

China

Connie Carnabuci and Yang Xun, Freshfields Bruckhaus Deringer



www.practicallaw.com/7-384-4584

REGULATORY OVERVIEW

1. Please give a brief overview of the regulatory framework for medicinal products/pharmaceutical products/drugs (as they are called in your jurisdiction), including the key legislation and regulatory authorities.

The State Food and Drug Authority (SFDA) is the primary regulatory authority for the evaluation, registration and approval of new and generic pharmaceutical products, imported pharmaceutical products and traditional Chinese medicines. The main areas of responsibility of the SFDA are the:

- Issue of permits for the manufacture and import of pharmaceutical products.
- Approval and registration of enterprises engaged in the manufacture and sale of medicinal products.
- Conducting of post-marketing monitoring of adverse reactions.
- Overseeing a classification system for prescription and over the counter (OTC) pharmaceuticals.

Although the SFDA is the overarching regulator for the pharmaceutical and medical devices sectors, many of its powers have been delegated to Food and Drug Authorities at provincial, municipal and county level (local FDA). Local FDA are authorised to issue, for example, Pharmaceutical Production Licences.

The key legislation governing the regulation of the pharmaceutical industry includes the:

- Pharmaceutical Administration Law 2001.
- Implementing Regulation for Pharmaceutical Administration Law 2002.
- Pharmaceutical Marketing Authorisation Administration Regulation 2007.
- Pharmaceutical Advertisement Examination Measures 2007.
- Administration Regulation for Importation of Pharmaceutical Materials 2005.
- Administration Regulation for Supervision of Pharmaceutical Manufacture 2004.
- Administration Regulation for Internet Pharmaceutical Information Services 2004.

- Administration Regulation for Licensing Requirement for Operation of Pharmaceutical Business 2004.
- Administration Regulation for Importation of Pharmaceutical Products 2003.
- Traditional Herbal Medicine Regulation 2003.
- Administration Measures for Circulation of Pharmaceutical Products 1999.

These national regulations are supplemented by many local government regulations.

Chinese law treats pharmaceuticals as being substances used for the prevention, treatment and diagnosis of conditions affecting human patients. Traditional Chinese medicines are therefore regulated as pharmaceuticals, as are antibiotics, vaccines and some diagnostic drugs. Manufacturers of pharmaceuticals are required to obtain and hold a Pharmaceutical Production Licence, while wholesale and retail sellers are required to obtain a Pharmaceutical Operations Licence. Products cannot be placed on the market without first obtaining a pharmaceutical marketing authorisation.

PRICING AND STATE FUNDING

2. Please give a brief overview of the structure and funding of the national healthcare system.

Most medical institutions in China are state-owned and funded either by national or local government. Privately-owned medical institutions are few in number and, in most cases, focused on family clinical treatment, where services are considered more important than medical capacity, as well as on dentistry and ophthalmology which are heavily reliant on imported medical materials.

The following government agencies have primary responsibility for the healthcare sector in China:

- The Ministry of Health, under whose umbrella the SFDA was brought in March 2008, is mandated with the administration of the national healthcare system and supervises the implementation of government policies in the healthcare field.
- The Ministry of Labour and Social Security is in charge of urban health insurance.
- The Ministry of Civil Affairs is responsible for rural health protection.

- The Ministry of Science and Technology conducts health-related research.
- The State Family Planning Council is responsible for the administration of family planning programmes.
- The Work Safety Authority is responsible for the administration of occupational health programmes.

In addition to these ministry-level agencies, other partially government funded key public health institutions such as national and local Centres for Disease Control, the Chinese Academy of Medical Sciences, and the National Institute for Control of Pharmaceuticals and Biological Products, also have a role in the implementation of government policy. Other ministries that oversee major industrial sectors, such as the Ministry of Defence, Ministry of Railways and Ministry of Mining, maintain separate community health clinics and public hospitals that are outside the jurisdiction of the Ministry of Health.

State funding of healthcare in 2008 stands at around CNY250 billion (about US\$36.6 billion), of which about CNY83 billion (about US\$12.1 billion) comes from central government with the remainder provided by local government. Additional funding is derived from patient contributions for medical treatment.

3. In what circumstances are the prices of medicinal products regulated?

The price of the following medicines is fixed:

- Medicines included on the National Reimbursable Drug List (NRDL). Prescription charges for medicine on the NRDL are wholly or partially paid out of the social medical insurance fund. The NRDL contains a large proportion of the most commonly used pharmaceuticals in China.
- Pharmaceuticals protected by patents. Prices for such products are controlled by the State Development and Reformation Commission (SDRC).
- Pharmaceuticals covered by administrative protection during the period of data exclusivity. Prices for such products are controlled by the SFDA.
- Medicine manufactured subject to national controls; being mainly narcotics, psychotropics and birth control products, as well as some vaccines.

