and other countries in the same region as the PRC.

2.4 Government pricing procedures

2.4.1 Application for pricing

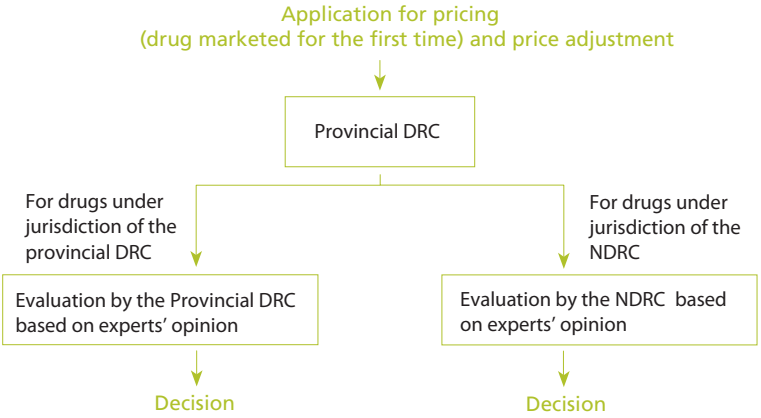
Where drugs are to be marketed in the PRC for the first time, if they are included in the National Catalogue, the manufacturer must apply to the NDRC to obtain a price (via a preliminary review by the provincial DRC).

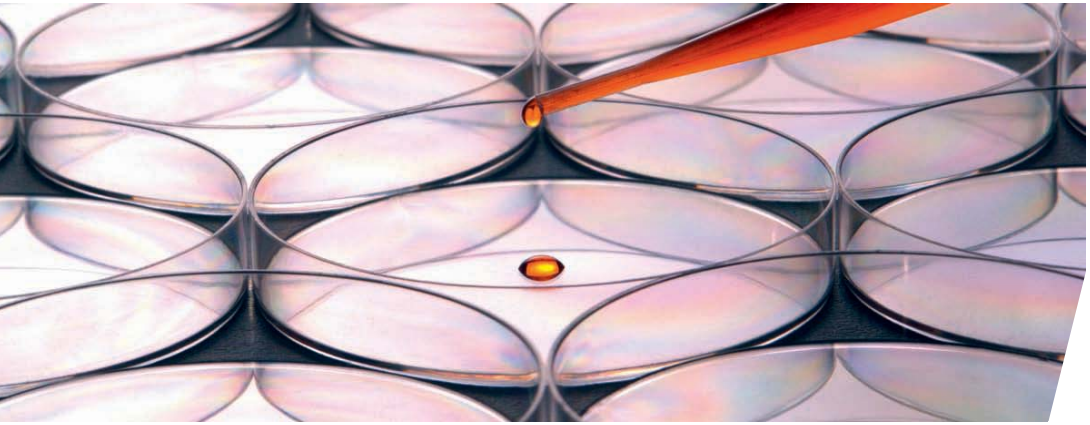
If the drugs are included in the Provincial Catalogue, the competent provincial DRC will approve the application for pricing.

There is no pricing application procedure for marketed drugs listed in the National or Provincial Catalogue. The authorities will investigate the industry and will determine the price.

2.4.2 Price adjustment

Once a price for a drug is fixed by the relevant authority, it may be adjusted once a year. The company can apply for a price adjustment, according to the following procedures:





Chapter VI
MARKETING AND ANTI-CORRUPTION

1. Marketing regulatory issues

1.1 General introduction

Pharmaceutical manufacturing companies are entitled to distribute drugs and/or medical devices if they have been granted a Drug Manufacturing Licence, GMP Certificate and/or Medical Device Manufacturing Licence. They may also distribute drugs and medical devices manufactured by third parties if they hold a Drug Trading Licence, GSP Certificate and/or Medical Device Trading Licence (please refer to Paragraph 3 of Chapter 1). Companies holding a Drug Trading Licence, GSP Certificate and/or Medical Device Trading Licence are permitted to distribute drugs and medical devices (please refer to Paragraph 3 of Chapter 1). Drugs and medical devices must be granted a Drug Licence or Medical Device Licence respectively prior to distribution (please refer to Chapter 2).

Foreign companies may engage a pharmaceutical company holding a Drug Trading Licence and GSP Certificate to distribute their products in the PRC or establish an FIE to apply independently for a Drug Trading Licence and GSP Certificate. While PRC law requires that drugs can only be distributed by companies holding such licences and certificates, promotional activities for drugs and medical devices do not require those licences and certificates.

