Are there any notable trends or recent legal developments in your jurisdiction’s pharmaceutical industry?

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On May 26 2016 the State Council announced a detailed pilot plan for the marketing authorisation holder system for drugs in 10 Chinese provinces. The three-year pilot programme was launched in November 2015 by the Standing Committee of the National People’s Congress as an important reform measure to encourage drug innovation. Until now, China has not had a marketing authorisation holder system; the marketing authorisation for a drug has been, in essence, an import permit or a drug production approval.

According to the plan, domestic drug research and development institutions and individuals residing in the piloted regions are eligible to apply for and hold drug product licences. They can commercialise their drug assets without having to become drug manufacturers themselves. As marketing authorisation holders, they can completely outsource manufacture to contract manufacturing organisations.

A number of other policy changes have been initiated by the China Food and Drug Administration (CFDA), the main drug regulatory agency in China. The new policies promise to streamline and accelerate domestic and imported drug approvals in China. These recent changes include:

- introducing an umbrella clinical trial authorisation for all three phases of registration studies (instead of the original phase-by-phase approvals);
- implementing a filing and recordation system for bioequivalence studies on generics (instead of the original review and approval system); and
- admitting more types of drug as innovative drugs eligible for the fast-track/green-channel approval pathway.

Historically, the fast-track approval pathway has been mainly available for drugs that have not been marketed anywhere in the world or those addressing critical or unmet medical needs. The CFDA recently expanded the fast-track approval pathway to cover more types of drug, including:

- paediatric and geriatric drugs;
- drugs treating China-prevalent diseases;
- drugs sponsored by national science and technology grants;
- foreign innovative drugs to be manufactured locally in China;
- innovative drugs using advanced technology or innovative treatment methods, or having distinctive clinical benefits; and
- drugs manufactured at a US or EU-qualified facility and under review by the US Food and Drug Administration or the European Medicines Agency for concurrent marketing authorisations.
Are any legislative changes proposed or expected in the near future?

Ropes & Gray LLP

The China Food and Drug Administration (CFDA) recently published draft revisions to the Drug Registration Rules, the core regulation for seeking drug approvals in China. Although the revisions have yet to be finalised and come into effect, they reflect the recent reform initiatives of the CFDA (eg, the marketing authorisation holder system). In addition, the CFDA has proposed the following new changes:

- removing the provisions addressing international multi-centre clinical trials, reflecting the CFDA's understanding that such trials are not directly conducted for product registrations;
- removing the existing requirement that a clinical trial be launched within three years of the date of receipt of the clinical trial authorisation;
- abolishing the statutory technical review time limit, allowing the CFDA more flexibility in reviewing and approving different types of application;
- simplifying the licence renewal procedure;
- limiting amendment of pending applications to non-material changes during clinical trials; and
- eliminating the link between patent protection and the drug approval process.

In addition, the CFDA recently proposed revisions to the Good Clinical Practices for Pharmaceuticals. The revisions have rewritten all the articles of the current good clinical practices, but these sweeping changes are not especially innovative, as most of the concepts and principles have already been addressed in the International Conference on Harmonisation Good Clinical Practices. Highlights of the proposed changes include:

- regulating the handling and retention of biological specimens;
- extending insurance coverage and indemnification to both investigators and institutions;
- allowing individuals to serve as sponsors and contract research organisations;
- specifying the requirement and quantity of retention samples;
- detailing the process of seeking informed consent from subjects; and
- revising the data retention requirement and requirement to specify direct access to source records.

Which bodies regulate medicinal products in your jurisdiction and what is the scope of their powers?

Ropes & Gray LLP

The CFDA is the primary regulatory body for pharmaceuticals. In addition, the National Health and Family Planning Commission regulates the operation of public hospitals and the conduct of healthcare professionals. The State Administration of Industry and Commerce regulates pharmaceutical advertising and promotion. The National Development and Reform Commission regulates pharmaceutical pricing. The Ministry of Human Resources and Social Security regulates pharmaceutical reimbursement from the Chinese Basic Medical Insurance scheme.