In accordance with the Measures on Government Fixed Price Pharmaceuticals (promulgated by the National Planning Commission in November 2000), the price of fixed-price drugs is determined by considering factors such as the reasonable cost of operation and production, profit margin, the price of identical or substitutable products and, if necessary, the price of the same products in the international market.

The prices of certain other commonly use products are subject to mandatory government guidelines, which effectively amount to a price cap.

4. When is the cost of a medicinal product funded or reimbursed by the state? Please briefly outline the procedure and pricing for state funding or reimbursement (for example, is the reimbursement paid to the producer, pharmacist or end-user)?

The National Basic Medical and Work-Related Injury Insurance Scheme (Basic Medical Scheme) grants basic medical access for most urban residents. Money from the Basic Medical Scheme is paid into a social medical insurance fund. Contributions are paid by both employees and their employers based on a percentage of the employee's salary. Additional funding is provided by the Government.

A portion of the cost of the medical treatment of an urban resident by a state-owned medical institution is paid out of the social medical insurance fund, with the remainder payable by the patient.

The proportion of his salary that an individual is required to contribute to the fund depends on, among other things:

- The age of the individual.
- The individual's employment status.
- The administrative ranking of the individual (if any).
- The category of medicine or medical treatment concerned.

Generally, the more basic the medical treatment is, or commonly used the medicine is, the higher the portion of the cost that will be reimbursed.

MANUFACTURING

5. Please give an overview of the authorisation process to manufacture medicinal products. In particular:

- To which authority must the application be made?
- What conditions must be met to obtain authorisation?
- Are there specific restrictions on foreign applicants?
- What are the key stages and timing?
- What fee must be paid?
- How long does authorisation last and what is the renewal procedure?

Application

To establish a pharmaceutical manufacturing company, an investor must first apply to the relevant local branch of the FDA for a Pharmaceutical Production Licence. After the issuance of the licence, and subsequently, a business licence, the company can begin to build the plant and to install machinery for production of pharmaceutical products.

Within 30 days of the commencement of full operations of a pharmaceutical manufacturing plant, and every five years after then, a manufacturer must apply to the relevant local FDA for verification of its compliance with the Good Pharmaceutical Production Management Protocol (GMP). The GMP sets standards for plant, equipment and raw materials, requirements for the qualification and behaviour of personnel and rules for internal management control.

Conditions

To obtain a Pharmaceutical Production Licence, the applicant must have:

- Qualified pharmaceutical and engineering professionals whose qualifications are recognised in accordance with relevant law, and the necessary technical workers.
- The premises, facilities, and hygienic environment required for the production of medicinal products.
- The necessary infrastructure instruments, equipment and personnel capable of carrying out quality control and testing of the medicinal products to be produced.
- Promulgated and implemented rules and regulations to ensure the quality of the medicinal products.

Restrictions on foreign applicants

The Provisions for Guiding Foreign Investment Direction categorise foreign direct investment projects into four categories, namely, encouraged, restricted, prohibited, and permitted projects.

The Foreign Investment Industrial Guidance Catalogue (2007 Revision) (Foreign Investment Catalogue) restricts foreign investment in the production of:

- Chloramphenicol, Penicillin G, Lincomycin, Gentamicin, Streptomycin Dihydrochloride, Amikacin, Tetracycline Hydrochloride, Oxytetracycline, Midecamycin, Leucomycin, Ciprofloxacin, Norfloxacin, and Ofloxacin.
- Analgin, Paracetamol, vitamin B1, vitamin B2, vitamin C, vitamin E, various vitamin preparations and oral calcium.
- Vaccines under a state immunisation plan (except for BCG and polio vaccines), vaccine category and anti-toxin, class toxins (DTP, measles, JE, ECM vaccines, and so on).
- Crude drugs for narcotic drugs and Type 1 psychotropic drugs (controlling stake to be held by Chinese party).
- Blood products.
- Non-auto-disposable syringes, infusion sets, blood transfusion devices and blood bags.

The Foreign Investment Catalogue prohibits foreign investment in the following activities:

- Chinese medical herbs listed in the Protection Rules for Wild Medical Herb Resources and the "Catalogue of Chinese Rare and Endangered Plants".

- The application of Chinese medicine moxibustion techniques such as steaming, frying, moxibustion, calcination or by using confidential prescriptions for Chinese ready-made herbal medicine.

Activities falling outside of the restricted and prohibited categories are available to foreign investors.

Key stages and timing

An applicant wishing to establish a pharmaceutical manufacturing enterprise must make an application to the local branch of the FDA. The local FDA is required to review the application within 30 days to decide whether the construction of the pharmaceutical manufacturing plant is in accordance with state pharmaceutical development planning and industry policy.

Once the manufacturing facility is ready to commence operation, the applicant must apply to the local FDA to arrange an inspection. The local FDA is required to inspect the factory and facility within 30 business days of receipt of the application, and to issue a Pharmaceutical Production Licence if it is satisfied with the result of the inspection.

