Pharma & Medical Device Regulation 2022

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LEXOLOGY
Getting The Deal Through

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Lexology Getting The Deal Through is delighted to publish the third edition of *Pharma & Medical Device Regulation*, which is available in print and online at www.lexology.com/gtdt.

Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes a new chapter on Armenia.

Lexology Getting The Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.lexology.com/gtdt.

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Lexology Getting The Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editors, Alexander Ehlers of Ehlers, Ehlers & Partner and Ian Dodds-Smith of Arnold & Porter, for their continued assistance with this volume.

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China

Cindy Hu and Jason Gong

East & Concord Partners

HEALTH SERVICES FRAMEWORK AND COMPETENT AUTHORITIES

Healthcare bodies

1 Describe the bodies and their responsibilities (public and private sector) concerned with the delivery of healthcare and appropriate products for treatment.

Products for treatment in China can mainly be divided into drugs and medical devices.

The marketing authorisation holder (MAH) is responsible for the safety, efficacy and quality control of the drug throughout its development, production, distribution and use.

The MAH, manufacturer and distributor for a drug must obtain a business licence for marketing, manufacturing or distribution. The manufacturer or distributor for a medical device must obtain a licence or complete a record filing procedure for manufacturing or distribution that corresponds to the category and classification of the product.

Medical institutions must hold a licence for practice and use drugs and preparations in compliance with the Drug Administration Law.

The Pharmaceutical Industry Association and the Medical Device Industry Association are mainly responsible for establishing and improving industry norms, participating in the formulation of industry standards, organising technical exchanges and cooperation, and such like.

Competent authorities for authorisation

2 Identify the competent authorities for approval of the marketing of medicinal products and medical devices. What rules apply to deciding whether a product falls into either category or other regulated categories?

The National Medical Products Administration (NMPA) is in charge of drug marketing approval. The following institutions are involved in the approval process: the Centre for Acceptance and Service, the Centre for Drug Evaluation (CDE) (for clinical and marketing technical review), the Institute for Food and Drug Control (for sample testing and quality standards) and the Centre for Drug Inspection (for on-site inspection), among others. These institutions are all directly affiliated to the NMPA.

Medical devices are classified according to their risk level, which determines the form of their market access, registration or record-filing. Class I products are subject to record filing and should be filed with the food and drug administration of the local municipal government above the district level. Class II and Class III products are subject to registration. Class II products should be registered by the provincial level local food and drug administration where the applicant resides. Class III products should be registered by the NMPA.

Definitions and classifications of drugs, health food, food and cosmetics can be found in the Drug Administration Law, the Measures for the Administration of Health Food, the Food Safety Law, the Technical Specifications for Health Food Inspection and Evaluation and the Regulations on the Supervision and Administration of Cosmetics.

Approval framework

3 Describe the general legislative and regulatory framework for approval of marketing of medicinal products and medical devices.

Classification-based management is carried out with regard to drug marketing approval. Drug registration is divided into three categories (ie, traditional Chinese medicine, chemical drugs and biological products) and the review is conducted in consideration of the safety, efficacy and quality control of the drugs, as well as the applicant's quality management, risk prevention and control and liability compensation capability.

The applicant completes research concerning pharmacology, pharmacotoxicology and drug clinical trials and then determines the quality standards, completes the commercial-scale production process validation and prepares to receive the inspection and verification of drug registration. The applicant then submits the drug marketing application accompanied by relevant research materials in accordance with the application requirements.

The CDE then organises pharmacological, medical and other technical personnel to conduct reviews in accordance with the requirements. If the review conclusion is passed, the drug is approved for marketing, and a drug registration certificate is issued.

The approved manufacturing process, quality standards, instruction sheet and labels are issued to the applicant as appendices of the drug registration certificate, together with the requirements for post-marketing studies, if necessary.

The following materials must be submitted for the record filing and registration of medical devices:

- product risk analysis information;
- product technical requirements;
- product inspection reports;
- clinical evaluation information;
- the instruction sheet and label samples;
- quality management system documents related to product development and production; and
- other information necessary to demonstrate the safety and effectiveness of the product.

