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China: Law & Practice

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Global Law Office

CHINA

Law and Practice

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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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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, the DAL governs various drug-related activities, including drug development, registration, manufacturing and distribution.

In order to address statutory requirements under the DAL, GxP (good practice) rules on laboratory, clinical trials, manufacturing, distribution and pharmacovigilance have also been enacted, as well as administrative measures on drug registration, manufacturing, distribution and recall, etc. 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 Medical Devices Administration Law was included in the national legislative planning in 2023, and its legal hierarchy is higher than the effective Regulations for the Supervision and Administration of Medical Devices (RSAMD); it aims to better regulate the medical device market by consolidating the responsibilities of related parties. The RSAMD were amended in 2021 to officially incorporate marketing authorisation holder (MAH), conditional approval, emergency use, device unique identification, etc, into the regulatory frameworks. The amendments significantly increased administrative punishment for violation and imposed legal liabilities on the legal representatives and persons in charge of entities violating RSAMD. 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.

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 update and specify the regulatory procedure and requirements for medical device and IVD reagent registration and filing, respectively.

Regulatory Bodies

State Administration for Market Regulation (SAMR)

The SAMR is the national authority for the market supervision, administration and law enforcement of pharmaceuticals and medical devices, in the areas of anti-monopoly, product quality safety, food safety, fair competition and commercial bribery, the issuance of business registrations, and certifications and accreditations, among other things.

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 (AMR) are in charge of certain permit issuance and law enforcement on pharmaceuti-

cals and medical devices on the city and county levels.

National Health Commission (NHC)

The NHC 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. It supervises the National Administration of Traditional Chinese Medicine and the National Disease Control and Prevention Administration.

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.

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.

Administrative review is the prepositive procedure to challenge regulatory body decisions. If the decisions made by the reviewing body are unacceptable, a lawsuit before the court could be filed, unless the administrative review decisions are final as prescribed by law. Alternatively, proceedings may be instituted directly with a court, except in certain circumstances in which an administrative review must first be applied for. Once the court accepts the case, no further administrative review could be resolved.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals

The DAL classifies and differentially regulates drugs as prescription drugs and non-prescription (over-the-counter – OTC) drugs. 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 three classes according to their risk levels and expected purposes, structural features, methods of use and other qualities. Class III medical devices have the highest risk level, and their safety and effectiveness should be ensured under strict control.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The DAL and the Administrative Measures for Drug Registration 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. Notably, the newly issued Measures for the Supervision and Inspection of Drug Clinical Trial Institutions (Trial) tailor the rules on supervising compliance with the GCP for Drug Trials

and other relevant rules by the institutions in the process of filing and clinical trials. These Measures stipulate that provincial medical products administration (MPA) may employ various inspections to supervise clinical trial institutions. The MPA will require those institutions found to be "non-compliant" to suspend any new clinical trials for drugs.

The Frequently Asked Questions on Rapid Reporting of Safety Data during Drug Clinical Trials was updated to version 2.0 in 2023, aiming to align with the relevant International Council for Harmonisation regulations.

Likewise, 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. For clinical trials for IVD reagents, the NMPA provides special principles with a separate guideline.

The newly issued Trial Measures for the Review of Sci-tech Ethics Clinical requires that entities engaged in the life sciences, medicine and other sci-tech activities shall set up a sci-tech ethics (review) committee to assess the sci-tech ethics risks, conduct an ethical review, etc. As such, clinical trials for drugs and medical devices must comply with the relevant ethical review requirements.

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). A clinical trial must be authorised by the Centre for Drug Evaluation (CDE) of the NMPA before its implementation. The general steps for securing pharmaceutical 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 if it has not received any objection or query from the CDE within 60 days of acceptance of the clinical trial application;
- if there is no objection from the CDE, the sponsor may implement the clinical trial after the 60-day period, which will be re-calculated if supplementary documents are required; and
- if the CDE issues an objection, the sponsor may reply in writing concerning 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.