The applicant must apply for a business licence with the relevant state or local Administration of Industry and Commerce when it receives the Pharmaceutical Production Licence and Approval Certificate (if applicable).

If foreign investment is involved, the applicant must also apply to the local branch of the Ministry of Commerce (MOFCOM) for an Approval Certificate. This usually takes between one and two months to process.

Fee

Fees vary in different local FDA branches.

Period of authorisation and renewals

A Pharmaceutical Production Licence is valid for five years and can be renewed by submitting an application for renewal six months before the expiry date on the certificate.

6. What powers does the regulator have to:

- Monitor compliance with manufacturing authorisations?
- Impose penalties for a breach of a manufacturing authorisation?

The SFDA and its local FDA branches supervise and monitor compliance with the manufacturer's Pharmaceutical Production Licence and with the Pharmaceutical Production Administration Protocol. The local FDA is empowered to inspect the pharmaceutical production companies periodically to ensure compliance.

The SFDA and its local branches impose incremental sanctions depending on the severity of non-compliance. These include:

- Giving a warning to rectify within a prescribed time period.

- Issuing an order to stop production or order to cease operation and restructure.
- Imposing monetary fines.
- Revoking the Pharmaceutical Production Licence.

CLINICAL TRIALS

7. Please give an overview of the regulation of clinical trials. In particular:

- Which legislation and regulatory authorities regulate clinical trials?
- What authorisations are required and how is authorisation obtained?
- What consent is required from trial subjects and how must it be obtained?
- What other conditions must be met before the trial can start (for example, the requirement for a sponsor and insurance cover)?
- What are the procedural requirements for the conduct of the trial (for example, using certain medical practices and reporting requirements)?

China adopted the World Health Organisation (WHO) clinical trial registry platform in July 2007.

Clinical trials must be carried out as a precondition to obtaining registration for new medicinal products. Clinical trials are mainly regulated under the Pharmaceutical Products Registration Administrative Measures (promulgated on 28 February 2005 and effective on 1 May 2005) and the technology guidelines published by the SFDA.

All clinical trials must be approved by the SFDA before commencement. On approval, the applicants must employ a qualified institution to carry out the clinical trial and the clinical trial plans must be submitted to the Clinical Trial Agent Ethics Committee for its examination and approval. Clinical trials must be implemented within three years of approval, otherwise the approval expires.

The SFDA and the local FDA supervise and inspect the approved clinical trials. Applicants must submit the results of the clinical trials and statistical analysis report to the SFDA and local FDA after every phase of the clinical trial.

MARKETING

8. Please give an overview of the authorisation process to market medicinal products. In particular:

- To which authority must the application be made?
- What conditions must be met to obtain authorisation?

- What are the key stages and timing?
- What fee must be paid?
- How long does authorisation last and what is the renewal procedure?

Application

Pharmaceutical products cannot be placed on the market without first obtaining a pharmaceutical marketing authorisation (in addition to a Pharmaceutical Operations Licence). Each approved pharmaceutical is allocated a unique registration number.

An applicant must first apply to the FDA at provincial level for preliminary approval and submit the results of clinical trials conducted by it. If preliminary approval is granted, the local FDA will forward the application to the SFDA, which will organise an expert panel to review and assess the clinical trial data.

Conditions

The conditions for obtaining a pharmaceutical marketing authorisation are not clearly set out in any law or regulation. Generally, the applicant must demonstrate that the relevant pharmaceutical product is effective and safe for use by human beings.

Key stages and timing

The local FDA is required to conduct a preliminary examination of the application within 30 days.

If the application passes the preliminary examination, the local FDA will instruct a pharmaceutical inspection bureau to conduct an independent test of the pharmaceutical concerned. An independent test normally takes place within 60 days.

Based on the testing report and the supporting materials and data, the SFDA will organise an expert panel to appraise the pharmaceutical. This can be expected to take a further 120 days.

If the conclusion of the appraisal is positive, the SFDA will verify the appraisal report and grant the marketing authorisation within a further 30 days.

If the conclusion of the appraisal is negative, the applicant will have another opportunity to supply supplementary application documents within four months of the date of issuance of the appraisal report. The SFDA will re-examine the appraisal report and supporting materials and data within 40 days of the application being made.

Fee

Fees vary in different local FDA branches.

Period of authorisation and renewals

A Pharmaceutical Operations Licence is valid for a term of five years and can be renewed by submitting an application for renewal six months before the expiry date recorded on the certificate.

9. Please briefly outline the abridged procedure for obtaining marketing authorisations for medicinal products. In particular:

- Which medicinal products can benefit from the abridged procedure (for example, generics)?
 - What conditions must be met?
 - What procedure applies and what information can the applicant rely on?
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An abridged approval procedure is available for certain entirely new pharmaceuticals, and generic pharmaceuticals.