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CLINICAL PRACTICE

Applicable rules

4 What legislation controls and which rules apply to ethics committee approval and performance of clinical trials in your territory for medicinal products and medical devices?

Drugs

The main applicable legislation includes:

- the Civil Code;
- the Drug Administration Law;
- the Measures for the Administration of Drug Registration;
- the Administrative Measures for the Registration of Pharmaceutical Preparations of Medical Institutions;
- the Quality Management Norms for Drug Clinical Trials;
- the Drug Clinical Trial Management Norms (for Trial Implementation); and
- the Guidelines for International Multi-centre Drug Clinical Trial (for Trial Implementation).

The relevant rules from the above legislation are as follows.

- Drug clinical trials conducted to develop new drugs, medical devices or new prevention and treatment methods, should comply with ethical principles. The clinical trial plan must be approved by the ethics committee.
- With regard to clinical research of preparations in medical institutions, the medical institution must acquire the appropriate form of approval and obtain informed consent from the participant and the ethics committee.
- For international multicentre drug clinical trials, the sponsor must ensure that the clinical trial is conducted only after obtaining approval from the ethics committee. The sponsor and the researcher must submit updates on the trial to the ethics committee in accordance with the internationally accepted good clinical practice principles and the requirements of the ethics committee.

Medical devices

The main applicable legislation includes the Quality Management Norms for the Clinical Trials of Medical Devices and the Provisions on the Administration of Extended Clinical Trials of Medical Devices (for Trial Implementation). The relevant rules are as follows:

- medical device clinical trials should be approved by the ethics committee of the medical device clinical trial institution;
- serious adverse events occurring during clinical trials that affect the rights, safety and health, etc, of the participants must be reported to the ethics committee; and
- the ethics committee should follow up and supervise the clinical trials, and it may demand, in writing, the suspension or termination of the clinical trial at any time if it finds that the rights and interests of the participants cannot be protected.

Reporting requirements

5 What requirements exist for reporting the commencement of a trial and its results to the competent authorities or the public?

Drug clinical trials should be reviewed and approved by the National Medical Products Administration (NMPA). The NMPA shall decide whether to approve or disapprove the clinical trial application within 60 working days of the date of receipt of the application. If no notice is given after that date, approval is deemed to have been granted.

Before launching the drug clinical trial, the sponsor registers the trial plan and related information on the platform for drug clinical trial registration and information disclosure. During the trial, the sponsor must continuously update the registration information, including the annual safety report, and register the results after the trial is completed. The registration information is made public on the platform, and the sponsor is responsible for the authenticity of the information.

The Administrative Regulations for Drug Clinical Trial Registration and Information Disclosure (Trial), which came into effect on 1 July 2020, contains the specific requirements concerning registration and information disclosure of drug clinical trials.

Consent and insurance

6 Are there mandatory rules for obtaining trial subjects' consent to participate? Must sponsors arrange personal injury insurance to a particular limit?

Laws and regulations, such as Drug Administration Law, the Measures for the Administration of Drug Registration and the Quality Management Norms for Drug Clinical Trials, stipulate that, when conducting a drug clinical trial, the participant or his or her guardian must be given truthful explanations of the purpose, risks and other details of the clinical trial. Informed consent must be obtained from the participant or his or her guardian voluntarily. Effective measures must be taken to protect the legitimate rights and interests of the participant.

Existing laws and regulations do not compel the sponsor of a clinical trial to arrange personal injury insurance, but the Quality Management Norms for Drug Clinical Trials requires that the sponsor should bear the costs of treatment of the participant's trial-related injuries or death, as well as the corresponding compensation. The sponsor and the researcher must pay compensation to the participant in due time.

MARKETING AUTHORISATION

Time frame

7 How long does it take, in general, to obtain an authorisation from application to grant, what fees are payable and what is the normal period of validity of the authorisation?

According to the Measures for the Administration of Drug Registration, the time limit for a drug marketing authorisation review is 200 days, and in practice it might be longer. According to the Regulations on the Supervision and Administration of Medical Devices, the period for obtaining approval for medical device registration is generally within 23 days, and in practice it generally takes around three months.

Registration fees are charged separately for drug clinical trial applications and drug marketing authorisation applications. The fees are different for new drugs and chemical generic drugs.