Are any other legal regimes applicable to the trade of medicinal products (eg, competition,
General legal regimes applicable to consumer products are also applicable to the trade of medicinal products, including:

- anti-unfair competition laws;
- commercial bribery laws;
- tort law;
- contract law;
- international trade rules;
- IP law;
- data protection regulations; and
- consumer protection regulations.

**Are any medicinal products exempt from regulation (eg, complementary and alternative medicines)?**

In principle, all medicinal products are subject to the above rules, which are enforced by the respective competent authorities.

**What is the authorisation procedure for the manufacture of medicinal products in your jurisdiction?**

A company must obtain a pharmaceutical manufacturing permit and a good manufacturing practices certificate to manufacture active pharmaceutical ingredients and finished pharmaceutical products.

The process for obtaining the pharmaceutical manufacturing permit and the good manufacturing practices certificate for a newly established drug manufacturer consists of the following steps:

1. The applicant submits an application to the provincial food and drug administration (FDA) where it is located for approval of the pharmaceutical manufacturing permit.
2. The provincial FDA organises an on-site inspection and issues the manufacturing permit within 30 working days of the application date if the applicant passes the inspection and review process.
3. The applicant obtains domestic drug licences from the China Food and Drug Administration (CFDA) for the active pharmaceutical ingredients and finished pharmaceutical products.
4. The applicant can apply for a good manufacturing practices certificate within 30 days of the date on which it obtains the domestic drug licences.
5. Once the applicant passes the good manufacturing practices on-site inspection, it will obtain the good manufacturing practices certificate.

A qualified pharmaceutical manufacturer applicant must:

- employ qualified pharmaceutical and engineering professionals and technicians;
- possess the necessary premises, facilities and a hygienic environment for drug manufacturing;
- have the functions and personnel capable of quality management and testing for drugs to be manufactured together with the necessary instruments and equipment; and
- implement internal rules and policies to ensure product quality.
What is the fee for obtaining authorisation?

The application for pharmaceutical manufacturing permits is free of charge. When applying for the good manufacturing practices certificate, the applicant must pay certification fees.

What is the validity period for authorisation?

The pharmaceutical manufacturing permit is valid for five years.

How robust are the standard good manufacturing practices followed in your jurisdiction?

The CFDA and local FDAs are authorised to monitor the compliance of licensed pharmaceutical manufacturers – for example, by unannounced good manufacturing practices inspections (ie, fly-in inspections). Failure to continuously comply with the statutory requirements may lead to rectification orders being imposed on the manufacturers. Penalties for breach of a manufacturing authorisation can vary depending on the degree of seriousness. Administrative penalties range from a rectification notice to fines, suspension of production and business operations and revocation of the pharmaceutical manufacturing licence and pharmaceutical good manufacturing practices certificate.

What are the consequences of failure to obtain manufacturing authorisation and/or follow good manufacturing practices?

The CFDA and its local counterparts are responsible for conducting inspections of manufacturing sites. The frequency of inspections is at the discretion of the CFDA and local FDAs. The authorities will not charge fees for such inspections. Once deficiencies are identified, the FDA may impose administrative penalties on the manufacturer (eg, ordering the manufacturer to rectify within a specific period, issuing a warning letter, requiring product recalls, withdrawals or revocation of the pharmaceutical manufacturing permit or ordering the cessation of manufacturing activities), or transfer the case to the public security bureaux if said deficiencies constitute crimes.

Distribution

How are the distribution and storage of medicinal products regulated?

In order to engage in distribution and storage of pharmaceutical products, a company must obtain a pharmaceutical distribution permit and a good supply practices certificate. The process for obtaining the pharmaceutical distribution permit and goods supply practices certificate for a newly
The applicant submits an application to the provincial FDA where it is located for approval to prepare to establish a pharmaceutical wholesaler (some provinces have abolished this requirement). Once approval for the preparation to establish a pharmaceutical wholesaler is granted, the applicant can apply for approval of the pharmaceutical distribution permit and the good supply practices certificate. Once the applicant passes the on-site good supply practices inspection and the review procedure, the relevant FDA will issue the pharmaceutical distribution permit and good supply practices certificate.