New pharmaceuticals that may be eligible for the abridged procedure include newly discovered compounds and new pharmaceuticals for treating serious illnesses. Pharmaceuticals in this general category include:

- Materials abstracted from plants, animals, and minerals, and newly-discovered pharmaceutical substances, as well as new methods for their preparation, which have not previously been marketed in China.
- Chemical or biotech pharmaceuticals which have not been marketed in either China or in a foreign jurisdiction.
- New pharmaceuticals for AIDS, cancer and certain other rare diseases.
- New pharmaceuticals for diseases which currently lack any effective medical treatment.
- Pharmaceuticals necessary for dealing with emergencies.

The term generic pharmaceuticals refers to pharmaceuticals for which the Chinese authorities have already established a technical standard. Generally, if a pharmaceutical product is approved by and registered with the SFDA, the applicable standard for pharmaceuticals having the same active substance is considered to have been established.

The procedure for approval and registration of the above new pharmaceuticals and for generic pharmaceuticals is similar to that for approval and registration of general pharmaceuticals, except that the time for appraisal by the expert panel is shortened to 100 days for new pharmaceuticals and to 80 days for generic products.

10. Are foreign marketing authorisations recognised in your jurisdiction? If so, please briefly outline the recognition procedure.

Foreign marketing authorisations are not recognised in China. However, foreign marketing authorisation documents (if any) need to be submitted for consideration as a reference when applying for the registration of imported pharmaceuticals.

11. What powers does the regulator have to:

- Monitor compliance with marketing authorisations?
 - Impose penalties for a breach of a marketing authorisation?
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The SFDA and local FDAs monitor compliance with marketing authorisations, monitor the effectiveness and safety of registered pharmaceutical products, and monitor the market to ensure that unregulated products are not being sold. Breach of a pharmaceutical marketing authorisation can result in:

- A fine of up to RMB30,000 (about US\$4,400).
- Revocation of the marketing authorisation.
- An embargo on applying for future marketing authorisations for up to three years.
- Revocation of the offending entities' Pharmaceutical Production Licence, in the most serious cases.

12. Are parallel imports of medicinal products into your jurisdiction allowed? If so, please briefly outline what conditions must be met by the parallel importer. Can intellectual property rights be used to oppose parallel imports?

Although parallel imports are not explicitly prohibited under any Chinese law or regulation, generally they are prohibited in China. The current Patent Law grants a patent owner/exclusive licensee the right of importation. This entitles the patent owner to prohibit the importation of patented products without its consent, even if the products have been manufactured or sold under proper authorisation in the jurisdiction of export.

The Trademark Law does not mention the trade mark owner or licensee's exclusive right of importation. However, in the case *Shanghai Unilever v Guangzhou Import and Export Co*, the court determined that the importation from Thailand of Lux Soaps without the consent of the exclusive licensee constituted trade mark infringement. In other words, and although not binding in the Chinese legal system, the decision indicates a possible willingness to allow brand owners to control the inflow of branded parallel imports.

13. Please briefly outline the restrictions on marketing practices such as gifts or "incentive schemes" for healthcare establishments or individual medical practitioners.

Marketing practices such as giving monetary or other kinds of incentives to a healthcare establishment or practitioner are prohibited. The Industry and Commerce Authority can impose sanctions such as monetary fines, revocation of Pharmaceutical Production or Operations Licences or business licences for operators offering rebates or other benefits attaching to the sale or purchase of pharmaceuticals.

An individual doctor who accepts rebates can also be subject to disciplinary proceedings by the Chinese Medical Doctors Association. In serious cases, both the individual offering a rebate and the doctor receiving the rebate can be held criminally liable.

14. Please briefly outline the restrictions on marketing medicinal products on the internet, by e-mail and by mail order.

Websites publishing information about medicinal products must be approved by the SFDA and must maintain an Internet Medical Information Provider Certificate. Information related to anaesthetic, chlorpromazine, poison, or radioactive medicine must not be published online.

There are no specific rules or regulations governing the purchase of medicinal products by mail order. Usually, they can be ordered by mail (subject to restrictions on prescription medicines and other regulatory restrictions), provided that anaesthetic medicine can only be sent by registered mail with a special label “anaesthetic medicine” fixed on it.

In China, e-mails containing commercial advertising content cannot be sent without the express consent of the recipient.

ADVERTISING

15. Please briefly outline the restrictions on advertising medicinal products. In particular:

- Which legislation applies and which regulatory authority enforces it?
 - What types of medicinal product cannot be advertised?
 - What restrictions apply to advertising that is allowed?
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All advertisements for medicinal products must be approved by the provincial counterpart of the Ministry of Health before publication in any media. The State Administration for Industry and Commerce has laid down a series of restrictions on medicine related advertising, including the following:

- Adverts are not allowed for anaesthetic, chlorpromazine, products preventing cocaine addiction, radioactive medicinal products, or medicinal products for AIDS, tumours, or claiming to improve sexual performance.
- Adverts are not allowed for medicinal products which have not been approved for production or are not sold under a registered trade mark.
- The names or images of medical institutions, doctors, patients, medical experts and children cannot be used as evidence of the effectiveness of a medicinal product.
- Adverts for medicinal products cannot contain an undertaking relating to effectiveness of the medicinal products, such as “refund if not effective” or “recommended/preferred by X insurance company”.