In the case of medical device registration applications, registration fees are different for the initial registration, change of registration and renewal of registration.

Both the drug registration certificate and the medical device registration certificate are valid for five years. The holder can apply for re-registration or renewal of registration six months before expiry.

Protecting research data

8 What protection or exclusivities apply to the data submitted by originators to gain initial approval and, on variation or new application, to add indications or pharmaceutical forms?

China protects the undisclosed test data and other data submitted by manufacturers or distributors who have obtained licences to produce or sell drugs containing new chemical ingredients. No one can make improper commercial use of such undisclosed test data and other data. Within six years, if other applicants use the aforementioned data to

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apply for a licence to produce or sell the same or similar drugs without the consent of the approved applicant, the National Medical Products Administration (NMPA) will not grant the authorisation. The data protection provided does not equate to market exclusivity, and the NMPA does not exclude applications based on self-acquired data.

On 26 April 2018, the NMPA announced the Implementation Measures for the Protection of Drug Test Data (Interim) (Exposure Draft), which expands the data protection of innovative drugs and special drugs, such as orphan drugs and children's drugs, and proposes mechanisms for application, review, authorised publicity, objection and revocation of data protection.

Freedom of information

9 To what extent and when can third parties make freedom of information applications for copies of research data submitted by applicants for authorisation to market medicinal products or medical devices?

With regard to drugs, the NMPA makes public the conclusion and basis for the evaluation of drugs approved for marketing. The main published information includes the acceptance number, acceptance date, drug name, type, instruction sheet and drug marketing technical review report. The publication time varies depending on the specific circumstances but is generally within one to two years of the acceptance date of the Centre for Drug Evaluation (CDE). However, the data submitted by the applicant will not be published, and there is no provision regarding third parties' applications to obtain a copy of that data.

As for medical devices, the drug regulatory authority publishes, through the information platform, daily supervision and management information, but does not publish copies of data submitted by applicants for marketing approval. There is no provision regarding third parties' applications to obtain relevant data.

Regulation of specific medicinal products

10 Are there specific rules for approval, and rewards or incentives for approval, of particular types of medicinal products, such as traditional herbal and homeopathic products, biologicals and biosimilars, controlled drugs, orphan drugs and those for paediatric use?

To encourage drug innovation, the Measures for the Administration of Drug Registration has set up four time-saving procedures to meet the needs under different circumstances: breakthrough therapeutic drug procedures, conditional approval procedures, priority review and approval procedures, and special approval procedures. The policy support offered by these procedures to eligible drugs includes communication with and guidance from the drug review centre, submission of supplementary applications after marketing and shortening of the review time frame.

Breakthrough therapeutic drug procedure

This concerns drugs in clinical trials that are used to prevent and treat a disease that severely threatens life or affects quality of life. While there is no other effective means of prevention or treatment, or there is sufficient evidence of significant clinical advantages over existing treatment methods, the breakthrough therapeutic drug procedure may be applied. Applicants can enjoy policy support such as requesting for communication and exchanges with the CDE during the clinical trial, soliciting comments or suggestions on the next stage of research after submitting phased research materials to the CDE, and applying for priority review and approval procedures.

Conditional approval procedure

Drugs in clinical trials that meet the following conditions are eligible to seek conditional approval:

- drugs used to treat severely life-threatening diseases with no effective treatments, of which the efficacy and clinical value can be validated by clinical trial data;
- drugs urgently needed for public health, of which the efficacy and clinical value can be shown and predicted by clinical trial data; and
- vaccines urgently needed in response to major public health emergencies or other vaccines identified by the National Health Commission as urgently needed, where the benefits are assessed to outweigh the risks.

Applicants may enjoy policy support such as continuing to complete the research after the drug is marketed.

Priority review and approval procedure

The following drugs with obvious clinical value may undergo the priority review and approval procedure:

- urgently needed clinical drugs in shortage, innovative drugs and improved new drugs used to prevent and treat major infectious diseases and rare diseases;
- new paediatric drugs that meet the physiological characteristics of children;
- vaccines urgently needed for disease prevention and control and innovative vaccines;
- drugs included in the breakthrough therapeutic drug procedure;
- drugs included in the conditional approval procedure; and
- drugs under other circumstances specified by the NMPA for priority review and approval.

