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China: Law & Practice

Alan Zhou, Coco Fan, Stephanie Wang and Xuchun Huang
Global Law Office

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CHINA

Law and Practice

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Global Law Office

Contents

Global Law Office (GLO) has become one of the largest, leading Chinese law firms, with more than 500 lawyers practising in its Beijing, Shanghai, Shenzhen and Chengdu offices. Its life sciences and healthcare practice group was one of the first in China and provides "one-stop" legal services for every area of the industry, including M&A, investment and funding, licence in and out, daily operation, IP protection, and advice on compliance, including internal and government investigations as well as anti-bribery matters and dispute settlement. Under a changing regulatory environment, GLO's team has the perfect combination of international experience and local knowledge to support various innovation or pilot projects, including digital healthcare and MAH/cMAH trial cases. The team participates in the formulation of local codes of conduct and benchmark policies/rules, and also co-operates closely with associations such as the CPIA, the RDPAC and the ACCP.

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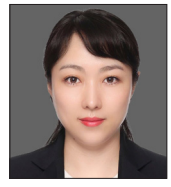

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Legislation and Regulations

The primary statute regulating pharmaceuticals in China is the Drug Administration Law (DAL). Together with its implementing rules, referred to as the DAL Implementing Regulations, the DAL governs various drug-related activities, including drug development, registration, manufacturing and distribution.

In order to address statutory requirements under the DAL for each of these activities, GxP (good practice) rules on laboratory, clinical trials, manufacturing, distribution and pharmacovigilance (PV) have also been enacted, as well as administrative measures on matters such as drug registration, manufacturing, distribution and recall. Product-specific laws, rules and guidelines, such as the Vaccine Administration Law and the Administrative Measures on Blood Products, also apply to the respective products.

The Regulations for the Supervision and Administration of Medical Devices (RSAMD) have been enacted to set up the regulatory framework for the administration of medical devices. The development, registration/filing, manufacturing and distribution of medical devices are, like pharmaceuticals, regulated by GxP rules and administrative measures. Product-specific rules and guidelines have also been released and implemented.

RSAMD were amended in 2021 to officially incorporate marketing authorisation holder (MAH), conditional approval, emergency use, device unique identification, etc, into the regulatory frameworks. RSAMD 2021 also significantly increase administrative punishment for violation and impose legal liabilities on the legal representatives and persons in charge of the entities violating RSAMD. Furthermore, the Administrative Measures on the Registration and Record-filing of Medical Devices ("Device Registration Measures") and the Administrative Measures on the Registration and Record-filing of In Vitro Diagnosis (IVD) Reagents were released to respectively update and specify the regulatory procedure and requirements for medical device and IVD reagent registration and filing.

Regulatory Bodies

State Administration for Market Regulation (SAMR)

The SAMR is the authority on the national level for the market supervision, administration and law enforcement of pharmaceuticals and medical devices, in the areas of anti-monopoly, product quality safety, food safety, IP, fair competition and commercial bribery, the issuance of business registrations, and certifications and accreditations, among other things. The SAMR is a ministry-level government agency directly under the State Council.

National Medical Products Administration (NMPA)

As a national bureau operating under the supervision of the SAMR, the NMPA regulates the registration, post-market risk management, administration of safety and quality, formulation of industrial/national standards, and supervision and inspection of pharmaceuticals and medical devices.

The NMPA also supervises permit/filing receipt issuance and law enforcement on pharmaceuticals and medical devices on the provincial level, while the local administrations for market regulation are in charge of certain permit issuance

and law enforcement on pharmaceuticals and medical devices on the city and county levels.

National Health Commission (NHC)
The NHC is a constituent department of the State Council and is mainly responsible for national health policies, the reform of the medical and healthcare system, disease prevention and control, national drug policies, and the national basic drug system. The NHC supervises the National Administration of Traditional Chinese Medicine.

National Healthcare Security Administration (NHSA)
The NHSA is mainly responsible for the preparation and implementation of regulations and policies related to basic medical insurance (BMI), including policies regarding reimbursement, pricing and procurement for pharmaceuticals and medical services. The NHSA is a sub-ministry-level government agency directly under the State Council.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

The decisions of the regulatory bodies that apply and enforce regulations of pharmaceuticals and medical devices can be challenged through an administrative review or administrative litigation; these procedures also apply in general vis-à-vis administrative regulatory bodies for other regulated products.

Citizens or legal entities who wish to challenge regulatory body decisions may first apply for administrative review. If they refuse to accept decisions made by the reviewing body, they may file a lawsuit in court, unless the administrative review decisions are final as prescribed by law. Alternatively, they may institute proceedings directly with a court, except in certain circumstances where laws and regulations provide that they must apply for an administrative review first. Once the court has accepted the case, citizens or legal entities may no longer ask for an administrative review.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals
The DAL classifies drugs as prescription drugs and non-prescription (over-the-counter – OTC) drugs, and they are regulated differently. A patient must present prescriptions when purchasing prescription drugs, while OTC drugs can be bought without prescriptions. China further subdivides OTC drugs into Class A and Class B, according to their safety level.

Medical Devices
The RSAMD classify medical devices into Class I, Class II and Class III according to their risk levels and expected purposes, structural features, methods of use and other qualities. Class III medical devices are those with the highest risk level, and their safety and effectiveness should be ensured by strict control and regulation.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials for pharmaceuticals are regulated by laws and an array of guidance and technical review standards. Specifically, the DAL and the Administrative Measures for Drug Registration (2020 Revision) establish the primary principles and statutory requirements for clinical trials. Guidance and technical review standards such as Good Clinical Practice (GCP) for Drug Trials and Pharmaceutical Research Information Guide for phase III Clinical Trials of Innovative Drugs (Chemical Drugs) provide guidance detailing the

obligations of the parties involved, operational procedures, technical requirements, etc.

Likewise, for clinical trials for medical devices, the RSAMD and Device Registration Measures set out the legal framework on whether and how clinical trials of medical devices should be conducted, while an array of review standards and guidance such as GCP for Medical Devices Trials further specify operation guidance and technical requirements for conducting clinical trials. It is noteworthy that GCP for Medical Devices Trials was amended in 2022 to be consistent with the latest regulatory framework of medical devices. For IVD reagents (a special type of medical devices), the NMPA published a separate guideline to provide special principles for IVD clinical trials.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Clinical trials for drugs are generally required before the sponsor applies for marketing authorisations, unless otherwise exempted by law (such as certain generic drugs and IVD administrated under drug-related laws). Before a clinical trial can be conducted, it must be authorised by the Centre for Drug Evaluation (CDE) of the NMPA. The general steps for securing clinical trial authorisation are as follows:

- a review by an ethical committee prior to initiation;
- a sponsor may need to apply for a pre-consultation meeting with the NMPA;
- the sponsor may conduct a clinical trial for a pharmaceutical if it has not received any objection or query from the CDE within 60 days of the date the clinical trial application is accepted;
- if there is no objection from the CDE, the sponsor may implement the clinical trial at the conclusion of the 60-day period – if the sponsor is required to submit supplementary documents, the 60-day review period will be re-calculated; and
- if the CDE issues an objection to the sponsor, the sponsor may reply in writing with regards to all issues raised by the CDE and reapply for approval of the clinical trial. The CDE will further review and determine whether to approve that clinical trial within 60 days of receiving the reapplication, and the sponsor is only allowed to implement the clinical trial upon receipt of the CDE's written approval.