A qualified pharmaceutical wholesaler must:

- employ qualified pharmaceutical professionals, including licensed pharmacists;
- possess the necessary premises, equipment, warehouse and a hygienic environment for drug distribution;
- operate an independent computerised information system that monitors the purchase, storage, sale and distribution of pharmaceuticals and records quality control activities;
- set up premises, office buildings, warehouse management, quality control and safety safeguards in the warehouse, storage and maintenance of the warehouse in compliance with good supply practices; and
- implement internal rules and policies to ensure the quality of drugs that it distributes.

The application for a pharmaceutical distribution permit is free of charge. However, for the good supply practices certificate, the applicant must pay a certification fee.

The pharmaceutical distribution permit is valid for five years.

### Import and export

**How are the import and export of medicinal products regulated?**

**China**

Ropes & Gray LLP

The procedure for importing medicines into China consists of the following steps:

- The product to be imported must first obtain an imported drug licence issued by the CFDA.
- Before each import, the import agent must file for a record with the local FDAs at the port of entry.
- The relevant FDA issues a customs clearance notice of imported drugs and port inspection notice of imported drugs.
- Once the relevant drug inspection institution receives the port inspection notice of imported drugs, it will sample the imported drugs at the port and issue an inspection report of imported drugs within 20 days of the date of sampling.

Exporting medicinal products to foreign countries is not as rigidly regulated as importing, although certain restrictions apply to exporting specialty drugs (eg, blood products and scarce traditional Chinese medicines). Chinese drug exporters mainly must comply with the laws and regulatory requirements of the country of destination.

### Sale and purchase

**What rules govern the dispensing, sale and purchase of medicinal products?**

**China**

Ropes & Gray LLP

The Trademark Law does not expressly address the import and distribution of non-counterfeit, genuine pharmaceutical products (ie, parallel imports). However, past cases have indicated that parallel imports can constitute trademark infringement if the reputation of the trademark owner is damaged.
The Measures for the Administration of Prescriptions issued by the National Health and Family Planning Commission (NHFPC), effective as of May 1 2007, regulate prescriptions by physicians and dispensing by pharmacies within hospitals. Physicians must prescribe in accordance with the approved drug indications and the clinical practice guidelines issued by the NHFPC. Those who prescribe drugs for off-label uses can be subject to warnings, orders to suspend medical practice or revocation of medical licences.

Pharmacists, on the other hand, must confirm the appropriateness of prescriptions and then fill the prescriptions accordingly. Drug dispensing by retail pharmacies outside hospitals is mainly subject to the good supply practices requirements. Patients purchasing prescription drugs at retail pharmacies generally must present the prescription notes issued by physicians.

**Are there any restrictions on the online sale and purchase of medicinal products?**

China

Ropes & Gray LLP

A company must obtain special approval from the competent local FDA to market pharmaceuticals online. If the company wants to operate an online pharmacy, it must be a duly licensed operator of retail pharmacies offline. The existing regulations prohibit distribution of prescription drugs by mail or via the Internet.

**Named patient supply**

**What rules govern named patient supply of pre-launch medicinal products?**

China

Ropes & Gray LLP

Patients are not allowed to access medicinal products before they are approved by the CFDA. The supply of pre-launch medicinal products is permitted only if it is structured as a registration study.

**Clinical trials**

**Authorisation**

**What is the authorisation procedure for conducting clinical trials in your jurisdiction?**

China

Ropes & Gray LLP

Clinical trials of pharmaceuticals are governed by the China Food and Drug Administration’s (CFDA) Drug Registration Rules and the Pharmaceutical Good Clinical Practices. The Guidelines on Ethics Committee Reviews of Clinical Trials also apply. A clinical trial authorisation issued by the CFDA is required to conduct Phases I to III clinical trials seeking product approvals. However, as of December 1 2015, the bioequivalent study for generic drugs need only be filed with the CFDA.