Applicants can enjoy policy support such as shortening of the review time frame, priority arrangement for verification, testing and approval of common names of drugs.

Special approval procedure

In the event of the threat of a public health emergency and after the occurrence of a public health emergency, the NMPA may decide in accordance with the law to apply the special approval procedure to the drugs required for handling the emergency. Applicants can enjoy policy support such as shortening of the review time frame.

Post-marketing surveillance of safety

11 What pharmacovigilance or device vigilance obligations apply to the holder of a relevant authorisation once the product is placed on the market?

In the case of drugs, marketing authorisation holders (MAHs) have the following pharmacovigilance obligations:

- taking responsibility for the drugs' non-clinical research, clinical trials, production and distribution, post-marketing research, monitoring, reporting and handling of adverse reactions;
- formulating a post-marketing risk management plan, taking the initiative to conduct post-marketing studies, further validating the safety, efficacy and quality control of drugs, and strengthening the continuous management of the marketed drugs;
- conducting post-marketing adverse reaction monitoring, actively collecting, tracking and analysing information on suspected adverse reactions, and taking risk control measures for drugs with identified risks in a timely manner; and
- stopping the sale of drugs immediately if there are quality problems or other safety hazards, notifying relevant drug distributors and medical institutions to stop sales and use, recalling the drugs

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that have been sold, and disclosing recall information in a timely manner, as well as, if necessary, stopping production immediately and reporting to the relevant authorities the situation of the recall and disposal of the drugs.

In the case of medical devices, the manufacturer and distributor have the following vigilance obligations:

- carrying out adverse event monitoring, and reporting adverse events or suspicious adverse events to the government agency; and
- immediately stopping production, notifying the relevant manufacturers and distributors, users and consumers to stop sales and use, if necessary recalling medical devices on the market, taking remedial and destruction measures, recording the relevant situation, releasing relevant information, and reporting the recall and handling of the medical devices to relevant authorities upon discovering that the product does not meet the mandatory standards, the technical requirements concerned or other defects.

Other authorisations

12 What authorisations are required to manufacture, import, export or conduct wholesale distribution and storage of medicinal products and medical devices? What type of information needs to be provided to the authorities with an application, what are the fees, and what is the normal period of validity?

In the case of drugs, the production of drugs requires a drug manufacturing certificate (valid for five years), the application for which requires the information of relevant personnel, such as the pharmaceutical technicians, engineering and technical personnel, as well as the conditions of the plant, facilities, equipment and sanitary environment, etc. The wholesale and retail sale of drugs requires a drug supply certificate (valid for five years), the application of which requires information similar to that for a drug manufacturing certificate.

Imported drugs must apply for registration in accordance with the NMPA regulations. For drugs produced abroad, the imported drug registration certificate is required before importation. After the imported drugs arrive at the port, the importing drug company must make a filing with the drug regulatory authority at the port location, and customs handles the customs clearance procedures. For drug export, an application for a drug export sales certificate is required

In respect of medical devices, the medical device production licence and the distribution licence are both valid for five years.

There is no uniform fee schedule for the aforementioned permits; different fees are charged in different regions.

Sanctions

13 What civil, administrative or criminal sanctions can authorities impose on entities or their directors and officers for breach of the requirements concerning controlled activities?

The drug regulatory authority may impose the following administrative penalties on the manufacturer and distributor or their directors and officers for breach of the relevant regulations:

- a warning;
- confiscation of illegal income;
- confiscation of drugs and medical devices illegally produced and sold, as well as tools, equipment, raw materials, etc, used in illegal production and distribution;
- an order to suspend production and distribution;
- fines;
- revocation of the production or distribution licence; or
- if the violation is serious, the legal representative, the principal person in charge, the directly responsible person and other responsible persons may be subject to administrative penalties, such as confiscation of the income obtained from the company during the period of the violation, fines, prohibition from production and distribution for life or for a certain period of time, and detention.