Clinical trial requirements for medical devices vary according to the relevant classification. Specifically, Class I medical devices are exempted from clinical evaluations, while Class II and III medical devices may undergo clinical evaluations or clinical trials 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 conducted by the NMPA.

- Clinical trial – if the existing clinical literature and clinical data are insufficient to demonstrate 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. The newly issued Specifications for Drug Clinical Trial Plan Submission and Review reiterate that an applicant shall register the drug clinical trial plan on the platform prior to conducting a drug clinical trial.

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; using such tools is subject to generally applicable laws and regulations concerning personal information protection, online advertising, etc.

2.5 Use of Data Resulting From Clinical Trials

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

The Personal Information Protection Law (PIPL) provides a legal framework for the administration of handling personal information. During clinical trials, sites, principal investigators, sponsor-designated monitors and other third parties may access trial subjects' personal information. However, sponsors will generally only receive anonymised data from the trial. Moreover, the sharing and transferring 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 samples and data (HGR) are governed by the Biosecurity Law and the Administrative Regulation on Human Genetic Resources ("HGR Regulation"). Currently, foreign parties are only permitted to use Chinese HGR upon filing/approval by the HGR authority and are strictly prohibited from collecting or storing Chinese HGR in the PRC and transferring the Chinese HGR overseas. Failure to obtain such filing/approval may result in administrative liabilities or even criminal liabilities. The newly issued Implementation Rules on the HGR Regulation provide specific guidance on determining foreign parties and a more specific scope of HGR, excluding clinical data, imaging data, protein data and metabolic data on the top of the HGR Regulation.

2.6 Databases Containing Personal or Sensitive Data

In addition to the statutory requirements set out in **2.5 Use of Data Resulting From 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, the standardisation of clinical trial data, quality control and the assessment of clinical data.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The DAL defines a "drug" as a substance used to prevent, treat or diagnose human diseases and intended to regulate human physiological functions, for which usage and dosage are specified for indication/primary treatment. The list of types of drugs 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, IVD reagents and calibrators, materials and other similar or related articles (including computer 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 Center for Medical Device Evaluation (CMDE) of the NMPA is responsible for the technical evaluation of medical devices. The NMPA released Opinions on Further Strengthening and Improving Medical Device Classification Management in 2023, outlining critical tasks concerning medical device classification, including improving classification principles and catalogue and proposing to modify the classification-related rules. The NMPA has updated the Medical Device Classification Catalogue accordingly, indicating its commitment to maintaining the regulatory environment with the rapid development of medical device technologies and the industry.

The following applies to 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 submit a registration application accordingly.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Marketing authorisation applications for biologic medicinal products generally follow 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 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 Pharmaceuticals 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 can revoke a 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, the NMPA could cancel the marketing authorisation if an approved product lacks effectiveness, has material adverse effects or risks human health.

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

There are three types of registration applications for drugs:

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

Drug Registration

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 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.

Specifically, the CDE has issued specifications on facilitating the registration review of marketing authorisation applications for innovative drugs that are specific to children, used for the treatment of rare diseases or applicable to special procedures for drugs with breakthrough effects. These specifications clearly outline the timeframe for communications (30 days) and registration review (130 days) for innovative drugs that fall within their scope.

Re-registration

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

Supplemental Applications

These are generally required for changes to drugs with marketing authorisation, such as material changes in the drug manufacturing, changes related to drug effect and risks in the instructions, changes of the MAH, etc. Notably, when changing the MAH, the transferee must be capable of quality management, risk prevention and control, and of providing liability compensation to ensure drug safety, effect and quality control. For approved changes, the MAH may be granted a grace period of up to six months from the date of approval to implement the change, except for changes related to drug security.

The NMPA issued the Administrative Measures for Drug Standards in 2023, requiring MAHs to submit the proposed standards for drug registration during their applications or supplemental applications. Any change to registration standards requires a supplementary application, filing or report, depending on the risk levels.