(A) Classic marketing models

Manufacturing companies established in the PRC may decide to distribute their products through pharmaceutical distribution companies or alternatively, directly to hospitals and clinics throughout the PRC.

Foreign manufacturing companies may not distribute directly to hospitals and clinics in the PRC, but must use a Chinese pharmaceutical company (including an FIE), holding a Drug Trading Licence, GSP Certificate and an import and export licence to import the drugs and/or medical devices into the PRC.

(B) Online sales

Only manufacturing or trading companies which are lifesciences specific 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 SFDA. If the company sets up its own website for online sales, it must obtain a "Certificate for Online Sales" from the provincial FDA. A Certificate for Online Sales does not entitle its holder to provide online trading services as a third party.

Online sales of drugs and medical devices made to end consumers may only be conducted by a qualified distribution company engaged solely in retail.

Any ".cn" top level domain name is subject to approval by the telecommunication administration.

Drug and medical device distribution companies must fulfill the following conditions in order to be permitted to conduct online sales:

(i) have in place facilities and equipment for maintaining transaction records;

(ii) have in place measures ensuring for transaction safety and a well-established management system;

(iii) be able to provide online search services, online ordering and electronic contracts;

(iv) have in place facilities and equipment for examining the authenticity of information involved in an online transaction; and

(v) have in place professionals in the pharmaceutical sector dedicated to examining the online transactions.

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

1.1.1 Liability of purchasers of the drugs and medical devices

Each drug and medical device purchaser (including manufacturers, wholesalers, retailers, hospitals and clinics), must ensure that they only purchase approved drugs and medical devices from qualified manufacturing or distribution companies.

The law requires purchasers to verify the qualifications of the sellers and the products, by (as a minimum) reviewing and retaining copies of the following documents:

(i) the supplier's business licence, Drug or Medical Device Manufacturing Licence stamped with the supplier's official seal;

(ii) the Drug or Medical Device Licence stamped with the supplier's official seal; and

(iii) copies of the testing report for imported drugs (if applicable).

The FDA is entitled to inspect a buyer's purchasing records. The purchaser must keep the documents identified above for at least one year after the expiry of the shelf life of the drug or medical device, and in any event for at least three years.

1.1.2 Storage and transportation

(A) Storage

Drugs and medical devices are only allowed to be stored in qualified warehouses. Warehouses operated by manufacturing companies must be inspected in order to be granted a GMP Certificate, while warehouses operated by trading companies must be inspected in order to be granted a GSP Certificate. Each warehouse will be registered on the Manufacturing and/or Trading Licence.

Storage of drugs or medical devices in any place other than the registered warehouses is prohibited.

Storage methods and requirements for drugs (such as maximum temperature) are set out in the pharmacopoeia or other approved drug standards and printed on the instructions accompanying the drugs.

If a company does not comply with the above requirements, the FDA may seal or seize the stored drugs or medical devices for further inspection.

(B) Transportation

The transportation of drugs and medical devices is not specifically regulated, with the exception of narcotic drugs and psychotropic substances.

Requirements for storage set out by the pharmacopoeia or approved drug standards and printed on any instruction sheet accompanying the drugs should be respected. A "first in, first out" rule for manufacturers and wholesalers applies to storage and transportation of products, to ensure better shelf-life management.

Vaccines must be transported in vehicles equipped with refrigerated containers and temperature monitors ("cold-chain").

A carrier which knows or should know that the transported drugs or medical devices are counterfeits or substandard drugs, must refuse to provide transportation services for these products. If it fails to do so, the carrier may face penalties.

The consignor (being the seller or buyer as the case may be) of narcotic drugs and psychotropic substances must have been granted a transportation certificate from the FDA for each consignment. The carrier should ask for a copy of this certificate at the time of each delivery.

1.2 Tendering

Since 2000, the PRC has adopted a statutory tendering scheme (the "Scheme") applicable to the purchase of drugs by State-sponsored hospitals which currently purchase 70% of drugs distributed in PRC market. The aim of the Scheme is to crack down on bribery and reduce unreasonable increases to drugs prices.

The Scheme is predominantly implemented by the MOH, with assistance from the NDRC, SAIC and SFDA.

1.2.1 Drugs falling within the scope of the Scheme

The Scheme applies to state-sponsored hospitals. However, the government encourages all hospitals to apply the Scheme.