Generally, clinical trial requirements for medical devices are divided according to relevant classification. Specifically, Class I medical devices are exempted from clinical evaluations. A clinical evaluation or even clinical trials could be triggered for Class II and III medical devices, subject to their safety and effectiveness.

- Clinical evaluation – unless otherwise exempt from a list issued by the NMPA, Class II and III medical devices are subject to clinical evaluation. Clinical evaluation will be conducted by the NMPA according to the technical guidance.
- Clinical trial – if the existing clinical literature and clinical data are insufficient for evidencing the safety and effectiveness of a medical device, a clinical trial should be implemented instead.

2.3 Public Availability of the Conduct of a Clinical Trial

The Drug Clinical Trial Registration and Information Platform (www.chinadrugtrials.org.cn) hosted by the NMPA is a public database providing detailed information regarding clinical trials of pharmaceuticals for the purpose of registration.

There is no publicly available database for clinical trials of medical devices in China.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no specific restrictions on using online tools to support clinical trials, provided that the use of such online tools is subject to generally applicable laws and regulations with respect to personal information protection, online advertising, etc.

2.5 Use of Data Resulting From the Clinical Trials

Raw data generated from clinical trials may consist of trial subjects' personal information, health data, genetic resources, etc.

The Personal Information Protection Law of the People's Republic of China (PIPL) came into effect on 1 November 2021 and provides a legal framework for the administration of handling personal information. During the conduct of clinical trials, sites, principal investigators, sponsor-designated monitors and other third parties such as site management organisations may access trial subjects' personal information. However, sponsors will not generally receive any information that may identify trial subjects, but will receive other anonymised data from the trial. Moreover, the sharing and transfer of personal data are subject to other statutory requirements, such as the receipt of data subjects' consent, restrictions on cross-border data transfer, etc.

Human genetic resource sample and data (HGR) are governed by the Biosecurity Law, which came into effect on 15 April 2021, and by the Administrative Regulation on Human Genetic Resources (the "HGR Regulation"). According to the HGR Regulation, HGR collection, use, storage and transfer to foreign parties may be subject to strict statutory requirements. For the time being, foreign parties are only permitted to use Chinese HGR upon filing/approval by the HGR authority. Failing to obtain such approval/filing may result in administrative liabilities or even criminal liabilities.

2.6 Databases Containing Personal or Sensitive Data

In addition to the statutory requirements set out in **2.5 Use of Data Resulting From the Clinical Trials**, the Guidelines for Clinical Trial Data Management issued by the NMPA set out the basic standards for the responsibility, qualification and training of parties responsible for data management, and requirements for the design of data management systems, standardisation of clinical trial data, quality control and the assessment of clinical data.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

The DAL defines a "drug" as a substance that is used to prevent, treat or diagnose human diseases and that is intended to regulate human physiological functions, for which usage and dosage are specified for indication/primary treatment. The list of types of drugs now includes traditional Chinese medicines, chemical drugs and biological products. The CDE evaluates drug marketing authorisation applications submitted by manufacturers or development institutions.

The term "medical devices" refers to instruments, equipment, appliances, in vitro diagnostic reagents and calibrators, materials and other similar or related articles (including com-

puter software) that can be used directly or indirectly with human bodies to achieve specified purposes (such as diagnosis, prevention and monitoring) and whose effectiveness is primarily achieved by physical or other similar means rather than by pharmacological, immunological or metabolic means (or under circumstances where these latter means serve only auxiliary functions). The NMPA's affiliated organisation, the Center for Medical Device Evaluation (CMDE), is responsible for the technical evaluation of medical devices.

The following applies for products containing both a drug and a device (ie, a combination product):

- if similar products on the market are categorised as a drug or a medical device, the product under discussion shall follow the same recognition standard for registration; and
- if no similar products are registered on the market, the applicant shall apply for the product attribute identification with the NMPA and thereafter submit an application for registration to either the CDE or the CMDE.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Market authorisation application for biologic medicinal products generally follows a similar process as mentioned in **3.1 Product Classification: Pharmaceutical or Medical Devices**. Having said that, it is compulsory to conduct verification and examination on manufacturing sites for biologic medicinal products that are being registered, while such verification and examination for other drugs are subject to the CDE's discretion.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

Marketing authorisations for drugs and Class II and III medical devices are valid for five years and can be renewed for another five years. Marketing authorisations for Class I medical devices (ie, filing receipts) do not expire.

The NMPA has the power to revoke marketing authorisation for reasons such as the conduct of clinical trials without pre-approval, the use of unapproved package materials or containers, the use of unapproved labels or instructions, bribery, obtainment of a marketing authorisation by fraudulent means, etc. Conversely, even after obtaining market authorisation, the NMPA could cancel the market authorisation if a product that has been approved lacks effectiveness, has material adverse effects or risks human health.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

There are three types of registration applications for drugs:

- drug registration applications;
- re-registration applications; and
- supplemental applications.

Drug Registration

Regarding the requirements under traditional Chinese medicines, chemical drugs and biological products, the following steps are generally required in a drug registration:

- study prior to clinical trials;
- clinical trials;
- submission of a drug registration application;
- registration verification and examination; and
- registration inspection.

The NMPA further provides four kinds of special procedures to shorten the time or facilitate the registration review, including:

- registration for drugs with breakthrough effects;
- registration for drugs with additional approval conditions;
- fast-track registration for drugs with obvious clinical values; and
- registration for drugs that are required to confront public health emergencies.

Re-registration

This is applicable when renewing a valid drug marketing authorisation before expiry.

Supplemental Applications

These are generally required when there are changes to drugs with market authorisation, such as material changes in the drug manufacturing, changes related to drug effect and risks in the instructions, changes of the market authorisation holder, etc. It is worth noting that, when changing the market authorisation holder, the transferee is required to be capable of quality management, risk prevention and control, and of providing liability compensation to ensure drug safety, effect and quality control.