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

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

- a registration procedure for an innovative medical device;
- a priority registration procedure for medical devices that:
  (a) have obvious clinical advantages for certain diseases or are in urgent clinical demand without homogeneous approved medical devices; and
  (b) are listed in the national key R&D projects; and
- an emergency registration procedure for medical devices required 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 the marketing authorisation of medical devices.

Regarding the application for Class I devices, the municipal MPA (for domestic devices) or the NMPA (for imported devices) shall be provided with the filing materials, which are generally as same as those for Class II and III medical devices administrated by the registration process. The MAH must file any changes to the filing items of Class I devices with the original filing authority.

Subject to the above procedures, the NMPA has required registration applications for drugs and certain medical devices to be conducted via the electronic system since 2022.

3.5 Access to Pharmaceuticals 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 is used on patients outside the clinical trial setting but with similar conditions.

In addition to the above requirements under the DAL, certain regions have introduced regional

rules for expanded access programmes. Both Tianjin and Shenzhen have issued Regulations on the Promotion of Cell and Gene Industries, which permit expanded access programmes regarding cell and genetic drugs held in Tianjin and Shenzhen Special Economic Zone on certain premises, such as approval for expanded clinical trials and submission of the marketing authorisation application to the CDE for such drugs.

The RSAMD also has similar requirements for an expanded access programme for investigational medical devices. Moreover, the newly issued Regulations for the Emergency Use of Medical Devices specify an emergency use system that permits the use of medical devices without marketing authorisations in public health emergencies, including implementing authorities and their responsibilities, detailed procedures for expert verification, etc.

3.6 Marketing Authorisations for Pharmaceuticals 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:

- implementing 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 NMPA has promulgated Guidelines on Pharmacovigilance Inspections and Good Practice for Pharmacovigilance Systems to guide a drug MAH in establishing a pharmacovigilance system.

To refine the quality and safety management throughout the entire drug life cycle and clarify the key responsibilities of an MAH, the newly issued Provisions on the Supervision and Administration of Drug Marketing Authorisation Holder Implementation of the Main Responsibility of Drug Quality and Safety summarise relevant provisions previously scattered across the DAL and other laws and regulations.

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 medical device adverse events; and
- establishing a tracking and recall system.

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

The official websites for the CDE (for drugs), the CMDE (for medical devices) and the NMPA (for both drugs and medical devices) enable third party 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 CDE's official website. The public can also access granted

marketing authorisation information such as approval number, manufacturing enterprise with production site, approved date, dosage form and specification via the relevant database on the NMPA's official website. Third parties can access refused application information on the NMPA's official website.

Medical Devices

Third parties can access less information about medical devices compared to drugs. The pending marketing authorisation information is only available to applicants. Refused marketing authorisation information for refused devices, including acceptance number, device name, the applicant and its local deputy (if it is an overseas medical device), can be accessed 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 during 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 Pharmaceuticals and Medical Devices

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") sets out the provisional measures and special requirements related to border measures and criminal procedures against counterfeited products. As a WTO member, China follows the obligations outlined by the TRIPS Agreement. Moreover, the Regional Comprehensive Economic Partnership requires that committed members, including China, have procedures in place to suspend the release of suspected counterfeit goods or to destroy counterfeit goods.

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 and provides certain evidence, it could request Customs to seize the infringing goods. Furthermore, voluntarily completing IP Customs Filing would obtain more assistance from Customs, which will proactively notify the rights-holder of suspected infringing drugs or medical devices upon discovery.

Customs will seize counterfeit goods if the rights-holder confirms and provides a bond. Besides, Customs is authorised to suspend imports or exports of counterfeit goods and to impose fines accordingly. Such wrongdoing may trigger criminal liability. 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 Pharmaceuticals and Medical Devices

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

Pharmaceuticals

Pharmaceutical manufacturing plants are required to obtain drug manufacturing licences, even for MAHs that lack manufacturing capacity and outsource manufacturing work to other manufacturers. 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.