The procedure for securing a clinical trial authorisation consists of the following key steps:

- formal review of the application by the CFDA Administrative Services Centre (for imported pharmaceuticals) or the provincial FDA where the manufacturer is located (for locally manufactured pharmaceuticals);
- testing of samples by the relevant drug control institute to verify compliance with quality standards;
- technical review by the Centre for Drug Evaluation, including evaluation of the test report, clinical data and other supporting information; and
- administrative review and issuance of the clinical trial authorisation by the CFDA.

Prior to the commencement of the clinical trial, the approval of a qualified independent ethics committee must be obtained. Generally speaking, the ethics committee will review the protocol, informed consent form, investigator brochure and clinical trial authorisation to assess whether the rights and interests of study subjects can be fully protected.
Clinical practices

How robust are the standard good clinical practices followed in your jurisdiction?

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The conduct of clinical trials must adhere to the Pharmaceutical Good Clinical Practices and the protocols approved by the ethics committee of each study site. Investigators must take necessary measures to protect the safety of trial subjects and ensure the authenticity, accuracy and completeness of study results. On completion of a clinical trial, each investigator must produce, sign and date a summary report for submission to the sponsor.

Any serious adverse events must be promptly reported to the CFDA, the sponsor and the ethics committee. The sponsor and the investigator must promptly study serious adverse events and adopt necessary measures to protect the safety of trial subjects. The sponsor must also relay this report to any other investigators involved in the same study. In the case of any voluntary suspension of a clinical trial, the sponsor must notify the investigator, the ethics committee and the CFDA with reasons.

Since 2015, the CFDA has strengthened enforcement measures against widespread data integrity issues associated with clinical trials in China. To ensure authenticity and reliability of clinical study data, the CFDA ordered all applicants of pending drug registration submissions to conduct self-inspections. Companies that identify serious data integrity issues through self-inspections are encouraged to voluntarily withdraw their applications. The CFDA has also launched regular on-site clinical trial inspections over selected study sites, rejected new drug applications found to include data forgery and may blacklist the relevant applicants and sponsors.

Reporting, disclosure and consent

What are the reporting and disclosure requirements for the results of clinical trials?

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A clinical trial authorisation holder must register all CFDA-approved registration studies on a drug clinical study registration platform (www.chinadrugtrials.org.cn) for public disclosure. Information to be disclosed includes:

- the drug name;
- indications;
- information about the sponsor;
- information about the study (eg, objectives, design, phases of trials, grouping methods, end points and subject eligibility);
- information about the investigator; and
- the status of the study (ongoing or completed).

However, the detailed outcome of the study is not required for public disclosure on the platform.

What are the informed consent obligations with respect to clinical trial subjects?

Ropes & Gray LLP

Investigators must obtain an informed consent from each trial subject. The information in the informed consent form must include:

- the purpose, process and timeline of the trial;
- anticipated benefits and risks to the subject; and
- the treatment and compensation that the subject may be entitled to in the event of trial-related injuries.

The informed consent form must be signed and dated by both the investigator and the individual trial subject or, if the subject is a child or incapacitated person, by his or her legal guardian.
What are the insurance requirements for clinical trials?

The sponsor of the trial must arrange insurance for the trial subjects to cover potential study-related losses.

What data protection issues should be considered when conducting clinical trials?

Individuals’ privacy is required for conducting studies of pharmaceutical products. For example, the Pharmaceutical Good Clinical Practices requires anonymity of subjects in the case report forms for clinical trials. Medical records in both physical and electronic format must be exclusively maintained and used by healthcare professionals at medical institutions and can be revealed to relevant third parties only under exceptional circumstances.

What is the marketing authorisation procedure for medicinal products in your jurisdiction?

There are two types of marketing authorisation for pharmaceuticals: one for pharmaceuticals manufactured in China (i.e., a domestic drug licence) and the other for pharmaceuticals manufactured outside China (i.e., an imported drug licence). In order to obtain marketing authorisation, the safety, efficacy and quality of the drug should be proven.