- Adverts for medicinal products must not use unscientific statements or absolute claims such as “best curative effect”, “no side effects”, or “most advanced”.

Adverts for curative medicinal products must have statements that such products should be purchased and used only according to a doctor’s instructions.

PACKAGING AND LABELLING

16. Please briefly outline the regulation of packaging and labelling of medicinal products. In particular:

- Which legislation applies and which regulatory authority enforces it?
 - What information must the packaging and/or labelling contain?
 - What other conditions must be met (for example, information being stated in the language of your jurisdiction)?
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China has a series of regulations governing the manufacture of packaging materials and the selection of packages. The manufacture or import of packaging materials that are intended for use in direct contact with medicinal products must be registered with the SFDA. There are strict controls on the type of materials permitted for use in pharmaceutical packaging.

The following information must be put on labels for medicinal products:

- Name of the medicine.
- Registered trade mark.
- Marketing authorisation number of the medicine.
- Chemical ingredients.
- Volume.
- Diseases to be treated by the medicine.
- Usage instructions.
- Side effects and contraindicated usage.
- Manufacturer and manufacturing number.
- Use by date.

Anaesthetic, chlorpromazine, poison, and radioactive medicines must be clearly labelled as such. The relevant regulations also set out procedural rules regarding the manufacture and use of medical labels to prevent them from entering independent circulation. Content which cannot be included on labels is also regulated and co-branding, or the use of a sign or design to suggest endorsement, is not permitted.

TRADITIONAL HERBAL MEDICINES

17. Please briefly outline the regulation of the manufacture and marketing of traditional herbal medicinal products in your jurisdiction.

China pays great attention to the development of traditional Chinese medicinal products. In addition to those regulations applied to western medicinal products, China has adopted the following measures which apply only to traditional Chinese medicinal products:

- The manufacture, packaging and transportation of traditional Chinese medicinal products is regulated to ensure their safety and quality.
- The Good Agricultural Practice for Chinese Crude Drugs (GAP) quality recognition system has been adopted. The GAP recognition system lays down rules on the plants used as Chinese medical herbs, as well as for the manufacture of traditional medicinal products.
- The government offers a subsidy to support the development of traditional Chinese medicinal products.
- Traditional Chinese medicinal products and materials which have high medical value and have the ability to treat diseases that are difficult to treat are given special administrative protection. These medicinal products and materials can be granted exclusive protection for an initial period of up to 30 years.
- State-owned and collectively-owned traditional Chinese medicine enterprises are required to pay the inventor of any new formulation of traditional Chinese medicine 5% to 10% of any royalties they receive under licences granted to third parties relating to the formulation.

PATENTS

18. What types of medicinal products and related substances and processes can be protected by patents and what types cannot be patent protected? What are the legal criteria to obtain a patent? Which legislation applies?

Generally, medical products (including pharmaceuticals and medical devices) as well as the manufacturing process can be protected by patents. The methods for diagnosis or for the treatment of diseases are not patentable.

Under Chinese law, there are three types of patent:

- Invention patent.
- Utility model patent.
- Industrial design patent.

Pharmaceuticals (usually in the form of a compound), medicinal equipment or processes for manufacturing pharmaceuticals or medical equipment are patentable as invention patents.

According to the Patent Law, the criteria for patentability are the same as for other types of subject matter (such as mechanical products or processes), that is:

- Novelty.
- Inventiveness.
- Practical applicability (utility).

Medical appliances can be protected as utility model patents. The criteria is the same as for other types of subject matter as listed above.

Certain packages for pharmaceuticals, medical appliances or medical equipment can be protected by industrial design patents. The criteria for patentability are novelty and non-infringement of prior rights.

19. How is a patent obtained? In particular:

- To which authority must the application be made?
- What fee must be paid?
- What are the key stages and timing?

The authority

Patent applications should be submitted to the Patent Division of the State Intellectual Property Office (SIPO) (www.sipo.gov.cn), or to any of the local SIPO branches of the following municipalities: Beijing, Shenyang, Jinan, Changsha, Chengdu, Nanjing, Shanghai, Guangzhou, Xi'an, Wuhan, Zhenzhou, Tianjin, Shijiazhuang, Ha'erbing, and Changchun. For local SIPO branches, see www.sipo.gov.cn/sipo/zlsq/dbc/dbctxl/200604/t20060425_97201.htm

Fee

The following official fees apply:

- Application fee for an invention patent is CNY900 (about US\$132).
- Application fee for a utility model patent or a design patent is CNY500 (about US\$73).
- Maintenance fee for an invention patent ranges from CNY900 for the first year to CNY8,000 (about US\$1,170) for the twentieth year.
- Maintenance fee for a utility model patent and an industrial design patent ranges from CNY600 (about US\$88) for the first year to CNY2,000 (about US\$292) for the tenth year.