To further implement the responsibility of MAHs in ensuring the quality and safety of outsourced drug manufacturing, since October 2023 the NMPA has imposed more stringent and detailed requirements in terms of licensing, quality management and supervision of outsourced drug manufacturing. The NMPA has developed corresponding on-site inspection guidelines, which ensure that MAHs and manufacturing enterprises have more detailed reference criteria.

Medical Devices

In accordance with the Measures for the Supervision and Administration of Medical Device Production (2022 revision), the types of authorisation for medical device manufacturers differ depending on the classification of devices.

- Class I devices: the manufacturer shall conduct a filing with the municipal MPA for the manufacturing of Class I devices.
- 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 Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

Drug Distribution Licence

In support of the revised DAL (2019), the SAMR officially implemented the Measures for the Supervision and Administration of Drug Quality in Operation and Usage in January 2024. These measures govern matters related to drug distribution licences, and integrate and replace the earlier Measures for the Administration of Drug Operation Licences and Measures for the Supervision and Administration of Drug Circulation.

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 distribu-

tion licence. The licence is valid for five years and can be renewed within two to six months before expiry. The relevant provincial MPA will review the application, conduct on-site examinations and decide whether to approve it. An application for changes to licensed matters of a drug distribution licence must be submitted to the issuing authority, which will decide within 15 days from the date of receiving the change application. In addition, a wholesale drug distributor must have a self-operated warehouse that is appropriate for its range of products and scale of operations.

If a wholesale drug distributor (including an MAH) is an online seller, it shall report to the provincial MPA by filing an information report form.

Medical 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 an application for renewal within 30 to 90 working days before expiry.

Any violations of the Quality Management Standards for the Operation of Medical Devices may lead to the revocation of the wholesale medical devices distribution licence due to the impact on product safety and effectiveness. Thus, a wholesale medical device distributor is also required to comply with the revised Quality Management Standards for the Operation of Medical Devices, which will officially come into effect on 1 July 2024. This includes new requirements related to the establishment and improvement of the distribution quality management system.

If a medical device distributor (including an MAH) is an online seller, it shall complete the medical device online sales information form. This form requires pre-filing with the local municipal MPA, providing information such as the medical device manufacturing licence, the medical device distribution licence or medical device filing certificate number, etc. Any changes to the filed information should be promptly notified.

5.2 Different Classifications Applicable to Pharmaceuticals

For the 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 Pharmaceuticals and Medical 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.

The SAMR, the NMPA, the NMPA’s designated drug test institutions, the Ministry of Commerce

of the PRC (MOFCOM) and China Customs all have the power to enforce relevant laws and regulations. The NMPA and its local counterparts govern the administration of the use of imported pharmaceuticals and medical devices.

6.2 Importer of Record of Pharmaceuticals 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/ exported goods).

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 or a Drug Manufacturing Licence (for active pharmaceutical ingredients and intermediate agents).

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Prior Authorisations for Importation of Pharmaceuticals

The following require prior authorisation:

- in general, imported pharmaceuticals must obtain marketing authorisations from the NMPA prior to importation – an additional 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;
- 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 Importation of Medical Devices

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;
- if the imported medical devices fall into the Catalogue of Commodities Subject to the Automatic Import Licence Administration, an automatic import licence is required; and
- if medical devices are imported for emergency use, an approval from expert evaluation organised by the CMDE of the NMPA is required.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

The importation of drugs or medical devices is subject to registrations/permits, compulsory national or industrial standards, and specific regulations. To guarantee the public's safe use of pharmaceuticals and medical devices, the laws and regulations specify several reasons for prohibiting importing, including but not limited to uncertain curative effect, serious adverse reac-

tion, harm to the human body, expired, invalid, obsolete or used.

6.5 Trade Blocs and Free Trade Agreements

China has signed and acceded to various trade blocs and free trade agreements, including the Regional Comprehensive Economic Partnership, the Framework Agreement on Comprehensive Economic Cooperation with ten members of the Association of Southeast Asian Nations, the Preferential Trade Agreement (the Asia-Pacific Trade Agreement) and 17 bilateral Free Trade Agreements (FTAs). 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

Pharmaceuticals

The prices of most drugs are mainly determined by market competition, while the prices for narcotic drugs and Class I psychotropic drugs that are listed in the Central Pricing Catalogue are capped by the government.