If the acts constitute the crime of producing or selling medical equipment that does not meet the requisite standards or the crime of producing or selling counterfeit or inferior drugs, the defendant may be sentenced to fixed-term imprisonment, life imprisonment, the death penalty, criminal detention, fines or confiscation of property.

Where any harm is caused by defective drugs or medical devices, the patient may claim civil compensation from the responsible party (eg, the MAH, manufacturer or medical institution).

Exemptions

14 What, if any, manufacture and supply of medicinal products is exempt from the requirement to obtain an approval to market?

Medical institutions may set up preparation laboratories upon approval by the health administration of the provincial government and the drug regulatory authority, and they may make preparations (except for narcotic drugs and biological preparations) according to clinical needs. However, these preparations can only be prescribed by the medical institutions themselves and are not allowed for sale.

Parallel trade

15 Are imports allowed into your jurisdiction of finished products already authorised in another jurisdiction, without the importer having to provide the full particulars normally required to obtain an authorisation to market? What are the requirements?

These imports are normally not allowed. If the drug is already authorised in another jurisdiction, it falls into the category of generic drugs, which means that the review would focus on ethnic sensitivity and bridge studies instead of a full clinical study. Nonetheless, the importer must apply for marketing authorisation in accordance with the detailed classification of drugs and corresponding materials provided in the Measures for the Administration of Drug Registration and other related regulations. The CDE reviews the application and issues the drug registration certificate if the comprehensive review conclusion is passed.

In the case of medical devices, an overseas manufacturer exporting products to China must, through its representative office established in China or a corporate legal person designated in China as its agent, submit to the drug regulatory authority the filing or registration materials and the documents, as requested depending on the category and classification of the products.

AMENDING AUTHORISATIONS

Variation

16 What are the main requirements relating to variation of authorisations for medicinal products and medical devices?

Post-marketing changes are divided into changes in registration matters and changes in production matters. Based on the degree of risk the changes may affect the drug safety, efficacy and quality control, the changes can be divided into three categories: changes that require approval; changes that need to be filed; and changes that need to be reported. For major changes in the production process of drugs and

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changes related to the efficacy content and content on the increase of safety risk printed in drug instructions, as well as the transfer of the drug marketing licence that requires approval, the drug marketing authorisation holders (MAHs) should submit to the National Medical Products Administration (NMPA) a supplementary application and implement the changes only after approval. For medium changes to the drug production process and changes in the content of drug packaging and labelling, etc, the drug MAH should file with the provincial level local drug regulatory authorities for the record before implementing the changes. For minor changes in the drug production process, etc, the drug MAH should declare them in its annual report (see relevant provisions of Measures for the Administration of Drug Registration and Administrative Measures for Drug Post-marketing Changes (for Trial Implementation)).

For post-marketing changes to drugs, classification management is implemented according to the degree of risk and impact on the safety, efficacy and quality control of the drug. If it is a major change, it should be approved by the NMPA before implementation. Other changes should be filed or reported in accordance with regulatory authority rules.

With regard to medical devices, changes made in the filing materials of Class I products should be filed with the original filing authority. For registered Class II and Class III products, if substantial changes have been made to the raw materials, production process, scope of application, among others, and the safety and effectiveness of the medical device may be affected, the registrant must apply for a change of registration. If the changes are non-substantial, the registrant files the changes with the original registration authority.

Renewal

17 What are the main requirements relating to renewal of authorisations for medicinal products and medical devices?

MAHs and medical device registrants must apply for re-registration or renewal before the expiration of the validity period. Registered drugs and medical devices must continue to meet the quality management norms and requirements of drugs and medical devices. There are no conditions prohibiting re-registration or renewal stipulated in the Measures for the Administration of Drug Registration and Regulations on the Supervision and Administration of Medical Devices.

Transfer

18 How easy is it to transfer the existing approvals or rights to market medicines and medical devices? How long does this take in general?

The MAH may transfer the authorisation upon approval by the NMPA. The transferee must be capable of quality management, risk prevention and control, and liability compensation to ensure the safety, efficacy and quality control of the drug and fulfil the obligations of the MAH.