At present, the regulations require that the following drugs be purchased through tendering procedures:

(i) drugs listed in the National and Provincial Catalogues;
(ii) drugs used heavily in clinical practices and purchased in large quantities; and
(iii) any other drugs specified by the provincial health authorities from time to time.

Narcotic drugs, psychotropic substances, medicinal toxic drugs, radioactive drugs, TCM materials and prepared slices of TCM are exempt from the tendering scheme.

Regulations require the provincial health authorities to select drugs to be involved in the tendering scheme pursuant to the above requirements and to publish a catalogue of such drugs. The government encourages an increasing number of drugs to be included in the Scheme. Hospitals may purchase drugs not included in the Scheme through normal commercial agreements.

1.2.2 Bidders

Only qualified drug and/or medical device manufacturers or wholesalers which have not operated illegally during the preceding two years, are permitted to bid in any tendering process.

The purchasers may also impose additional requirements on bidders provided that those requirements apply equally to all bidders and are reasonable in the circumstances of the specific transaction.

A pharmaceutical wholesaler may only be an eligible bidder if it obtains prior consent from the manufacturer of the products.

1.2.3 Tendering agencies

The purchasers may use certified tendering agencies to provide part or all of the services in the tendering procedures. Any tendering agencies used for such purpose must hold a "Certificate of Pharmaceutical Tendering Agency" from the provincial FDA.

1.2.4 Forms of tender

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.

A public tender is the more usual form of tender, except in the following cases:

(i) where the products to be purchased are small in quantity and there are only a few potential qualified bidders; or

(ii) the purchase needs to be completed in a very short time.

1.2.5 Tendering procedures

In principle, hospitals should join a tendering process organised by health authorities at the city or provincial level. If a hospital intends to initiate a tender alone, it must obtain approval from the health authority at the city or provincial level, as appropriate. The tendering process follows. the following steps:

Tendering procedure	
Step 1	— Establish a tendering organisation or choose a qualified tendering organization and notify the local health authority — Submit the purchaser's purchasing records for the preceding year to the qualified tendering agency
Step 2	— Prepare the tendering documents — Determine the evaluation methods and standards
Step 3	— Publish the offer bid and the tendering documents — Reply to questions raised by bidders
Step 4	— Review and accept the bidding documents
Step 5	— Bid opening
Step 6	— Organise the evaluation committee and transfer the information and bidding documents to the committee
Step 7	— Evaluate the bidding documents and determine the winners
Step 8	— Confirm the results and issue a notice specifying the ning bidder
Step 9	— Execute purchase contracts

Under step 3, the offer bid must be widely published in the media. This should also specify how the tendering documents can be obtained. For an invitational tender, the bidding offer shall be sent to at least three qualified bidders. The offer period must be left open for at least 20 days from when the tendering documents become available.

1.2.6 Evaluation committee

The evaluation of the bidding documents and selection of the winner should be conducted by an evaluation committee organised by the purchaser. The members of the committee should be selected from a list of experts put together by the local health authority through a random selection procedure, under supervision by a notary public or the relevant health authority. The committee must consist of an odd number of members between nine and 25.

The committee members should be nominated after the tendering process has been opened and should not have any interest or connection with the bidders. A committee member should not meet any bidder privately during the tendering process and must keep the bidding documents and information about the evaluation status confidential prior to deciding on a winner.

1.2.7 Evaluation methods and standards

The evaluation methods and standards to be employed should be included in the published tendering documents. Generally, any methods and standards not disclosed to the bidders should not be used during the evaluation.

Purchasers are encouraged to use a comprehensive evaluation method, meaning that the evaluation is based on both quantitative and qualitative methods.

(A) QUANTITATIVE METHOD

The quantitative method is a scoring system based on certain factors with different weights (see the chart below). The scoring results determine the rank of each candidate product.

Quantitative method chart	
Factor	Weight
Quality ("Q")	Q weight ≥ 40%
Price ("P")	Q weight / 2 < P weight < Q weight
Patented drugs	Increase of scores of no more than 50% of the price factor calculated scores
Credibility in the drug and the manufacturer	15%
Violations of laws and regulations	Reduction of credibility scores
Assessment based on certificates	Minimum 2/3 of the total score

(B) QUALITATIVE METHOD

Using this approach, a bidder's rank is determined by the committee members' using their subjective expertise, experience and judgement.