Process and timing

For invention patents, the SIPO publishes the application at the end of 18 months from the application date, or at an earlier date if requested by the applicant. Substantial examination

takes place within three years from the application date, or at an earlier date if requested by the applicant. Usually, it takes one to two years to complete the substantial examination. After the substantial examination, the SIPO decides whether to grant the invention patent.

For utility model patents and design patents, decisions as to whether to grant the patent are made on a preliminary examination by the SIPO (that is, without substantive examination). Usually, it takes one year to complete the preliminary examination for utility model patents and seven to eight months for design patents.

20. How long does patent protection last? How is a patent renewed or patent protection extended?

An invention patent is valid for 20 years. A utility model patent or an industrial design patent is valid for ten years. A maintenance fee must be paid annually to maintain the patent protection.

Patents cannot be renewed and the protection period of a patent cannot be extended.

21. In what circumstances can a patent be revoked?

Anyone can apply to the Patent Re-examination Board (PRB) to invalidate a patent by arguing that the grant of the patent does not comply with the requirements under the Patent Law, for example for lack of novelty, inventiveness or non-patentable subject-matter, among other things. PRB's decision can be appealed to the courts.

22. When is a patent infringed? How is a claim for patent infringement made and what remedies are available?

A patent holder's right is infringed when any other party, without authorisation, manufactures, sells, uses, offers to sell, or imports any patented products or products manufactured through the patented process.

The use or resale of patented products (or products manufactured through a patented process) which are manufactured and sold with the patentee's authorisation are not infringing activities.

Patent infringement can be enforced by either administrative authorities or courts. The main administrative authority in charge of enforcing patent infringement is the SIPO and its local offices (collectively, IPOs). Under the current Patent Law, IPOs can issue orders to stop infringing activities and impose a fine on the infringing party. The draft Third Revision to the Patent Law of 2006 may entitle IPOs to confiscate infringing products and equipment used for infringing activities. In addition to IPOs, local Authorities of Industry and Commerce (AIC) sometimes also participate in (or initiate) investigations of patent infringement activities and issue relevant administrative orders. The administrative orders issued by the IPOs and AIC can be appealed to courts.

Courts have independent jurisdiction over patent disputes and are generally the preferred forum not least because of their typical complexity. Patent disputes courts can issue preliminary or permanent injunctions to cease infringing activities and grant damages. Damages are determined as follows:

- **Actual losses.** The general principle is that the damages represent the loss suffered by the patent owner. The amount is calculated by multiplying the loss in sales of the patent owner's products by the reasonable profit attributable to the sale of each product. If the loss in sales is difficult to calculate, the volume of sales of the infringing products can be used instead.
- **Illegal gains.** When actual losses are difficult to determine, illegal gains from infringing activities will be taken as reference to calculate the damages. Illegal gains are determined by multiplying the infringer's volume of sales by the reasonable profits of each infringing product. The infringer's profit is generally its operating profit (after deducting management costs), unless the whole of its business is based on the infringement of the patent, in which case overall sales profits are used instead.
- **Statutory damages.** If both the actual losses and the illegal gains are difficult to assess, courts can award statutory damages instead. The statutory damages are generally between CNY5,000 (about US\$731) and CNY300,000 (about US\$44,000), and in any case no more than the statutory minimum of CNY500,000 (about US\$73,100). In the draft Third Revision to the Patent Law, the amount of statutory damages is substantially higher (the current proposal is CNY1 million (about CNY146,000)).

TRADE MARKS

23. Can a medicinal product brand be registered as a trade mark? What are the legal criteria to obtain a trade mark? Which legislation applies?

Product brands can be protected by registration as a trade mark. According to the Trademark Law, to obtain a trade mark registration the following criteria must be met:

- The trade mark must be distinctive.
- The use of trade mark must not infringe on prior rights of any other party, such as copyright, right of compilation or another registered trade mark.
- The trade mark cannot be:
 - the same as or similar to any national, governmental, official, or military signs or the signs of certain international organisations;
 - immoral;
 - generic names or descriptions of products.

24. How is a trade mark registered? In particular:

- To which authority must the application be made?
 - What fee is payable?
 - What are the key stages and timing?
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The authority

All applications for a registered trade mark must be submitted to the Trade Mark Office of the State Administration for Industry and Commerce (TMO) (www.ctmo.gov.cn; www.saic.gov.cn).

Fee

The official application fee is CNY1,000 (about US\$146) for one trade mark to be registered on one category of products or services. In each category, the applicant can select ten sub-categories. If the applicant selects more than ten sub-categories, CNY100 (about US\$15) is charged on each additional sub-category.