The statutory technical review timeline of a marketing authorisation application for a pharmaceutical product ranges from 150 working days (for new drug applications) to 160 working days (for generic drug applications).

Key stages governing the marketing authorisation application process include a formality review, sample testing, technical review and administrative review. Applicants for the domestic drug licence are subject to an additional on-site inspection of the manufacturing site. For sample testing, the applicant must pay a testing fee to the relevant drug control institute; for technical review and on-site inspection, the official registration fee submitted to the provincial food and drug administration (FDA) or the China Food and Drug Administration (CFDA) will cover such activities.

What criteria are considered in granting marketing authorisation?

To obtain marketing authorisation, manufacturers must provide sufficient and reliable research data to prove the safety and therapeutic efficacy of the drugs, manufactured under proper quality control.

To import a pharmaceutical product into China, the product must in principle have already been marketed in another
country, except in the case of urgent clinical needs. The marketing authorisation issued by another country must be submitted to the CFDA for product registration in China. Local registration trials are normally required for an application for an imported drug permit.

What is the fee for obtaining marketing authorisation?

The official registration fees for a drug marketing authorisation application depend on the classification of the drug application, and range from Rmb183,600 (applicable to domestic generic drug applications without clinical trials) to Rmb593,900 (applicable to imported new drug applications).

What is the validity period for marketing authorisation?

Marketing authorisations for pharmaceuticals last for five years and can be renewed by application filed with the competent provincial FDA (for domestic products) or the CFDA (for imported products) within six months of the expiry date. The new period of validity following renewal is also five years.

What are the consequences of failure to obtain marketing authorisation?

In general, all pharmaceutical products must obtain marketing authorisation before being made available for sale in China; pharmaceuticals cannot be supplied unless they have a marketing authorisation issued by the CFDA. However, if an unapproved drug is urgently required by clinical needs, it may be possible to import the unapproved drug in order to supply healthcare institutions. In doing so, the applicant can submit an application to import such unauthorised products and the CFDA will issue a one-time drug import approval document.

Pharmacovigilance

What post-market monitoring mechanisms are in place to ensure the ongoing safety and efficacy of medicinal products after marketing authorisation has been granted?

The primary post-market obligations for a marketing authorisation holder include:

- pharmacovigilance, especially monitoring and reporting adverse drug reactions;
- monitoring and evaluating the manufacturing process, quality, stability, efficacy and adverse drug reactions of a new drug during the new drug monitoring period;
- product quality control and compliance with good manufacturing practices;
- product recall;
- renewal of marketing authorisation upon expiry;
- amendment of marketing authorisation to reflect changes in the product licence; and
- conduct of Phase IV clinical studies as required by the China Food and Drug Administration (CFDA). Phase IV
trials can be imposed as part of the marketing authorisation if the CFDA finds it necessary to confirm further the safety and efficacy of a new drug through post-market studies on a much larger population.

The application for marketing authorisation renewal can be rejected if the therapeutic efficacy is uncertain or if serious adverse drug reactions or other factors harmful to human health are found during drug safety re-evaluation by the CFDA.

In addition, granted marketing authorisations can be revoked under the following circumstances:

- The holder asks to annul its marketing authorisation before expiry.
- The drug manufacturing permit is revoked.
- Serious adverse drug reactions or other hazards to human health are found to be associated with a drug.
- The holder fails to meet the requirements for marketing or the Phase IV clinical trial requirements as imposed by the CFDA.
- Serious mislabelling of a drug is identified.

Post-market drug safety re-evaluation by the CFDA may also lead to mandatory changes to the granted marketing authorisations (e.g., to modify the package insert of a drug or to switch an over-the-counter drug to a new prescription drug classification).

Data protection

**What data protection issues should be considered when conducting pharmacovigilance activities?**

**China**

Ropes & Gray LLP

Patient data obtained during adverse events reporting and monitoring must remain confidential. Medical records in both physical and electronic format must be exclusively maintained and used by healthcare professionals at medical institutions and can be revealed to relevant third parties only under exceptional circumstances.