1.2.8 Prohibition on bid rigging

If a company wins a bid by rigging the process, the results shall be void and the company may face serious administrative penalties. If this behaviour constitutes a crime, criminal prosecution and penalties (up to three years' imprisonment) may be imposed on the bidders and/or those submitting tenders.

2. Anti-corruption

Corruption is a serious concern for the lifesciences industry in the PRC. When selling drugs or medical devices, some companies or their sales representatives often try to bribe hospitals and clinics.

In 2006, the government launched strong anti-corruption measures aimed at suppressing bribes. In 2007, the MOH and its local level counterparts investigated 1,001 corruption cases with a combined value of RMB 31,474,000.

2.1 Business bribery

Any commercial rebates must be recorded properly in the financial accounts. of the business, otherwise, they will be treated as bribes. Lifesciences companies are not permitted to offer money, property or other interests to doctors, pharmacists, clinics and hospital staff in charge of purchasing, in return for the purchase of drugs and medical devices.

It is generally accepted that "money, property or other interests" includes sponsorship, R&D expenses, service charges, expense reimbursement, commissions, additional gifts (except for small gifts in line with normal business practices) and perks related to sales.

2.2 Authorities in charge

The SAIC and its local level counterparts are responsible for investigating bribery activities and imposing administrative penalties.

2.3 Legal liabilities

A company offering bribes may be liable to pay compensation for losses caused to third parties. If the losses are too complex to accurately assess, the amount of compensation will be calculated as being equal to the related profits made by the company.

Companies offering bribery may also face administrative penalties (fines and confiscation of all illegal income) imposed by the AIC. In serious cases, the company's business licence, Drug Manufacturing Licence and Drug Trading Licence may be revoked by the AIC and FDA. If a crime is committed, the company itself as well as the management team or other personnel responsible, may face criminal prosecution and penalties, including up to ten years' imprisonment.

2.4 Recent anti-corruption measures

For the last three years, an anti-corruption campaign has been implemented in the PRC. The government authorities have taken various measures to run the campaign in the most effective way.

2.4.1 Donations to hospitals

On 6 April 2007, the MOH provided a regulatory framework for the administration and use of donations made to hospitals.

Donations may only be made if they are in the public interest and must not be profit-making. Donations should not be linked with the sale of medical products.

In addition, a donation cannot be accepted in the name of an internal department or an individual hospital employee, unless required by the donor and approved by the management committee of the hospital.

A formal donation agreement must be executed in writing and financial receipts should be provided by the hospital to the donor.

2.4.2 Blacklisting system

On 19 January 2007, the MOH established a blacklisting system to keep a record of lifesciences companies that have offered bribes during the course of selling drugs and medical devices. These blacklists are published on the official websites of the provincial health authorities responsible for establishing and supervising them.

Lifesciences companies will be blacklisted if they meet any of the following criteria:

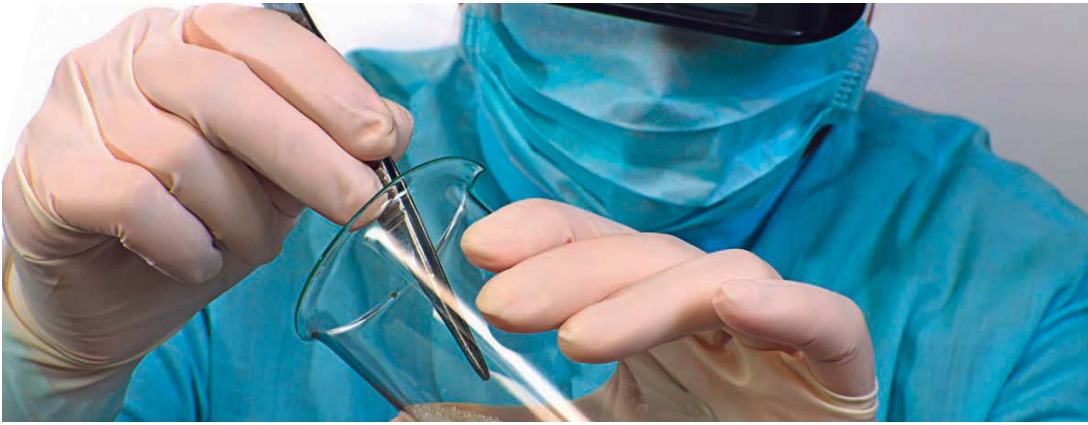
(i) a People's Court has adjudged that the company has committed a criminal offence by offering bribes, or a prosecutor has decided not to prosecute solely because the matter was deemed as minor;

(ii) the company is involved in a bribery case which has been investigated by the Ministry of Supervision (or its local counterparts) and penalties have been imposed;

(iii) the company has been ordered by the AIC or FDA to pay administrative penalties for having offered bribes; or

(iv) any other relevant circumstances added by provincial health departments from time to time.