The transferee shall submit a supplementary application to the CDE after obtaining the drug production licence, and the review period generally lasts from 60 to 200 days. The transferee shall have a production quality management system that complies with the requirements of the Good Manufacturing Practices for Drugs; assumes the obligations of drug life-cycle management; completes the continuous studies of the drug; and ensures that the drug meets the current technical requirements.

Medical device registration certificates are not allowed to be transferred.

RECALL

Defective and unsafe products

19 What are the normal requirements for handling cases of defective or possibly unsafe products, including approvals required for recall and communication with health professionals?

If drugs and medical devices have quality problems or other safety hazards, the marketing authorisation holders (MAHs) and medical device manufacturers should stop sales immediately, notify distributors and medical institutions to stop sales and use, recall products that have been sold, disclose the recall information in a timely manner, stop production immediately when necessary, and report the recall and disposal situation to the relevant competent authority.

If the MAH or the medical device manufacturer fails to recall the product in time, the competent authority has the power to order the recall.

PROMOTION

Regulation

20 Summarise the rules relating to advertising and promotion of medicinal products and medical devices, explaining when the provision of information will be treated as promotional. Do special rules apply to online advertising?

To publish advertisements for medicinal products and medical devices, approval from the local drug regulatory authority is necessary.

Advertisements should be identifiable so that consumers can identify them as advertisements. The mass media must not publish advertisements disguised in the form of news reports. Advertisements published through the mass media must be clearly marked as advertisements, be distinguished from other non-advertising information and not mislead consumers. Except for advertisements for medical care, drugs and medical devices, any advertisements involving the function of treating a disease is prohibited, and no medical terms or terms that may confuse the promoted products with drugs and medical devices is allowed.

Special drugs (eg, narcotic drugs, psychotropic substances, toxic drugs for medicinal use and radioactive drugs), pharmaceutical precursor chemicals, medicines, medical devices and methods for drug dependence treatment cannot be advertised (this includes internet advertising). Other prescription drugs can only be advertised in medical and pharmaceutical publications designated by the competent authority.

Advertisements for drugs and medical devices must not contain the following content:

- assertions or guarantees of effectiveness and safety;
- descriptions of the cure rate or efficiency rate;
- comparisons in terms of effectiveness and safety;
- the use of advertising spokespersons for recommendation and certification; and
- other content prohibited by law and administrative regulations.

Drug and medical device advertisements published on websites should be reviewed and approved by the drug regulatory authority. The word 'advertisement' and the serial number of the advertisement review approval should be indicated. Promotional articles and videos on internet medical platforms that specify the manufacturers of drugs or medical devices and explain the efficacy of their use will be recognised as advertisements for drugs or medical devices and, therefore, are also subject to review and approval.

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Inducement

21 What regulations exist to discourage the provision of inducements to healthcare professionals to prescribe, sell, supply or recommend use of a particular medicinal product or medical device?

The Anti-Unfair Competition Law stipulates that distributors shall not use goods or other means to bribe the following entities or individuals to seek business opportunities or competitive advantages:

- the staff of the counterparty to the transaction;
- the entity or individual entrusted by the counterparty to handle the relevant affairs; and
- the entity or individual who uses their power or influence to affect the transaction.

The above regulations apply to drug and medical device manufacturers or distributors promoting products to medical and nursing staff.

The Chinese Physician Ethics Code requires that physicians shall not conduct research that is contrary to science and ethics because of funding from pharmaceutical enterprises and shall not promote any medical products or conduct academic promotion for personal benefit. Physicians shall not participate in or accept banquets or gifts, or travel, study, visit or carry out any other leisure and social activities that affect the impartiality of medical treatment, and must provide reports and explanations in the event of enterprises' funding for public interest, clinical research or academic promotion in accordance with the regulations.

Reporting transfers of value

22 What requirements apply to recording and publishing details of transfers of value to healthcare professionals and organisations by companies marketing medicinal products or medical devices?

The Circular on the Issuance of Opinions on Strengthening Pharmaceutical Management in Medical Institutions to Promote Rational Use of Drugs stipulates that medical institutions must publicise and file invitations to academic conferences, training programmes, among others, that are organised or sponsored by enterprises.