Medical Devices

Class II and III medical devices are administrated by the registration process, while Class I medical devices are administrated by the filing process.

The following processes are generally required to obtain a new marketing authorisation:

- submission of technical product testing report;
- submission of the clinical evaluation for the clinical data to confirm the safety and effectiveness, if required by law;
- examination of the quality management system, which shall comply with good manufacturing practice;
- submission of registration application documents; and
- regulatory review by the CMDE and the NMPA/provincial medical products administration (MPA).

There are certain special procedures to shorten the time or facilitate the registration review, under relevant regulations, including the following.

- A registration procedure for an innovative medical device.
- A priority registration procedure for the following specific medical devices:
  (a) those that have obvious clinical advantages for certain diseases or that are in urgent clinical demand without homogeneous approved medical devices;
  (b) those that are listed in the national key R&D projects; and
  (c) those that are needed in public health emergencies.
- Changes to these marketing authorisations are divided into modification registration item variations (eg, change of product specification or technical requirements) and filing item variations (eg, change of the MAH's name or address). Currently, both need to be approved by the NMPA/provincial MPA. Changes to modification registration items may trigger an additional technical review by the CMDE. There is no definitive regulation to permit the transfer of market authorisation of medical devices.
- With respect to the application for Class I devices, the municipal MPA (for domestic

devices) or the NMPA (for imported devices) must be notified. Filling an application for a Class I device generally requires the same materials as those for Class II and III medical devices administrated by the registration process. For any changes to the filing items of Class I devices, the MAH must apply to the original filing authority.

Subject to the above procedures, the NMPA promotes the e-application to accelerate the process of application and approval. It has required registration applications for drugs and certain medical devices to be conducted via the electronic system since 2022.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

The DAL explicitly establishes an expanded access programme allowing physicians and patients access to pre-approval, investigational drugs if:

- the drug is in a clinical trial;
- the drug is used for diseases that threaten life but lack effective treatment;
- the drug has potential effectiveness based on medical observations;
- the drug usage complies with ethical principles;
- the drug usage has been reviewed and the patient's informed consent has been obtained; and
- the drug is used only within the clinical trial site and used on patients outside of the clinical trial setting but with similar conditions.

In addition to the above requirements under the DAL, the Regulations of Shenzhen Special Economic Zone on the Promotion of Cell and Gene Industries permit expanded access programmes regarding cell and genetic drugs held in Shenzhen on certain premises, such as approval for the expanded clinical trials and submission of the market authorisation application to the CDE for such drugs.

Under the RSAMD, there are similar requirements as for drugs for an expanded access programme for investigational medical devices.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

A drug MAH (and its local MAH deputy, if it is an overseas MAH) has the following post-marketing obligations under the DAL and the detailed Provisions on Supervision and Administration:

- making a pharmacovigilance system;
- conducting regular post-market launch appraisals;
- establishing a release process for drug market launches;
- establishing and implementing a drug tracking system; and
- establishing an annual report system.

The newly promulgated Guidelines on Pharmacovigilance Inspections (2022) and Good Practice for Pharmacovigilance Systems (2021) guide marketing authorisation holders of drugs to establish a pharmacovigilance system.

A medical device MAH is also responsible for post-marketing obligations, including:

- establishing and maintaining a quality management system;
- setting up and implementing the post-marketing research and risk management and control plan;

- monitoring and re-evaluating the medical device adverse events; and
- establishing a tracking and recall system, etc.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

The CDE's official website (for drugs), the CMDE's official website (for medical devices) and the NMPA's official website (for both drugs and medical devices) enable third parties to gain access to certain information regarding pending, rejected and approved marketing authorisations.

Pharmaceuticals

For drugs pending approval, information such as acceptance number, drug name, drug type, application type, registration category, company name, accepted date and registration application status is publicly available on the CED official website. The public can also access granted marketing authorisation information such as approval number, manufacturing enterprise with its production site, approved date, dosage form and specification via the relevant database of the NMPA official website. Third parties can access the refused application information via the search function on the NMPA's official website.

Medical Devices

Third parties can access less information relating to medical devices than they can access relating to drugs. The pending marketing authorisation information is only available to applicants. Refused marketing authorisation information for refused devices, including acceptance number, device name, applicant and its local deputy (if it is an overseas medical device), can be accessed via the search function on the NMPA's official website. Marketing authorisation information for permitted devices is publicly available on the NMPA's official website, including the marketing authorisation number, the MAH's name and address, the manufacturing site, the device's name, type, specifications, structure, components, applicable scope and intended use, the approval date, the effective date and modified information.

The government is prohibited from disclosing any commercial secrets (such as manufacturing processes, key technical parameters, know-how, tests and data) or personal privacy accessed in the course of review and examination, unless the rights-holder has granted its consent or unless non-disclosure will have a material adverse effect on public interests.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The DAL and the RSAMD, respectively, regulate administrative penalties for:

- the production, distribution or use of counterfeit or substandard drugs and medical devices; and
- the production, importation or distribution of prohibited or unregistered drugs and medical devices.

Administrative penalties include warning, confiscation, suspension, fines and licence revocation. The personnel in charge and the legal representative of the violating entity could also face personal liabilities. Such wrongdoing may also trigger criminal liability.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") sets out the provisional

measures and special requirements related to border measures and criminal procedures against counterfeited products. As a member of the WTO, China follows the obligations outlined by the TRIPS Agreement.

China Customs will help rights-holders to protect their IP under the Regulations of Customs Protection of Intellectual Property Rights and its implementing measures. If a rights-holder discovers infringing drugs or medical devices by itself, it could request Customs to seize the infringing goods upon the provision of certain evidence. Furthermore, if a rights-holder voluntarily completes the IP Customs Filing, it would obtain more assistance from Customs, which will proactively notify the rights-holder of suspected infringing drugs or medical devices when they are discovered.

Customs will seize the goods if the rights-holder confirms that they are counterfeit and provides a bond. The 2020 Economic and Trade Agreement between the PRC and the United States of America (the "China–US Trade Agreement") further strengthens China's obligation to implement border measures.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

Pharmaceutical manufacturing plants are required to obtain drug manufacturing licences, even for MAHs who lack manufacturing capacity and outsource manufacturing work to other manufacturers. Although such MAHs do not need to build up their own plants, they are still required to establish manufacturing standard operating procedures, designate quality personnel, etc. MAHs who need to change the package specification of imported products shall appoint a Chinese legal person to submit the sub-packaging filing to the CDE. In the event of outsourcing the manufacturing and/or sub-packaging, the manufacturing enterprise that carries out the manufacture and/or sub-packaging shall also obtain the corresponding manufacturing licence, which is valid for five years and is renewable for another five years six months before expiry.