Hospitals and clinics are not allowed to purchase any drugs or medical devices from any lifesciences companies recorded on the blacklist for a period of two years from the date of inclusion of that company on a blacklist. The health authorities in Beijing, Sichuan, Fujian, Xinjiang, Zhejiang and other provinces already have established blacklisting systems. There are currently 18 companies in the lifesciences sector appearing on the blacklist issued by the Beijing Municipal Health Department (one of them being an FIE).



Chapter VII
PRODUCT LIABILITY

1. Quality liability

1.1 Defective drugs and medical devices

Generally, a product is considered defective when it threatens a person's safety or property or when the product does not comply with quality standards.

1.1.1 Defective drugs

The concept of a "defective drug" is not defined but reference may instead be made to the definitions of "counterfeit drug" and "substandard drug", to determine the administrative and criminal liabilities imposed for defective drugs. Where civil liabilities are at issue, "defective drug" shall be given the same meaning as the general definition of "defective product".

(A) Counterfeit drug

A "counterfeit drug" is (i) any drug whose composition is different from what is described in the national drug standards (please refer to Paragraph 1.1.1(c) of this Chapter), (ii) any substance other than a drug which is marketed as a drug, or (iii) a drug which is marketed as another drug.

In addition, a drug is regarded as counterfeit when it has one of the following characteristics:

(i) its use has been prohibited in the PRC by the SFDA;
(ii) it is being marketed in the PRC without a Drug Licence;
(iii) it has deteriorated;
(iv) it is contaminated;
(v) it contains unapproved API; or
(vi) its suggested applications or indicated functions as they appear on the drug instructions exceed the scope approved by the relevant authorities.

(B) Substandard drug

A "substandard drug" is any drug which ingredient content does not comply with the national drug standards (please refer to Paragraph 1.1.1(c) of this Chapter). In addition, a drug is regarded as substandard if any of the following apply:

(i) there is no indication or alteration of the approved shelf life period of the drug;
(ii) there is no indication or alteration of the production lot number;
(iii) the shelf life period has expired;
(iv) the immediate packaging material or container has not been granted a Drug Packaging Licence;
(v) the addition of colorant, preservatives, spices, flavourings or other excipients has been made without approval; or
(vi) it violates the national drug standards.

(c) Drug quality standards

The national drug standard specifies requirements for the quality of drugs, inspection methods and drugs manufacturing processes. Drugs are strictly prohibited from being manufactured, marketed or used if they fail to comply with the national drug standards circulated by the SFDA.

The national drug standards include the PRC Pharmacopoeia and the drug standards approved by the SFDA at the time of issue of the Drug Licence.

1.1.2 Defective medical devices

Medical devices are considered defective if they fall under the general definition of "defective products". Medical devices must comply with the medical device quality standards, which are comprised of the national, industry and product standards. Manufacture, distribution or use of medical devices in violation of the medical device quality standards is strictly forbidden.

The medical device quality standards include those drafted and reviewed by the Medical Devices Standardisation Technical Committee and circulated by the SFDA, and those approved by the SFDA at the time the Medical Device Licence is issued.

1.2 Liabilities for quality of drugs and medical devices

Manufacturers and distributors shall ensure that the drugs or medical devices they market comply with the relevant quality standards.

1.2.1 Civil liability

The time limit for claiming compensation for damages arising from a defective drug or medical device is two years from the date when the concerned party becomes aware or should have become aware of any bodily injury or property loss caused by the defective drug or medical device.

The right to claim compensation for damages arising from a defective drug or medical device shall terminate either ten years from the date of delivery by the manufacturer of the defective drug or medical device, or on the expiry of the specified shelf life period, whichever is later.

(A) Liability without fault for manufacturers

Manufacturers shall assume liability for any claim for bodily injury or property loss arising out of or in connection with defective drugs or defective medical devices, regardless of whether such claim arises as a result of the fault of the manufacturer (strict liability).