Nonetheless, government policies may 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;
- the "Two-invoice System" 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;
- the 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 Pharmaceuticals or Medical Devices

PRC law does not require the prices of pharmaceuticals and medical devices to be benchmarked or otherwise 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 drug suppliers with respect to BMI funds coverage.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Pharmaceuticals

The NHSA and the Ministry of Human Resources and Social Security (MOHRSS) jointly issued the latest version of the National Reimbursement Drug List (NRDL) in 2023. 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 January 2024, reiterates that all provincial authorities shall implement the same NRDL with limited exceptions, including ethnic medicines, preparations of medical institutions and Chinese medicine tablets.

Medical Devices

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 local BMI funds can reimburse.

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

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Pharmaco-economic 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 to add a drug into the NRDL or to adjust its reimbursement coverage.

A 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, to avoid wasting medical resources or taking advantage of the BMI funds.

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

- The BMI funds indirectly require physicians to consider the BMI budget when prescribing drugs and to use medical consumables reimbursed by the BMI funds.
- Hospitals are required to prioritise drugs and medical consumables that are centrally procured.
- Diagnosis-related group payment methods (DRGs) and the big data diagnosis-inter-

vention package (DIP) are aimed to be fully implemented and expanded to all medical institutions by the end of 2025, and will pressure hospitals to control medical expenses so may influence physicians' prescription behaviours. The NHSA is building an intelligent monitoring system for BMI fund supervision of the DRGs and DIP payment methods.
- Local authorities of the NHSA – along with other departments – conduct examinations of the use of BMI funds through diverse inspections, such as daily supervision, special inspections, joint inspections, unannounced inspections and inspections based on whistle-blowing. The increasingly severe punitive measures imposed on designated medical institutions and drug retailers contracting with the agencies of the BMI, 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. The special rectification campaign to crack down on BMI fund fraud led by the NHSA focuses on acts of obtaining insurance benefits in a deceptive manner and monitors how the BMI funds are reimbursed on key drugs and medical consumables with top billing.

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 a drug's use, 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, and are subject to the same regulatory requirements as general medical devices. 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 provide hospital-to-hospital technical support for diagnoses and treatments by means of modern information and communication technologies.

Physicians can conduct online diagnoses and treatments for patients with common or chronic diseases whose first diagnosis 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 relevant rules.

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 AMR. 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. In any case, information on pharmaceuticals and medical devices presented online shall be accurate and science-based.

The Measures for the Administration of Online Advertising further prohibit the publishing of advertisements for pharmaceuticals and medical devices by claiming health and well-being knowledge.

8.4 Electronic Prescriptions

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

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

- online retailers of pharmaceuticals shall be responsible for the authenticity and reliability of the electronic prescription sources, as well as the adoption of a real-name authentication system;
- the third-party platform for the online sales of pharmaceuticals shall be responsible for verifying the electronic prescriptions; and
- online retailers of pharmaceuticals shall mark used electronic prescriptions to avoid repeated use thereof.

As of 31 October 2023, electronic prescription centres have been deployed in all provinces and officially applied in more than 20 provinces.

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 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 legality of the information displayed.

If the drugs are sold to individuals, the distributor should also conduct a prescription examination, set up an online pharmaceutical service system and comply with special rules about the information displayed 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 with the local MPA, which will publish the filing information and be responsible for supervising the online distribution activities.

Online sales of medical devices are permitted. 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. Furthermore, relevant information regarding the online sale of a medical device 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, processing, provision, disclosure, deletion or transfer of such data records is subject to the PIPL, and the processing 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 the HGR Regulation with its Implementation Rules (see **2.5 Use of Data Resulting From Clinical Trials**); and
- aggregated electronic health records in hospitals, which may be deemed population health information and medical big data.