In accordance with the Measures for the Supervision and Administration of Medical Device Production (2022 revision), types of authorisation for medical device manufacturers are different based upon the classification of devices.

- Class I devices: the manufacturer shall conduct a filing with the municipal MPA for the manufacturing of Class I devices. The manufacturer will complete the filing and obtain the filling number after submitting all required documents.
- Class II and III devices: a manufacturing licence will be granted by the provincial MPA following the result of the review and on-site examination.

A filing for Class I devices does not specify the duration of authorisation, while a manufacturing licence for Class II and III devices is valid for five years and can be renewed for another five years within 30 to 90 working days prior to expiry.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Wholesale distributors of drugs or medical devices are required to obtain the following authorisations from the relevant MPA prior to distribution.

Drug Distribution Licence

Generally, a wholesale drug distributor must maintain a drug distribution licence, with an exception for drug MAHs that sell their drugs as a wholesaler without obtaining a drug distribution licence. The licence is valid for five years and can be renewable six months before expiry. The relevant provincial MPA will review the application, conduct on-site examinations and decide whether to approve the application.

If a wholesale drug distributor (including a MAH) is an online seller, it shall report to the provincial MPA by filing an information report form, including information such as the company name, name of the website, name of the app, IP address, domain name, drug manufacturing licence or drug distribution licence, etc. Any changes to such information shall be reported to the provincial MPA within ten business days.

Class I, II and II Devices

The wholesale distribution of Class I devices does not require authorisation. For Class II devices, a distributor should maintain a distribution filing receipt from the municipal MPA, which will grant the receipt if all the required documents are submitted. The wholesale distribution of Class III devices requires a distribution licence from the municipal MPA, which will review the application, conduct examinations when necessary, and decide whether to approve the application.

A filing receipt for Class II devices does not specify a validity period, while a distribution licence for Class III devices is valid for five years and can be renewed for another five years, subject to application for renewal within 30 to 90 working days before expiry.

5.2 Different Classifications Applicable to Pharmaceuticals

For different classifications that apply to pharmaceuticals (such as "available only on prescription"), see **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The import and export of pharmaceuticals and medical devices are subject to the Customs Law of the PRC, the DAL and various relevant regulations, such as the Implementing Regulations of the DAL, Administrative Measures for the Import of Drugs, the RSAMD, etc.

The SAMR, the NMPA, the NMPA's designated drug test institutions and China Customs all have the power to enforce the laws and regulations relating to the import and export of pharmaceuticals and medical devices. The NMPA and its local counterparts govern the administration of the use of imported pharmaceuticals and medical devices.

6.2 Importer of Record of Pharmaceutical and Medical Devices

An importer of record of pharmaceuticals and medical devices is required to conduct a filing with Customs as the Customs Declaration Enterprise (either as a customs broker or as a consignee of imported or exported goods). A Consignee of Imported or Exported Goods must complete a filing with the Ministry of Commerce (MOC) as a Foreign Trade Business Dealer and then apply to Customs for the filing as a Customs Declaration Enterprise.

If the importer of record concurrently acts as the applicant for the NMPA's import filing (see **6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices**) and port inspection for imported pharmaceuticals, it must maintain a drug distribution licence.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Prior Authorisations for Drug Importation

The following require prior authorisation:

- in general, imported pharmaceuticals must obtain marketing authorisations from the NMPA prior to importation – an additional special import permit issued by the NMPA is required for narcotic drugs and psychotropic drugs;
- in exceptional cases, pharmaceuticals can be imported by means of a special approval by the NMPA instead of the aforementioned marketing authorisations;
- a small number of drugs to be imported by a hospital and used for specific medical purposes due to urgent clinical needs;
- drug samples for drug registration purposes; and
- comparator drugs (except narcotic drugs and psychotropic drugs) for the purposes of drug registration or consistency evaluation of generic drugs.

Individuals bringing drugs to China for their personal use are exempted from the above requirements.

Prior Authorisations for Medical Device Importation

The following applies:

- imported medical devices shall first be filed/registered with the NMPA and obtain marketing authorisations;
- if the imported medical devices fall into the Catalogue of Products Subject to the Compulsory Product Certification System, a China Compulsory Certification is required; and
- if the imported medical devices fall into the Catalogue of Commodities Subject to the Automatic Import Licence Administration, an automatic import licence is required.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

The non-tariff regulations and restrictions are scattered across different rules. Generally, the importation of drugs or medical devices is subject to the registrations/permits as set forth in **6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices**. Another example would be that imported medical devices should meet the compulsory national standards or industrial standards. Special drugs and medical devices are subject to specific regulations – for instance, products subject to compulsory inspection as per their Harmonized Tariff Schedule (HTS) Codes shall be inspected upon the relevant importation.

6.5 Trade Blocs and Free Trade Agreements

For trade/regulatory facilitation, China has 24 Free Trade Agreements (FTAs) under construction, 16 of which have been signed and implemented already. China maintains FTAs (including FTA Upgrade) with Australia, Korea, Switzerland, Iceland, Singapore, New Zealand, Chile, Mauritius, Maldives, Georgia, Costa Rica, Peru, Pakistan, Hong Kong, Macao and Cambodia. It is also part of the Regional Comprehensive Economic Partnership and the Framework Agreement on Comprehensive Economic Cooperation with other members of the Association of Southeast Nations (ASEAN), and one Preferential Trade Agreement (the Asia-Pacific Trade Agreement). Based on the official website of the China FTA Network, several other FTAs are also under negotiation and consideration.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Drugs

The prices of most drugs are not directly controlled by the government but are mainly determined by market competition, while the prices for narcotic drugs and Class I psychotropic drugs are capped by the government.

Although the government aims to leave the pricing of drugs to the market, government policies may nonetheless have a significant effect on the pricing of drugs. For example:

- prices for drugs reimbursed by the BMI funds are determined by authorities including the NHSA, and prices for certain drugs covered by the BMI funds are fixed through negotiations between the NHSA and suppliers thereof;
- the government centralised procurement, which offers strong bargaining power to the procuring side, gives a favourable procurement price to hospitals and drug stores participating in centralised procurement, and may set pricing rules for manufacturers and wholesalers, such as demanding the lowest price compared to certain other provinces, requiring re-evaluation of price after procurement (for COVID-19 drugs involved in the centralised procurement, the NHSA has promulgated further guidelines to specify the conditions under which the relevant enterprises shall re-evaluate the prices of drugs for COVID-19 and fulfil the price adjustment commitment);
- the "Two-invoice System" (ie, a maximum of two invoices are allowed between agents of imported products/domestic manufacturers and public hospitals) eliminates multi-tiered distribution channels and lowers drug prices; and
- the enforcement of a "zero mark-up policy" means that public hospitals may not add any mark-up when selling drugs to patients.