Pricing and reimbursement

**Are there rules governing the pricing of medicinal products in your jurisdiction?**

**China**

Ropes & Gray LLP

The Chinese government has historically set and controlled prices for pharmaceutical products by setting maximum retail prices. As of June 1, 2015, the vast majority of pharmaceutical products in China – except for narcotic and Type 1 psychotropic drugs – are free from government-set pricing. The price of pharmaceutical products will be set on the basis of reasonable reimbursement standards determined by the social insurance administrations through a transparent and multilateral negotiation mechanism involving the manufacturers and social insurance administrations, government procurement or independently by manufacturers.

Since 2015, the National Health and Family Planning Commission has taken the initiative to lead national-level price negotiations with several manufacturers of expensive drugs with apparent clinical values. For example, GSK has agreed to undertake a 67% price cut for one of its hepatitis B drugs in exchange for a favourable listing position and larger market size.

**What is the structure for state reimbursement of medicinal product costs?**

**China**

Ropes & Gray LLP

What is the structure for state reimbursement of medicinal product costs?
The cost of pharmaceuticals can be reimbursed from the Basic Medical Insurance funds in China if these pharmaceuticals are listed in the National Reimbursement Drug List (NRDL) or provincial reimbursement drug lists (PRDLs). The NRDL, issued by the Ministry of Human Resources and Social Security (MOHRSS), is divided into Class A and Class B pharmaceuticals. Class A pharmaceuticals are those that are widely used in clinical treatment with good efficacy and lower prices in the specific category. They cannot be adjusted by any province and are fully reimbursable. Class B pharmaceuticals are those that are available for clinical treatment with good efficacy and higher prices than Class A pharmaceuticals in the specific category, and are not fully reimbursable. Provincial governments can vary up to 15% of the Class B drugs of the NRDL to create a PRDL and decide on the actual reimbursement ratio for those drugs.

Historically, the inclusion of drugs in the NRDL lacked a consistent process and allowed little transparency into the evaluation criteria. Opinions from key medical practitioners played a dominant role. The MOHRSS is currently seeking to update the NRDL and is adopting a more comprehensive approach for future NRDL listing processes. In addition to opinions from key medical practitioners, the MOHRSS will consider evidence-based data as well as health economic information.

How is the advertising of medicinal products to healthcare professionals and the general public regulated in your jurisdiction?

The promotion and marketing of pharmaceuticals, including both prescription-only and over-the-counter products, are primarily governed by the Drug Administration Law, the Advertising Law, the Rules for the Examination of Pharmaceutical Advertisements and the Examination and Release Standards of Pharmaceutical Advertisements.

In principle, pharmaceutical advertising content must strictly adhere to the drug labels approved by the China Food and Drug Administration (CFDA) and carry important information such as contraindications and adverse reactions. The advertising content must be examined and approved by local food and drug administrations (FDAs) before the drug advertisement can be released.

In addition, only over-the-counter drugs can be advertised directly to the consumer. Prescription drugs can be advertised only in designated medical and pharmaceutical journals intended for healthcare professionals.

The most common issues associated with pharmaceutical promotion and marketing in China are:

- off-label advertising;
- direct-to-consumer advertisement of prescription drugs;
- unscientific or misleading statements or guarantees of efficacy or safety; and
- illegal reference to authorities such as healthcare professionals, scientific experts and patients.

Do any special rules apply to online advertising of medicinal products?

Statutory requirements for drug advertising also apply to marketing medicinal products on the Internet; for example, online drug advertisements must also be approved by local FDAs before publication. Operators of websites hosting drug advertisements must file for content review with and obtain prior approvals from the relevant local FDA.