Process and timing

Applicants must submit their applications to the TMO. The application must describe the trade mark to be registered and the category of products or services it is to be registered on. Usually, the TMO will issue a receipt of acceptance of the application within one month if the application documents are complete and procedural requirements are complied with.

After acceptance of the application, the TMO conducts a preliminary examination of the application. Due to the current workload of the TMO, it usually takes 18 months to complete this. If the TMO determines, after the preliminary examination, that the applied trade mark meets the statutory criteria, it will publicise the trade mark for three months. During the three-month period, any party can challenge the trade mark. If no challenge is brought or all challenges are overruled by the TMO, the TMO will issue a trade mark certificate to the applicant evidencing registration of the trade mark.

25. How long does trade mark protection last? How is a trade mark renewed?

The initial duration of protection is ten years commencing on the date of registration.

A registered trade mark can be renewed every ten years within six months of the expiry of the current period of protection (including the initial ten year term of protection and each subsequent period of renewal). A fee of CNY2,000 (about US\$293) must be paid for each renewal application.

26. In what circumstances can a trade mark be revoked?

The TMO can revoke a registered trade mark if the trade mark owner:

- Modifies the registered trade mark without approval from the TMO.

- Changes its name, address, and other registration information without notifying the TMO.
- Fails to maintain the quality of the products for which the trade mark is registered.
- Fails to use the registered trade mark for three years or more; or
- Assigns the registered trade mark to any third party without notifying the TMO.

27. When is a registered trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

Trade mark infringement includes any of the following activities:

- Using a trade mark which is the same as, or similar to, a registered trade mark on the same or similar products without the consent of the trade mark owner.
- Selling products bearing marks similar to a registered trade mark.
- Manufacturing a material embodiment of another's registered trade mark without authorisation, or the sale of such material embodiment of trade marks.
- Removing another's registered trade mark from the goods bearing it, and putting the goods back on the market and attaching its own trade mark.
- Causing other harm to another's exclusive right to use a registered trade mark.
- Using a trade mark that is the same as, or similar to, a well-known trade mark, even in relation to a business which is dissimilar to the business in respect of which the well-known trade mark is registered, where such use would confuse the public and prejudice the interests of the well-known trade mark registrant.

In addition, the following activities concerning unauthorised use of a registered trade marks are deemed unfair competitive practice:

- The use of a registered trade mark without due authorisation as part of the name of an enterprise which engages in the same or similar business for which the trade mark is registered, leading consumers to mistake those commodities for those of the registered trade mark owner.
- The use of similar get up or product/packaging designs to those of a famous third party product, and leading consumers to mistake the former for the latter.
- Registering and using, in bad faith, a domain name which is the same as or identical to the letters or characters in a trade mark.

Trade mark owners can enforce the trade mark infringement through any of the following proceedings.

Administrative proceedings. Local AIC can enforce trade mark infringement on either the trade mark owner's petition or their own initiative. If infringement is found, the AIC can issue orders to stop infringement, to confiscate and destroy infringing products and tools used for infringement. In addition, the AIC can impose a fine of up to three times the illegal income from the infringement, or CNY100,000 (about US\$14,600) if the illegal income is difficult to determine. The advantage of administrative proceedings is that it is speedy and convenient. The orders issued by the AIC can be enforced through courts and can be appealed to courts. However, the AIC has no authority to award damages. Evidence obtained in the course of administrative proceedings can be introduced in evidence and relied on in subsequent civil proceedings.

Civil proceedings. A trade mark owner can bring a civil lawsuit against the infringing party. If the infringement is found, courts can order an injunction and award damages in the amount of (at the election of the trade mark owner) either the loss of the trade mark owner, or the benefit the infringing party derived from the infringement. If neither of these amounts can be determined, courts can order statutory damages of up to CNY500,000 (about US\$73,100). In addition, courts can order the infringing party to compensate the trade mark owner for its reasonable legal costs.

Criminal proceedings. In severe trade mark counterfeit cases, the infringing individual or responsible person of the infringing entity can be sentenced to imprisonment of up to three years. If the sales amount of counterfeit products/trade marks meets certain thresholds, the imprisonment can be up to seven years.

28. Is your jurisdiction party to international conventions on patent and trade mark protection?

China is a member country to the following international conventions and treaties:

- China entered into the WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention) (Stockholm version) on 14 November 1987. Under the Convention, industrial property (including patents) owned by an individual or entity of a member country receives the same protection in China as patents owned by Chinese citizens.
- China entered into the Patent Cooperation Treaty 1970 (PCT) on 1 October 1994. The PCT provides foreign inventors with a convenient method of registering their patents in China and also provides Chinese inventors with a convenient method of registering their patents in multiple jurisdictions.
- China entered into the WIPO Madrid Agreement Concerning the International Registration of Marks 1891 (Madrid Agreement) on 25 May 1989 and the WIPO Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989 (Madrid Protocol) on 1 September 1995.
- China entered into the Agreement On Trade-Related Aspects of Intellectual Property Rights (TRIPS) on 10 December 2001.