Medical Devices

There is no nationwide regulation or policy specifically and directly controlling the pricing of all medical devices. However, the pricing of medical devices may be significantly influenced by regulatory factors, as follows:

- the pricing of certain medical devices is indirectly restricted because national and local rules limit the amount that a public hospital may charge patients for medical services, and the cost of medical devices used in such services may be included in those charges;

- procurement of certain costly medical devices by hospitals is strictly controlled by planning at the central and provincial levels; and
- centralised procurement, the two-invoice system and the zero mark-up policy may also be applied to the procurement of certain high-value medical consumables by public hospitals, etc.

7.2 Price Levels of Pharmaceutical or Medical Devices

PRC law does not require the prices of pharmaceuticals and medical devices to be benchmarked or otherwise be set in reference to the prices of the same products in other countries. However, the NHSA does monitor drug prices at home and abroad for the purpose of making timely warnings of any abnormal changes to drug prices and supply. Prices in other countries might also be used as references during negotiations between the NHSA and suppliers of drugs with respect to BMI funds coverage.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Drugs

The NHSA and the Ministry of Human Resources and Social Security (MOHRSS) have jointly issued the latest version of the National Reimbursement Drug List 2022 (NRDL), which lists the drugs currently covered by the BMI funds. Under the NRDL, pharmaceuticals are classified into Class A and Class B, with each class being reimbursed differently by the BMI funds. Patients assume full costs for drugs excluded from the NRDL.

The latest effective NRDL, officially implemented on 1 March 2023, stipulates that all provincial authorities shall implement the same NRDL with limited exceptions, including ethnic medicines, preparations of medical institutions and Chinese medicine tablets.

Medical Device

Medical consumables may be considered "diagnosis and treatment items" or parts of such items for BMI reimbursement purposes. Certain local healthcare security administrations at the provincial level have promulgated effective lists of medical consumables that can be reimbursed by local BMI funds.

As public hospitals are supported by state financial funds, the procurement of medical devices by public hospitals above the designated amount would be regulated by rules regarding government procurement.

It should be noted that reform measures regarding BMI funds reimbursements, such as reimbursement based on the diagnosis-related groups payment method (DRGs) and the big data diagnosis-intervention package (DIP), are aimed to be fully implemented and expanded to all medical institutions by the end of 2025; if finally implemented, these measures may significantly affect how drugs, medical consumables and medical services are reimbursed in the future.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Pharmaco-economics analysis would be employed when assessing which drugs are to be included in the NRDL and the price for NRDL negotiations. Pharmaco-economic materials may be required to be submitted by applicants in order to add a drug into the NRDL or to adjust its reimbursement coverage.

Cost-benefit analysis would also be considered when assessing which medical consumables are to be covered by BMI funds.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Physicians and pharmacists must follow the principles of safety, effectiveness and economy when issuing or dispensing prescriptions.

A physician may decide what drugs are to be prescribed based on such physician's professional judgement that the prescription is rational and appropriate to a patient's condition. In no event shall the prescription be formulated by artificial intelligence (AI). The quantity of drugs a physician may prescribe is specifically limited for each prescription in order to avoid wasting medical resources or taking advantage of the BMI fund.

Government policies may affect or guide a physician's prescription decisions. For instance:

- the BMI fund is currently subject to budget management and total amount control, and hospitals are responsible for a portion of any over-expenditure so are incentivised to require physicians to consider the BMI budget when prescribing drugs and to use medical consumables reimbursed by the BMI fund;
- hospitals are required to prioritise drugs and medical consumables that are centrally procured, and the use of such drugs and medical consumables may be taken into consideration in the performance assessment of public hospitals and medical professionals;
- the DRGs and the DIP, being piloted in multiple cities, will pressure hospitals to control medical expenses, and thus may influence physicians' prescription behaviours; and
- the Regulations on the Supervision and Administration of the Use of BMI Fund specifically regulate the reimbursement by the BMI fund, and local authorities of the NHSA – along with other departments – conduct examinations of the use of BMI funds. The increasingly severe punitive measures imposed on designated medical institutions and drug retailers contracting with the agencies of the BMI ("Designated Institutions") in the Regulations on the Supervision and Administration of the Use of BMI Funds, as well as the mechanism and rewards for reporting incompliant use of BMI funds, aim to restrain fraudulent activities in the use of BMI funds, to strengthen the internal management control of the Designated Intuitions and to further standardise the medical services provided.

A pharmacist will dispense prescription drugs according to a physician's prescription. The examination of a prescription by an eligible pharmacist focuses on the appropriateness, rationality and correctness of the use of the drugs, rather than economic considerations.

8. Digital Healthcare

8.1 Rules for Medical Apps

Medical apps that have diagnostic or treatment functions that meet the regulatory definition of medical devices will be regulated as medical devices under PRC law.

Medical apps that fall within the scope of medical devices are subject to the same regulatory requirements as general medical devices, and must also meet the requirements under the standard of relevant registration review guidelines issued by the NMPA and the CMDE. The

NMPA and the CMDE have also promulgated specific guidelines to address the principles of reviewing the registration application and classification of AI medical apps.

8.2 Rules for Telemedicine

There are separate rules for telemedicine in the PRC.

Under the Measures for the Administration of Telemedicine Service, hospitals can hold hospital-to-hospital consultations on diagnoses and treatment by means of modern information and communication technologies.

Physicians can conduct online diagnoses and treatments for patients whose initial appointment or treatment is at an offline hospital for the same symptoms, provided that such online diagnoses and treatments comply with the Administrative Measures for Online Diagnoses and Treatment (Trial) and the rules for relevant supervision and administration.

Please see **11.6 Drivers for Digital Health Innovation Due to COVID-19** regarding the special regulations for encouraging telemedicine services during the COVID-19 pandemic.

8.3 Promoting and/or Advertising on an Online Platform

Besides the general legal requirements on the promotion and/or advertising of pharmaceuticals and medical devices, online promotion and/or advertising are specifically regulated. Online advertisements for pharmaceuticals and medical devices are subject to the examination and approval of the relevant local authorities under the SAMR, and must indicate the approval number for the advertisement. An entity providing information on pharmaceuticals or medical devices via the internet to online users is subject to the Qualification for Internet Drug Information Services issued by the relevant provincial MPA.