However, manufacturers shall be exempt from such liability if they can prove that the bodily injury or property loss occurred under any of the following circumstances:

(i) the defective drug or medical device had not yet been marketed;
(ii) the drug or medical device defects were non-existent when the products were first marketed; or
(iii) the defects could not be detected by the scientific or technological means applicable at the time when the defective drug or the medical device was first marketed.

(B) Fault liability of distributors

Distributors will be liable for any claim for bodily injury or property loss arising out of or in connection with a defective drug or medical device, provided that such defects are shown to be as a result of the fault of the distributors.

In addition, distributors which fail to identify the manufacturers and suppliers of a defective drug or medical device (because they have not recorded details of the manufacturers and suppliers licences) shall be liable for any related claim.

(C) Joint and several liabilities

Manufacturers and distributors shall bear joint and several liabilities. The manufacturer which has paid compensation to the victims is entitled to request compensation to the distributor if the defect is attributable to the fault of the distributor, and vice versa.

1.2.2 Administrative liabilities

The SFDA and FDA are responsible for implementing administrative penalties for the manufacture or distribution of counterfeit or substandard drugs.

If the authorities fail to discover a batch of defective drugs or medical devices within two years of the date of manufacture or distribution, they will no longer be able to impose sanctions on the manufacturer or distributor. However, should the manufacture or distribution of the defective products continue, the period in which the authorities can impose administrative penalties shall commence from the date when such manufacture or distribution ends.

(A) Sanctions for defective drugs

When a drug manufacturer or distributor markets a counterfeit or substandard drug, such drugs, together with the revenues obtained through this activity, shall be confiscated and the manufacturer or distributor will face administrative penalties, such as a penalty, suspension of manufacturing or distribution activities, revocation of the related Drug Licence, Drug Manufacturing Licence or Drug Trading Licence.

In addition to the above, the FDA or the SFDA may also require the AIC to modify or revoke the business licence granted to the manufacturer or distributor.

(B) Sanctions for defective medical devices

When a medical device manufacturer or distributor markets a defective medical device, the authorities responsible for health, the FDA or the SFDA have the power to confiscate any related gains, defective products and materials, equipment and raw materials used or obtained in the process of such illegal activities. In addition, a maximum penalty of 20 times the value of the defective medical devices can be imposed. For serious cases, the authorities which issue the manufacturing licence to the manufacturer have the right to revoke the relevant licence.

(C) Mitigation of or exemption from sanctions

The sanctions imposed on the manufacturer or distributor may be mitigated or exempted in the following circumstances:

(i) if the manufacturer or distributor takes the initiative to eliminate or lessen the harmful consequences arising from the illegal act;
(ii) if the manufacturer or distributor has been coerced by another party to commit the illegal act; or
(iii) if the manufacturer or distributor cooperates with administrative authorities in investigations.

Drug and medical device distributors will bear administrative penalties for defective products even if they prove that they are not at fault. If this is the case, the penalties imposed may be mitigated but cannot be exempted.

Distributors may be partially exempted from penalties (especially fines), related to counterfeit and substandard drugs if they are able to prove that they have complied with the approved drug standards and that they had no knowledge that the marketed drugs were counterfeit or substandard. In this case, only the counterfeit or substandard drugs and illegal gains will be confiscated. This partial exemption does not apply to the distributors of medical devices in similar circumstances.

1.2.3 Criminal liability

The standard time limit for prosecution of criminal activity relating to the manufacture and distribution of defective drugs or medical devices is 20 years. Prosecutions can be brought after the expiration of this time period with the approval of the Supreme People's Court prosecutor.

(A) Defective drugs

The manufacturer or distributor of counterfeit or substandard drugs that seriously endanger human health may face criminal penalties, including imprisonment. If the drug is a counterfeit, the death penalty may also be imposed on anyone involved in the counterfeit activity.

(B) Defective medical devices

The manufacturer or distributor of defective medical devices that seriously endanger human health may face criminal penalties, including indefinite imprisonment.

1.3 Assessment of damages

1.3.1 Bodily injury

Any compensation for bodily injury arising from a defective drug or medical device shall include related medical expenses, care expenses and lost income. If the victim suffers a permanent disability, the compensation may also include expenses arising for any related equipment, living allowances, compensation for disability and living expenses for any dependents of the victim. If the victim dies, compensation shall include funeral expenses, compensation for death and the required living expenses for dependents.

In addition, drug or medical device manufacturers may also need to provide compensation for any psychological damage caused.