The drug-related information to be displayed online must be scientific, accurate and comply with the relevant laws and regulations. Online advertising of medicinal products is deemed to be direct-to-consumer advertising via public media. Consequently, prescription drugs cannot be advertised online.
**What are the packaging and labelling requirements for medicinal products?**

**Ropes & Gray LLP**

The CFDA regulates the packaging and labelling of drugs primarily in accordance with the Provisions for Drug Insert Sheets and Labels. The insert sheets must contain:

- all active ingredients and traditional Chinese medical herbs in the prescription combinations (and all pharmaceutical adjuvants, where injections and over-the-counter drugs are concerned); and
- information on adverse reactions to the drug, with specification of any ingredient or pharmaceutical adjuvant that may cause a serious adverse reaction.

Both primary and secondary packaging must contain, among other things:

- the generic name of the drug;
- indications, specifications, usage and dosage; and
- the date of production and expiry, information about the manufacturer and the batch number.

The secondary packaging must also include:

- the drug's ingredients, character, adverse reactions, contraindications, precautions and storage instructions; and
- the drug's marketing authorisation number.

The insert sheets and labels must be written in Chinese; other languages are for reference only. They must also carry the special signs for narcotic drugs, psychotropics, toxic medicines, radioactive medicines, medicines for external use or over-the-counter drugs, where applicable.

The packaging materials and containers having direct contact with the drugs must be registered with local FDAs, suitable for use with the drug in question and good for human health and safety. Such packaging materials and containers are reviewed by the CFDA or local FDAs when the manufacturer applies for the drug's marketing authorisation.

**How is the promotion of off-label use regulated?**

**Ropes & Gray LLP**

Off-label promotion is prohibited and is primarily enforced by the CFDA, the State Administration of Industry and Commerce and their respective local counterparts. The administrative penalties imposed by enforcement authorities may range from an order to suspend the sale of products to an order to cease off-label promotion and monetary fines of between one and five times the advertising costs. In addition, the local counterparts of the National Health and Family Planning Commission will likely hold the physicians responsible where harmful or adverse incidents result from off-label use. Nevertheless, off-label promotion and use are not targets for active government enforcement in China.

**Relations with healthcare professionals**

**Gifts and incentives**

**Ropes & Gray LLP**

Restrictions on marketing practices are set out in the Anti-unfair Competition Law and related regulations, such as the Provisional Regulations on the Prohibition of Commercial Bribery. Serious offences can lead to criminal liabilities under the Criminal Law.

However, the statutory provisions do not provide specific guidance on common marketing practices. Multinational pharmaceutical companies typically refer to the Code of Practice on the Promotion of Pharmaceutical Products issued...
Liability

Defect products

How can a liability claim for a defective medicinal product be brought?

A claim for a defective medical product can be brought based on tort. Under Chapter 7 of the Tort Law, patients who have suffered injury caused by defective drug products provided by healthcare institutions have the right to claim against either the drug manufacturer or the healthcare institution.

Once claims are brought at trial courts, cases are heard by a panel of judges or a panel consisting of judges and jurors. If a case follows the simple trial procedures, the trial can be run by a single judge. Appeals must be conducted by a panel of judges.

Liability will be imposed if:

- the drug product is defective;
- the claimant suffers personal injury or property damage; and
- the personal injury or property damage is caused by the defective drug.

Which parties can be held liable for a defective medicinal product?

Drug manufacturers are strictly liable for injury or damages caused by defective drug products. A seller of defective drug products is liable only if its fault contributed to the defect of the drug or it fails to identify the manufacturer or supplier of the defective drugs. Other parties, such as transportation service providers and warehousing service providers, may also be liable if their fault contributed to the defect of the drugs.
What remedies are available to successful claimants?

The Tort Law gives consumers the right to demand that manufacturers and sellers eliminate the danger caused by unsafe drug products. Drug manufacturers and sellers must issue product warnings to caution consumers against the defects and, in severe cases, recall their drug products from the market. In the event of physical injury, the claimant is entitled to:

- compensation for medical costs, loss of income and the basic living costs of dependents; and
- statutory compensation for disability or death, funeral expenses and related expenses.

Compensation for moral losses is also available for severe psychological trauma caused by a major physical injury or the death of a spouse, child or parent.