THE REGULATORY AUTHORITY

State Food and Drug Authority (SFDA)

T +86 10 68313344
F N/A
E webmaster@sda.gov.cn
W www.sfda.gov.cn

Main areas of responsibility. The SFDA is responsible for the implementation and enforcement of pharmaceutical rules and laws covering biological materials, products and legal standards. Approvals, imports, manufacturing permits and distribution of drugs and medical-related products and materials are also the SFDA's responsibility.

The SFDA is charged with the registration, testing and administration of OTC drugs, traditional Chinese medicines and medical devices. In addition, the SFDA determines guidelines for the use of medical devices in China.

The SFDA also manages the pharmaceutical industry and reserves the right to intervene directly in pharmaceutical enterprises, regulating pharmaceutical production equipment, packaging and pricing.

PRODUCT LIABILITY

29. Please give an overview of medicinal product liability law, in particular:

- **Under what laws can liability arise (for example, contract, tort or statute)?**
- **What is the substantive test for liability?**
- **Who is potentially liable for a defective product?**

Legal provisions

Product liability is a type of strict tortious liability. It is different from contract liability because the claimant can be a user of products other than the purchaser and the defendant can be a manufacturer which does not have a contractual relationship with the end user.

Product liability is provided for under special regulations, the PRC Consumer Interests Protection Law and PRC Product Quality Law.

The Consumer Interests Protection Law provides that consumers or other users who suffer personal injuries or property losses can claim damages from either the manufacturer or the distributor. In addition, a person who provides a business licence or sales space to the distributor may be held jointly liable.

The Product Quality Law provides that the parties who suffer personal injury or property damage due to defects in products can claim damages against the manufacturer of the product or the distributor of the product.

Liability

Under the Consumer Interests Protection Law and the Product Quality Law, both the manufacturer and the distributor of the defective products can be liable for damages resulting from defects in the products. In addition, liability may extend to other merchants who are perceived by consumers to be responsible for the sale or distribution of products, including potentially exhibition fair organisers or the owners of department stores.

Substantive test

There are two elements which must be satisfied to establish product liability:

- The product has some defect.
- The defect of the product causes personal injury or damage to property, other than the product itself.

30. What are the limitation periods for bringing product liability claims?

Any product liability claim must be brought no later than the earlier of either:

- Two years from the date when the claimant discovers or ought reasonably to have discovered the damage.
- Ten years from the date when the product is sold to the first customer (though this does not apply where an express warranty period exceeds the ten-year period).

31. What defences are available to product liability claims?

Although no-fault is not a defence, product liability will not be established if any of the following circumstances are proved:

- The product has not been placed into distribution.
- The defect causing the harm did not exist when the product was sold.
- The science and technology level at the time when the product was sold was not sufficient to detect the existence of the defect.

32. What remedies are available to the claimant?

If property damage is caused by a product defect, the remedy is compensation for the damages. If personal injury is suffered because of a product defect, the remedies include compensation for:

- Medical expenses.
- Nursing expenses.

- Decrease in income caused by the injury.
- Cost of future living expenses of both the claimant and his dependants.
- Certain statutory compensation if the claimant is disabled or killed because of the defective products.
- Certain funeral costs if the claimant is dead.

33. Are class actions allowed for product liability claims? If so, are they common?

Class actions are in theory permitted for product liability claims. However, since there is no consumer lobby group which is capable of organising such class actions or to represent consumers in class actions, the authors are not aware of any product liability class actions in China to date.

REFORM

34. Please summarise any proposals for reform and state whether they are likely to come into force and, if so, when.

The SFDA issued draft Administration Rules for Pharmaceutical Sales Businesses for public consultation in July 2008. These rules set out the applicable requirements and application procedures for the establishment of pharmaceutical wholesale and retail companies. In addition, under the draft Rules, the SFDA and local FDAs will have the authority to revoke the Pharmaceutical Operations Licence, or to reduce the licensed scope of pharmaceutical sales businesses, if a pharmaceutical sales company is found to be in breach of its licence. It is not yet known when the new Rules will come into effect.

In addition, the SFDA issued draft Administration Rules for Special Examination of Pharmaceutical Marketing Authorisations for public consultation in October 2008. These rules set out detailed examination procedures for the registration of the category of new pharmaceuticals eligible for the abridged approval procedure. It is not yet known when these rules will come into effect.

SFDA issued draft Administration Rules for Recall of Medical Devices for public consultation in March 2008. These rules set out the circumstances in which defective medical devices are required to be recalled and the procedures for recall. It is not yet known when the new Rules will come into effect.

CONTRIBUTOR DETAILS

Connie Carnabuci and Yang Xun
Freshfields Bruckhaus Deringer

T +852 2846 3400

F +852 2810 6192

E connie.carnabuci@freshfields.com

xun.yang@freshfields.com

W www.freshfields.com