Information on pharmaceuticals and medical devices presented online shall be accurate and science-based. The publication of any information about narcotic drugs, drugs for mental health, toxic drugs for medical use, radioactive drugs, anti-drug medicines or the preparation products of hospitals is prohibited.

8.4 Electronic Prescriptions

Currently, there are no national laws or regulations that specifically regulate the use of electronic prescriptions in the PRC. In practice, all electronic prescriptions must be issued with a physician's e-signature and reviewed by a pharmacist.

For the online distribution of prescription drugs, there are some special rules related to the use of electronic prescriptions under the newly promulgated Measures for the Supervision and Administration of Online Sales of Pharmaceuticals (MSAOSP):

- online distributors of pharmaceuticals shall be responsible for the authenticity and reliability of the electronic prescription; and
- the third-party platform for the online sales of pharmaceuticals shall be responsible for verifying the electronic prescriptions.

The first electronic prescription centre at the provincial level has been listed in Hainan since the end of 2022, enabling the online distribution of all prescription drugs, except those expressly prohibited from being distributed online, without further requirement of approval in Hainan.

8.5 Online Sales of Medicines and Medical Devices

According to the MSAOSP, online sales of drugs are generally permitted, except for drugs that are subject to special administration. The NMPA also announced the first list of drugs prohibited for online sales in 2022. In addition to the requirements applied to an offline drug distributor, an online distributor of drugs is subject to the following further requirements:

- reporting certain information to the local MPA (ie, the website name, app name, IP address and domain name, among other information of the distributor);
- displaying certain information on the home page or the frontpage for distribution, such as its drug manufacturing or distribution permit information and the qualifications of designated pharmacists or other medical technical personnel; and
- being responsible for the authenticity, accuracy and consistency of the information displayed.

If the drugs are distributed online to individuals, the distributor should further conduct prescription examination, set up an online pharmaceutical service system, and comply with special rules about the information display for the prescription drug.

The third party providing the platform for the online distribution of drugs is subject to filing requirements of recording its information such as name, legal representative, unified social credit code, website name and domain name with the local MPA, which will publish the filing information. The MSAOSP further requires such third party to supervise the online distribution taking place on its platform.

Online sales of medical devices are permitted. According to the Measures for the Administration and Supervision of Online Sales of Medical Devices, besides the requirements applicable to a general medical device distributor, an online distributor is subject to additional filing requirements for its sales activities with the local MPA. Under RSAMD 2021, relevant information regarding the sale of a medical device online shall be notified to the local MPA, except for the online sale of Class I medical devices and certain Class II medical devices, which are exempted from filing in offline sales.

8.6 Electronic Health Records

Electronic health records may contain the following data types:

- personal information – any collection, use, storage or transfer of such data records is subject to the newly issued PIPL and the handling of sensitive personal information shall be subject to more stringent requirements;
- medical records, the storage or use of which is subject to the Use and Administration Rules for Electronic Medical Records (for Trial Implementation) and the Provisions on the Administration of Medical Records of Medical Institutions;
- human genetic resources, which are subject to the restrictions under the Biosecurity Law and Administrative Regulation on Human Genetic Resources mentioned in **2.5 Use of Data Resulting from the Clinical Trials**; and
- aggregated electronic health records in hospitals, which may be deemed population health information and medical big data.

According to the Data Security Law, the Guide for Health Data Security and the National Management Measures on Health and Medical Big Data Standards, Safety and Service, any health

information and medical data of PRC citizens generated in the territory of the PRC shall be subject to national regulation and use based upon concerns regarding national security and citizens' life and health. Medical big data must be stored in a reliable server located within the territory of the PRC, in a way that satisfies the national standards of data storage, disaster recovery, and back-up and security management. Regarding the transfer of data, the Data Security Law requires security assessment by cyberspace administration prior to the outbound transfer of certain data as stipulated by the law. The Measures for the Security Assessment of Data Outbound Transfer and relevant guidelines have been promulgated to instruct applications for the security assessment of outbound data transfer.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

The main sources of legislation that govern patents in China are:

- the Patent Law;
- the Rules for the Implementation of the Patent Law;
- the Administrative Measures for Prioritised Patent Examination;
- the Administrative Measures for Centralised Examination of Patent Applications (for Trial Implementation);
- the Measures on Compulsory Patent Licensing;
- the Provisions of the Supreme People's Court on Several Issues Concerning Application of Law in Trial of Administrative Cases involving Patent Grant and Confirmation (I) (Interpretation on Patent Grant and Confirmation);
- several Provisions of the Supreme People's Court on Issues Concerning the Application of Law in the Trial of Cases on Patent Disputes;
- the Interpretation of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Patent Infringement Dispute Cases;
- the Interpretation (II) of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Patent Infringement Dispute Cases;
- the Guidelines for Patent Examination;
- Measures for the Implementation of the Early Resolution Mechanism for Drug Patent Disputes (for Trial Implementation);
- the Administrative Adjudication Measures for Early Resolution Mechanism of Drug Patent Disputes; and
- the Provisions of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Civil Cases Involving Disputes over Patent Rights Relating to Drugs under Application for Registration.

Patent applications for pharmaceuticals and medical devices are most commonly rejected due to a lack of:

- inventiveness;
- enablement; or
- specifications' support on claims.

Generally speaking, an invention or utility model must possess novelty, inventiveness and usefulness in order to be patentable.

Supplemental Data

The extent to which applicants are allowed to submit supplemental data after the patent appli-

cation date has always been a difficult point in the drug-related patent examination system. This issue was also raised in the China–US Trade Agreement. The Guidelines for Patent Examination as amended in 2020 clearly provide that the examiner shall examine the supplemental data submitted by the applicant to meet the requirements of the Patent Law after the filing date, and the technical effect proved by the supplemental data should be able to be obtained from the published contents of the patent application by persons skilled in the art.

In terms of patentability requirements that are specific to pharmaceuticals or medical devices, the following are not patentable:

- inventions or creations that are in violation of Chinese laws or social morality, or detrimental to public interests;
- inventions or creations that are accomplished by relying on the basis of genetic resources, where their acquisition or use breaches Chinese laws and regulations;
- scientific discoveries;
- rules and methods of intellectual activities; and
- methods for diagnosing or treating diseases.

9.2 Second and Subsequent Medical Uses

A second and subsequent medical use of a known substance that takes the typical written form as "use of substance X in the preparation of a medicament for the treatment of disease Y" (Swiss-style claims) could be patentable in China.

If new dosage regimes and new or selected patient populations are merely present in the course of administration as distinguishing features but fail to define the procedure of manufacture per se, a claim for such use does not possess novelty and thus is not patentable.

Exploitation of a patent on a second or subsequent use of a drug, such as making, utilising or selling without the permission of the patentee, may constitute an infringement of second and subsequent patents of pharmaceutical products.