Punitive damages may be available where manufacturers or sellers were clearly aware of the defects and the defects have caused serious physical injury or death. According to the Consumer Protection Law, if a business operator has committed consumer fraud, it will be subject to punitive damages. The courts generally support compensation only for actual damages. However, pursuant to the recent Provisions on Issues Concerning the Application of Law on Food and Drug-related Disputes promulgated by the Supreme People’s Court, it is theoretically possible that a claimant may claim 10 times the purchase price of a defective drug product, even if the claimant has not suffered an injury.

Exclusion and limitation

On what grounds can liability be excluded?

The general defences available to product manufacturers (including drug manufacturers) include the following:

- The manufacturer had not released the product for distribution.
- The defect did not exist when the product was put on the market.
- The defect was not perceptible by the science and technology available when it was put on the market.

A product (including a drug product) that complies with all national standards and industry standards will not be deemed defective. However, a certificate of compliance issued by the manufacturer before sale is insufficient for the purpose of proving compliance.

The statute of limitations for product liability claims is two years from the date on which the claimant first knew or should have known that his or her rights were infringed. Claims become time barred 10 years after the date on which the defective product was delivered to the first consumers, unless the indicated term for safe use of the product has not yet expired. When determining the claimant’s knowledge of the infringement, the courts apply the standard of actual knowledge or constructive knowledge (ie, whether a reasonable person would know by using reasonable care).

What preventive steps can be taken to limit liability?

The claimant needs only prima facie evidence of the casual link between the defective drug product and the injury or damages. To limit liability, the defendant must actively prove a lack of causation between the defective drug product and the injury or damages.

Such causation will not be established if the quality of the product conforms to the relevant national and industry standards. The defendant must demonstrate compliance with the relevant national and industry standards to avoid liability.
**Compliance and enforcement**

**What measures are in place to enforce the laws governing medicinal products?**

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The legal recourse against falsified or illegally distributed medicines can be found under the Drug Administration Law, the Product Quality Law, the Consumer Protection Law and the Criminal Law. Violations can be addressed with either administrative or criminal procedures.

Breaches of licensing requirements, quality standards, good clinical, manufacturing and distribution practices and labelling rules (among other things) will mainly be enforced by the China Food and Drug Administration (CFDA) and their respective local counterparts. The CFDA is also responsible for initiating administrative procedures against falsified or illegal drug distribution. Parties that manufacture, distribute or sell counterfeit drugs face penalties including:

- confiscation of counterfeits and illegal revenues;
- administrative fines;
- revocation of manufacturing permits; and
- orders to cease infringement and illegal operations.

Breaches of the promotional rules for pharmaceutical products are generally enforced by the State Administration of Industry and Commerce (SAIC) and its local counterparts.

**Dishonest practices**

**What mechanisms are in place to combat bribery, fraud, collusion, counterfeiting and other dishonest practices in the pharmaceutical sector?**

Ropes & Gray LLP

The People’s Court is the main body charged with enforcing against fraud, adulteration, counterfeiting, bribery and other serious offences in drug marketing and promotion that constitute crimes. The criminal process is initiated by the Public Security Bureau, which is responsible for criminal investigations, and the People’s Procuratorate, which is responsible for indictment. If convicted by the court, parties manufacturing, distributing or selling falsified or adulterated medicines may be subject to criminal fines. Further, the personnel in charge of the organisation responsible for the wrongdoing may face criminal detention, fixed-term or life imprisonment or – in the most serious cases – the death penalty.

If the nature of bribery is not criminal but commercial, the local counterparts of the SAIC can investigate and impose administrative fines of 10% to 30% of the illegally generated business turnover, according to the latest proposed draft revision to the Anti-unfair Competition Law. The National Health and Family Planning Commission also maintains a blacklist to debar drug companies and individuals from participating in public tenders. Once blacklisted in a province, the relevant company and individual will be prohibited from selling drugs in that province for two years and will have less likelihood in winning hospital tenders in all other provinces in China.

**Law stated date**

Correct as of

Please state the date as of which the law stated here is accurate.

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January 1 2017.