The Opinions on Deepening the Reform of the Review and Approval System to Encourage Innovation in Drugs and Medical Devices stipulate that the marketing authorisation holder must record the names of medical representatives on the website designated by the competent authority and make them public. The academic promotional activities of medical representatives must be carried out openly and filed with the designated departments of medical institutions.

The Circular on the Issuance of the Administrative Measures for the Acceptance of Public Welfare Donations by Health and Family Planning Entities (Trial) provides that medical institutions receiving donated goods should disclose and publicise information about the donated goods and their uses.

The Chinese Physician Ethics Code requires that for research funded by pharmaceutical enterprises, physicians should declare the presence of funding when publishing, displaying or advocating research results.

ENFORCEMENT OF ADVERTISING RULES

Enforcers

23 Describe the bodies involved in monitoring and ensuring compliance with advertising controls for medicinal products and medical devices, distinguishing between any self-regulatory framework and control by the authorities.

The regulatory bodies for drug and medical device advertisements are mainly the drug regulatory authority and the market supervision authority. Advertisements for drugs and medical devices are reviewed by the drug regulatory authority before publication. After making a review decision, the drug regulatory authority will copy the approval documents to the market regulatory authority at the same level. For websites that provide internet drug (including medical device) information services, they must obtain the internet drug information service qualification certificate issued by the provincial drug regulatory authority.

Sanctions

24 What are the possible financial or other sanctions for breach of advertising and promotional controls for medicinal products or medical devices?

Depending on the severity of the violation, there are different penalties. The types of penalties include fines, confiscation of advertising fees, revocation of business licences, revocation of advertising registration certificates, cancellation of the advertiser's advertising review approval documents and suspension of the advertising application review for one year. The fine is generally between 200,000 and 1 million yuan. If the act constitutes the crime of false advertising, then the advertiser, advertising operator and advertising publisher will face a fixed-term imprisonment of up to two years or criminal detention, with or without a fine.

PRICING AND REIMBURSEMENT

Pricing

25 What are the controls imposed on pricing of medicines and medical devices and reimbursement by national social security systems that are applicable to manufacturers, distributors and pharmacists?

Medicine prices are determined by either the government or the market. Government-priced drugs are limited to narcotic drugs and first-class psychotropic drugs. The prices of all other drugs are set by the market, as the control of circulation margins has been abolished and the distributors set the prices on their own.

The scope of the basic medical insurance drugs is managed through the formulation of the Basic Medical Insurance Drug List. The cost of drugs included in the List is paid by the basic medical insurance fund in accordance with national regulations, and the prices of exclusive drugs are determined through access negotiations. For non-exclusive drugs, the state organises centralised procurement, the procedure of which determines the prices. The payment standards of other non-exclusive drugs are determined by an access bidding method. Narcotic drugs and first-class psychoactive drugs, which are government-priced, are paid at the price set by the government.

At present, public hospitals implement a 'zero-profit' policy for drug pricing, which means public hospitals sell drugs to patients at their original purchase price. However, private hospitals and pharmacies do not apply this policy.

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OFF-LABEL USE AND UNLICENSED PRODUCTS

Off-label use

26 | May health professionals prescribe or use products for 'off-label' indications? May pharmaceutical companies draw health professionals' attention to potential off-label uses?

Health professionals may prescribe or use products for off-label indications. However, pharmaceutical companies should not draw health professionals' attention to potential off-label uses as this could be considered illegal advertising to expand the product indications and functions, which may expose them to the risk of administrative sanctions and the suspension of the drug sales.

Unlicensed products

27 | What rules apply to the manufacture and importation and supply to healthcare providers of unlicensed medicines or medical devices?

The manufacture and supply of unlicensed medicines or medical devices is strictly prohibited. However, medical institutions can request for the importation of a particular unlicensed drug with the National Medical Products Administration (NMPA) for urgent clinical needs. Once approved, the NMPA will issue an approval notice, which is usually valid for one-time use. The approval procedure also applies to donated drugs, samples or reference drugs needed for research.

Compassionate use

28 | What rules apply to the establishment of compassionate use programmes for unlicensed products?