9.3 Patent Term Extension for Pharmaceuticals

The Patent Law provides two situations for Patent Term Extension:

- to compensate for unreasonable delay during the patent examination process, and is applicable to all types of patents; or
- to compensate for the time spent during review and approval for new drugs – this only applies to patents related to new drugs.

Any party can challenge the Patent Term Extension decision before the China National Intellectual Property Administration (CNIPA), whose decision in turn can be appealed through administrative action before the court.

9.4 Pharmaceutical or Medical Device Patent Infringement

Without the permission of the patentee, the following exploitation for production or commercial purposes may constitute an infringement of patents:

- the manufacture, utilisation, offer for sale, sale or import of the pharmaceutical or medical device containing a patented invention or utility;
- the utilisation of the patented process of an invention or utility;
- the utilisation, offer for sale, sale or import of the pharmaceutical or medical device directly

obtained through the patented process of invention or utility; or
- the manufacture, offer for sale, sale or import of any pharmaceutical or medical device containing the patented design.

The Patent Law provides an exemption from patent infringement where anyone manufactures, uses or imports patented drugs or medical devices to provide information that is necessary for the marketing authorisation (Administrative Approval Exemption).

Preliminary Injunctions
If a patentee or an interested party has evidence that proves the threatened infringement of a patent which, if not stopped promptly, will cause irreparable damage to its lawful rights and interests, the patent rights-holder may apply to the court for a preliminary injunction and an order for the preservation of infringing evidence and assets, even prior to the commencement of the court action. To be actionable, such a threat of infringement is required to be "imminent".

The China IP court will take the following factors into consideration in granting a preliminary injunction:

- the factual and legal basis, including the stability and validity of the patents at issue;
- whether the applicant's legitimate interests would be irreparably damaged if no injunction were issued;
- whether the loss caused to the applicant would exceed the loss incurred by the respondents through the issuance of the injunction if no injunction were issued;
- whether the injunction would harm public interests; and
- whether the applicant provides a sufficient bond.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

The specific defences to patent infringement in relation to pharmaceuticals and medical devices include the Administrative Approval Exemption (see **9.4 Pharmaceutical or Medical Device Patent Infringement**) and Experimental Use Type Defences (where the alleged infringement is used for research and experimentation), which collectively could be equivalent to the Bolar exemption. The patent exhaustion defence, prior art defence and transit exception could also apply to pharmaceuticals and medical devices as a general defence.

Compulsory licences are available for pharmaceutical products and medical devices to be used in China in the following circumstances:

- if a patentee has failed to exploit a patent without justification for more than three years since the date of granting the patent right and four years since the patent application date;
- if the patentee's act of exercising the patent right is determined to be monopolistic, and a compulsory licence would remove or reduce the anti-competitive effects of such patent use;
- if it concerns a national emergency, extraordinary State affairs or the public interest;
- for the manufacture and export of patented drugs to countries or regions that comply with the relevant international treaties to which China has acceded for the purpose of public health; or
- if a patented invention or utility model representing major technical advancements with remarkable economic impact relies on earlier patents. A compulsory licence could be granted to exploit both earlier and later patents in this scenario.

The party that is granted a compulsory licence enjoys neither an exclusive right of exploitation nor a right to authorise others to exploit, and such a party shall pay reasonable royalties to the relevant patentee.

9.6 Proceedings for Patent Infringement

The following main options are available to enforce patent rights in China:

- administrative actions:
  (a) the CNIPA – the patentee or any interested party can file complaints with competent evidence before the CNIPA (and its local counterparts). Also, the local IPA can conduct regular investigations against patent infringements. Remedies include ordering the infringers to cease the infringement, seizing/destroying infringing items, and the imposition of fines; and
  (b) Customs – border measures as discussed in **3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices**;
- civil litigation remedies include preliminary injunctions, permanent injunctions and monetary damages; and
- criminal penalties (in cases of severe patent counterfeiting).

For civil cases, the patentee or any interested party can bring proceedings for patent infringement. Interested parties can be the legitimate heirs of the property right of the patent or licensees.

The Infringement Procedure

The typical procedure for a patent infringement proceeding is as follows:

- the claimant submits a pleading to the court and files a copy of the pleading for each defendant;
- the court will serve a copy of the pleading to each defendant within five days of accepting the case, and the defendant must submit a statement of defence within 15 days of receipt;
- the claimant and defendant submit evidence, and the court will arrange the exchange of evidence;
- the defendant may also choose to file a patent invalidation application with the Re-examination and Invalidation Department under the CNIPA;
- the court will conduct oral hearings and make its decision; and
- an appeal to a higher court can be filed by either party within 15 days of receiving the judgment.

The typical procedure of administrative enforcement for a patent infringement action includes the following:

- an administrative complaint is lodged with the CNIPA or its local counterparts;
- the CNIPA or its local counterpart conducts an investigation and takes action to obtain evidence of infringement; the defendant can submit a formal defence and rebuttal evidence;
- oral hearings may take place;
- the CNIPA or its local counterparts issue a decision; and
- either party may choose to appeal the decision by filing an administrative lawsuit with the court.

The patent validity challenge is not a non-infringement defence that can be heard by a civil court. Generally, an accused infringer will

bring patent invalidation proceedings with the Re-examination and Invalidation Department of the CNIPA parallel with the civil litigation as a litigation strategy.

9.7 Procedures Available to a Generic Entrant

A potential generic entrant can conduct research and development and clinical trials, and file a product application with the NMPA under the Administrative Approval Exemption and Experimental Use Type Defences to patent infringement.

The Patent Law establishes the Chinese efficiency-first patent linkage system, which is further explained by the Measures for the Implementation of the Early Resolution Mechanism for Drug Patent Disputes (for Trial Implementation). The latter stipulates that a MAH shall register the patent information of the drug on the Chinese listed drug patent information registration platform, while a generic drug applicant should make one of the four categories of declarations with respect to the registered patents. Among others, the Category IV declaration claims that the registered patents should be declared invalid or do not cover the generic drug.

The patentee or the interested party (ie, the licensee of the patents or the MAH of the drug) can challenge the Category IV declaration before the court (judicial link) or the CNIPA (administrative link) within 45 days after such declaration being published. Within 15 business days of the case being accepted by the court or the CNIPA, the patentee or the interested party should provide the evident documents to the NMPA, which will withhold the administrative examination of the application for the generic drug for up to nine months to wait for an effective judgment or administrative decision, during which time the technical examination of the application will not be ceased. A 12-month exclusive period will be granted following the issuance of the marketing authorisation to the first chemical generic to successfully challenge a patent. Marketing authorisation of generic drugs of the same kind will not be approved within the aforementioned exclusive period.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

With regard to counterfeit pharmaceuticals and medical devices, the following ways may be used to protect the public interest and the lawful rights of the rights-holder.