Any health information and medical data of PRC citizens generated within the PRC shall be subject to national regulation and use based upon concerns regarding national security and citizens' lives and health. Medical big data must be stored in a reliable server located within the PRC, in a way that satisfies the national standards of data storage, disaster recovery, back-up and security management. Regarding the transfer of data, security assessment by cyberspace administration prior to the outbound transfer of important data and personal information is required. Furthermore, the Measures on the Standard Contract for Outbound Transfer of Personal Information promulgated in 2023 provide a more efficient way for the outbound transfer of data by entering the standard contract if certain conditions are met by the processor.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceuticals 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;
- several Provisions and Interpretations issued by the Supreme People's Court on patent-related issues;
- the Guidelines for Patent Examination; and
- the Administrative Adjudication Measures for, and Measures for the Implementation of, the Early Resolution Mechanism for Drug Patent Disputes (for Trial Implementation).

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 application 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 2023, clearly provide that the examiner shall assess whether the supplemental data submitted by the applicant meets 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 that are 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 of "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 manufacturing procedure 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, applicable to all types of patents; or
- to compensate for the time spent during review and approval for new drugs – this only applies to invention patents related to new drugs. The compensatory term is up to five years and the total Patent Term of relevant new drugs upon marketing authorisation approval shall not exceed 14 years.

If the patentee or an interested party is dissatisfied with the decision of whether to grant patent term compensation, it may apply to the China National Intellectual Property Administration (CNIPA) for administrative reconsideration. Such reconsideration decision can be appealed in turn through an 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 a patent:

- 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, it 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.

A party 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. If dissatisfied with the compulsory license decision or royalties, the patentee or related parties may file a lawsuit.

9.6 Proceedings for Patent Infringement

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

- administrative actions:
  - (a) the patentee or any interested party can file complaints with competent evidence before the CNIPA (and its local counterparts), and the local IPA can also 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 – see **3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices** regarding the border measures that can be taken;
- 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 Proceeding 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 decide whether to accept the case:
  - (a) if not, it will issue an award within seven days notifying the unacceptance, which is appealable;
  - (b) if yes, 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; and
- the court will conduct oral hearings and make its decision.

Either party can file an appeal to a higher court 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 investigates 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.

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. Relevant implementation measures stipulate that an 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 that they do not cover the generic drug.

The patentee or the licensee of the patent 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 is 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

Regarding counterfeit pharmaceuticals and medical devices, the public interest and the lawful rights of the rights-holder may be protected in the following ways.

- Administrative proceeding – a consumer can file a complaint to the local AMR, and any party can file a whistle-blowing report with the administrative authorities, such as the local AMR, the local MPA, Customs, etc. After

investigations, the administrative authorities may 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 decision.
- 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. Applicable laws prohibit any unauthorised use of a 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. 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.

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

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 clothing 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 clothing, rescue and treatment devices, and relevant materials may be carried out before the required customs procedures are completed.

Exportation

For exportation, China devotes greater efforts and adopts various measures to ensure the quality and safety of exported pharmaceuticals and medical devices. China Customs and its local counterparts have promulgated measures to accelerate the import and export process of COVID-19-related vaccines and reagents.

As the global health emergency status of the COVID-19 pandemic concludes, transitioning into the normalised management phase of epidemic prevention and control, the Chinese government has adjusted its quality supervision measures for the export of epidemic prevention materials since August 2023.

11.6 Drivers for Digital Health Innovation Due to COVID-19

China introduced certain rules to encourage digital healthcare innovation and digital transformation due to COVID-19, including 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 is 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 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).

To improve the pricing mechanism for COVID-19 therapeutic drugs, the NHSA further promulgated a regulation based on the aforementioned guidelines, which introduces a three-tiered classification system (A, B, C) for COVID-19 therapeutic drugs that are not included in the NRDL. The healthcare security department is allowed to implement temporary medical insurance payment policies in response to the needs of epidemic prevention and control.

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