The newly revised Drug Administration Law of August 2019 formally incorporates the compassionate use system. It provides that drugs undergoing clinical trials for the treatment of serious life-threatening diseases without effective treatments available may be used for other patients with the same condition in the institutions conducting the clinical trials after review and informed consent, if they are potentially beneficial based on medical observations and in compliance with ethical principles. There are no implementation rules regarding compassionate medication practice.

SALE AND SUPPLY

Regulation

29 | Are there special rules governing the dispensing or sale of particular types of medicinal products or medical devices?

Some medicinal products, such as vaccines, blood products, narcotic drugs, psychotropic drugs, toxic drugs for medical use and radioactive drugs, are subject to special regulations. The Vaccine Administration Act strictly regulates research, registration, circulation, vaccination, etc, in respect of vaccines. Furthermore, the State Council promulgated a series of regulations for these specially regulated drugs, including Regulations on Control of Narcotic and Psychotropic Drugs (revised in 2016) and Administrative Measures for Control of Radioactive Drugs (revised in 2017). In addition, all those specially regulated drugs are prohibited from online distribution.

Online supply

30 | What laws and guidelines govern online dispensing, sale and supply of medicinal products and medical devices?

The following regulations are mainly applied to online distribution of drugs and medical devices:

Type	Title
Law	Drug Administration Law (revised on 26 August 2019)
	E-Commerce Law (revised on 31 August 2018)
	Cybersecurity Law (revised on 7 November 2016)
Administrative Regulation	Regulations for the Implementation of the Drug Administration Law (revised on 2 March 2019)
	Regulation on the Supervision and Administration of Medical Devices (revised on 9 February 2021)
	Administrative Measures for Internet Information Services (revised on 8 January 2011)
State Council departmental rules	Measures for the Supervision and Administration of the Online Sale of Medical Devices (revised on 20 December 2017)
	Measures for the Supervision and Administration of Medical Devices (revised on 17 November 2017)
	Measures for the Administration of Drug Information Service over the Internet (revised on 17 November 2017)
	Good Supply Practice for Pharmaceutical Products (issued on 13 July 2016)
	Measures for the Supervision and Administration of Circulation of Pharmaceuticals (issued on 31 January 2007)
Other regulatory documents	Good Supply Practice for Medical Devices (issued on 12 December 2014)
	Interim Regulations on Approval of Internet Drug Trading Services (issued on 25 December 2005)

UPDATE AND TRENDS

Forthcoming legislation and regulation

31 | Is there any current or foreseeable draft legislation or other rules that will affect the regulation of pharmaceuticals and medical devices? What is likely to change, and what steps need to be taken in preparation?

Following the revision of the Drug Administration Law in 2019, the newly amended Measures for the Supervision and Administration of Drug Production and the Measures for the Administration of Drug Registration were released in 2020. At present, the Regulations for the Implementation of the Drug Administration Law, the Measures for the Supervision and Administration of Drug Circulation, the Measures for the Administration

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of Drug Distribution Licences and other supporting regulations are being revised.

In addition, the Patent Law was revised in October 2020 and came into effect on 1 June 2021. The new Patent Law established the drug patent linkage system and, in order to implement this new system, the National Medical Products Administration (NMPA) and the National Intellectual Property Administration (CNIPA) jointly announced and issued the Implementation Measures for the Mechanism for Early Settlement of Drug Patent Disputes (for Trial Implementation) on 4 July 2021 and, on the same day, the Supreme People's Court released Provisions on Several Issues concerning the Application of Law in the Trial of Civil Cases Involving Patent Disputes Related to Drugs Applying for Registration. Moreover, the new Patent Law offers compensation covering a maximum of five years of patent protection for new drugs that have been approved for marketing in China.

In January 2021, the NMPA issued the Administrative Measures for Drug Post-marketing Changes (for Trial Implementation) providing specific guidelines for postmarketing changes to drugs and processes. In February 2021, the NMPA issued the revised Regulation on the Supervision and Administration of Medical Devices, paying more attention to promoting the innovative development of the medical device industry, while focusing on ensuring the quality and safety of medical device products.

The above-mentioned legislative amendments comprehensively encourage and promote the development and innovation of new drugs; encourage the development of generic drugs; simplify the pre-administrative approval procedures for drugs; strengthen the interim and ex-post supervision; and increase penalties for violations.

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