- Administrative proceeding – a rights-holder can file an infringement complaint with supporting evidence to the administrative authorities, such as the local Administration for Market Regulation, the local MPA, Customs, etc. Also, the administrative authorities may conduct investigations ex officio against counterfeit pharmaceuticals and medical devices, and will issue a punishment ruling when infringement is affirmed. The dissatisfied rights-holder or the infringer can bring an administrative lawsuit to the court regarding the local authority's ruling.
- Civil proceedings – the patentee and the interested party can bring infringement actions before the courts. Punitive damages are allowed under the Trademark Law.
- Criminal proceedings – the manufacture and distribution of counterfeit pharmaceuticals and medical devices constitute violations of the Criminal Law of the PRC.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Trade marks used for pharmaceuticals and medical devices are subject to the general requirements of the Trademark Law (such as prohibitions on containing fraudulent content). In addition, the NMPA places special restrictions on trade marks to be used for pharmaceuticals and medical devices. For example, pharmaceuticals' generic names cannot be registered as trade marks, and unregistered trade marks cannot be used in the specifications and labels of pharmaceuticals.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

IP protection is available for the trade dress or design of pharmaceuticals and medical devices under various PRC laws. Trade dress is regulated under the Anti-unfair Competition Law, which prohibits any unauthorised use of the mark that is identical or similar to the package or decoration of another's commodity that is influential.

The patented design of pharmaceuticals and medical devices can be protected under the Patent Law. In addition, the trade dress or design of pharmaceuticals and medical devices could be protected as a copyrightable industrial design or product design under the Copyright Law and as a registered two-dimensional/three-dimensional trade mark under the Trademark Law.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Data exclusivity is currently only available for pharmaceuticals, not for medical devices. PRC law provides six-year protection from the date of the marketing authorisation, which prohibits unauthorised third parties from using undisclosed trial data and other data to apply for manufacturing or distribution approval of new chemical pharmaceuticals.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

During the COVID-19 pandemic, the distribution of medicines and medical devices was subject to distribution permits, as discussed in **5. Distribution of Pharmaceutical and Medical Devices**. China issued special regulations to severely crack down on the illegal manufacture and distribution of counterfeit and inferior pharmaceuticals, medical devices and hygienic materials, especially for pharmaceuticals and medical devices used for the treatment and prevention of COVID-19, such as pandemic prevention clothing, medical masks, diagnostic kits, ventilators, etc.

Since China announced its decision to manage COVID-19 with measures against Class B instead of Class A infectious diseases, the NMPA issued a special notice to emphasise the regulation on drug dividing distribution management (ie, the distribution of drugs by splitting the minimum package) and to ensure the supply of drugs commonly used to treat COVID-19.

11.2 Special Measures Relating to Clinical Trials

To ensure the effectiveness of safety management of clinical trials during COVID-19, the CDE published guidelines to ensure the progress of clinical trials under the condition of protecting the trial subject from COVID-19, with key measures focusing on reducing the trial subject's exposure to the virus and controlling the spread of infection.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

Two regulatory pathways have applied for emergency approvals of pharmaceuticals or medical devices in China since before the outbreak of COVID-19: emergency approvals and conditional approvals.

Regulatory pathways of special approvals greatly reduce the required time for the approval of pharmaceuticals and medical devices due to a public health emergency.

The other regulatory pathway is to obtain market authorisation for pharmaceuticals (including vaccines) or medical devices upon additional approval conditions being met. Conditional approvals for pharmaceuticals often occur when pharmaceuticals (including vaccines) have curative effects and predictable clinical value based on the data in clinical trials, and when they are used for the treatment of serious life-threatening diseases with no effective therapeutic means or for those with urgent need of public health. Conditional approvals for medical devices often occur when medical devices are used for the treatment of rare diseases or serious life-threatening diseases with no effective therapeutic means or for those with urgent need of public health.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

During the COVID-19 pandemic, many provinces and cities introduced special regulations to facilitate the application for manufacturing permits for medical devices. For example, the registration and manufacturing of medical masks and medical protective closing are no longer subject to approval by the provincial MPA: a simplified filing with the municipal MPA is sufficient.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

Importation

For importation, China Customs issued special regulations to ensure the rapid customs clearance of donations for COVID-19 research and treatment. Pursuant to the special regulations, the clearance of imported pharmaceuticals, disinfectants, protective suits, rescue and treatment devices and relevant materials may be carried out before completing the required customs procedures, such as declaration and tariff reduction and exemption.

Exportation

For exportation, China devotes greater efforts and adopts various measures to ensure the quality and safety of the exported pharmaceuticals and medical devices, including publishing the “white list” and the “blacklist”, and requiring the exporting enterprise to provide a written or electronic statement undertaking when making customs declarations that the exported products have obtained marketing authorisations of medical devices in China and meet the quality standard requirements of the importing countries (regions). China Customs and its local counterparts have promulgated measures to accelerate the import and export process of COVID-19-related vaccines and reagents.

11.6 Drivers for Digital Health Innovation Due to COVID-19

China introduced new rules to encourage digital healthcare innovation and digital transformation due to COVID-19, including but not limited to online health assessment, health guidance, health education, follow-up visits for chronic diseases, etc. It specially proposes to actively develop telemedicine services and to standardise internet diagnosis and treatment consulting services.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

Compulsory licensing of IP rights is regulated in the Patent Law, as discussed in **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

So far, COVID-19 treatments or vaccines are not exempted from liability under the PRC law.

11.9 Requisition or Conversion of Manufacturing Sites

In China, the Emergency Response Law and the Prevention and Treatment of Infectious Diseases Law provide that the requisition or conversion of manufacturing sites are allowed due to the outbreak of a public health emergency, including COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

Generally, public hospitals shall purchase medicines and medical devices that have been listed on a centralised procurement platform. After the outbreak of COVID-19, many provinces and cities issued special measures to allow public hospitals to procure the pharmaceuticals and medical devices to prevent and treat COVID-19 from certain suppliers directly.

Furthermore, to ensure the accessibility of COVID-19 therapeutic drugs, the NHSA issued the Guidelines for Price Formation for COVID-19 Therapeutic Drugs (for Trial Implementation), based on which the first-sale price of COVID-19 therapeutic drugs will be approved by one of the six appointed provincial Healthcare Security Administrations and applied to the whole country to ensure the newly approved COVID-19 therapeutic drugs can get to market faster.

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