1.3.2 Property loss

If a defective medical device causes any loss of property, the responsible party shall restore the property to its original state or financially compensate for such loss.

1.3.3 Punitive damages

As of 1 July 2010, manufacturers and distributors shall pay punitive damages if they explicitly know the product defects and continue to manufacture and sell and cause death or serious injury.

2. ADR

2.1 Reporting and monitoring ADR

The relevant drug manufacturing company, drug trading companies, hospitals and clinics shall establish an ADR reporting and monitoring mechanism. Any new or serious ADR cases should be reported to the ADR Monitoring Centre immediately if the ADR results in a death, and within 15 days in all other cases.

For new drugs within the monitoring period, each ADR case should be reported. After the monitoring period has expired, only new or serious ADR cases need to be reported. Drug manufacturers will be responsible for compiling annual ADR reports.

For imported drugs, each ADR case occurring within five years of import approval should be reported. After five years, only new or serious ADR cases need be reported. Drug manufacturers will be responsible for compiling annual ADR reports.

The local ADR Monitoring Centre will use the information provided to it to compile an ADR analysis report for each drug which results in an ADR.

On submission of this report by the ADR Monitoring Centre to the SFDA, the SFDA may order a revision of the instructions accompanying the drug, suspend production of the drug, suspend sales of the drug and advise cessation of use. If the drug endangers the physical health of consumers, the Drug Licence will be revoked. In this case, all supplies of the drugs which have been produced or imported will be destroyed or disposed of under the supervision of the SFDA and FDA.

The SFDA and FDA shall take urgent control measures over drugs which have endangered the physical health of consumers (including suspension of the drug's production and sale, and in some cases, advice on cessation of use), and shall make assessments and impose administrative penalties within 15 days of concluding the assessments.

2.2 Liabilities related to ADR

2.2.1 Civil liability

PRC law currently does not clearly define the civil liabilities that drug manufacturers should bear for ADR. The PRC Tort Liability Law to be effective on 1 July 2010 tends to apply liability without fault in ADR cases.

In practice, the courts often tend to hold drug manufacturers liable for at least part of the damages suffered by the patient based on equitable principles.

2.2.2 Administrative liability

The SFDA has the right to impose administrative sanctions (a warning or penalty), if a drug manufacturer fails to report an ADR case to the authorities within a reasonable time.

In addition, intentional omission or unclear description of an ADR on the insert sheet contained in the drug's packaging may also result in administrative penalties.

2.3 Special civil liability for AEFI

An AEFI is more fully defined as an adverse response to medicine which causes damage to the individual's tissues, organs or bodily functions, during or after inoculation with a qualified vaccine, without any individual fault. AEFIs are considered to be a type of ADR.

Vaccines are classified as either Class I vaccines (vaccines provided for free by the government) and Class II vaccines (vaccines purchased by individuals voluntarily at their own expenses). The civil liability related to AEFI differs from the general civil liability for ADR.

2.3.1 Civil liability

Compensation may be made to an inoculated person or his relatives when the drug results in one of the following:

(i) death;
(ii) extreme disability; or
(iii) serious damage to any organ or tissue.

An unusual response to a Class I vaccine should be compensated by the State (triggering administrative liabilities). An unusual response to a Class II vaccine should be compensated by the manufacturer (triggering civil liabilities). Compensation should be in the form of a lump sum final settlement with the amount determined on the basis of the applicable medial assessment report.

PRC law currently does not define the applicable civil liabilities to AEFI. The PRC Tort Liability Law to be effective on 1 July 2010 tends to apply liability without fault in AEFI cases. The courts often apply the principle of equity which allows parties to share liabilities as appropriate.

PRC law empowers each provincial government to elaborate method to calculate compensation for each province. Without any regulatory guidance, calculation of the compensation remains difficult.

The courts are inclined to protect the individual victim rather than the manufacturers, especially when determining a causal link between the damage caused and the vaccination.

Up till now, only the provinces of Qinghai, Hunan and Jiangxi have promulgated a method to calculate compensation, and some of these provinces even provide a cap amount of compensation.

2.3.2 Exclusion of liabilities

No AEFI will be found when the damage caused to the victim falls within one of the following categories:

(i) the complaint was a common post vaccine response;

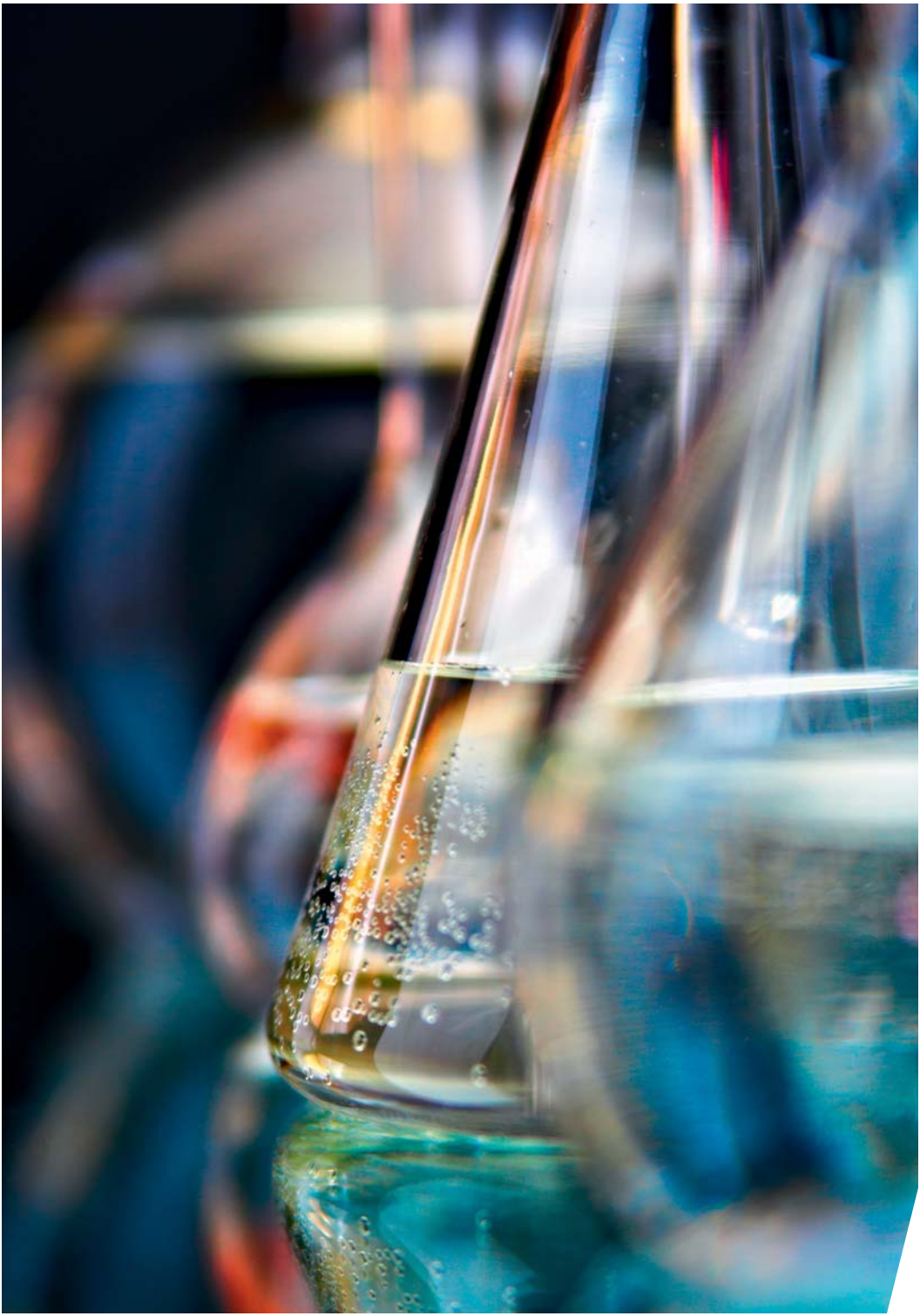
(ii) damage was caused due to the defective quality of the vaccine;

(iii) damage was caused due to violation of the applicable regulations by the medical practitioner;

(iv) the inoculated person was in the delitescence or prodromal phase of a certain disease at the time of inoculation and is later attacked by the disease by coincidence after inoculation;

(v) the inoculated person has the contraindication to the inoculation as stated in the vaccine instructions, but the said inoculated person or his guardian fails to truthfully provide the inoculators with the information about the inoculated person's health and any contraindication to the inoculation, prior to the inoculation, and the inoculated person's original disease recrudesces urgently or becomes worse after the inoculation; or

(vi) individual or mass psychogenic responses arise due to psychological factors which are not physically supported.



Notes

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