Chambers
Global Practice
Guides

Definitive global law guides offering
comparative analysis from top-ranked lawyers

Life Sciences 2022

China: Law & Practice

Alan Zhou, Coco Fan, Samantha He and Kelly Cao
Global Law Office

practiceguides.chambers.com

CHINA

Law and Practice

Contributed by:
Alan Zhou, Coco Fan, Samantha He and Kelly Cao
Global Law Office see p.25

CONTENTS

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). The DAL, together with its implementing rules, referred to as the DAL Implementing Regulations, 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), as well as administrative measures on matters such as drug registration, manufacturing, distribution, and recall, have also been enacted. In addition, 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) has been enacted to set up the regulatory framework for the administration of medical devices. The development, registration, manufacturing, and distribution of medical devices are, like pharmaceuticals, regulated by GxP rules, and administrative measures. Also, product-specific rules and guidelines have been released and implemented. The RSAMD was amended in 2021. The revised RSAMD officially incorporated marketing authorisation holder, conditional approval, emergency use, device unique identification, etc, into the regulatory frameworks. RSAMD 2021 also significantly increases administrative punishment for violation and further imposes legal liabilities on the legal representatives and persons in charge of the entities violating RSAMD. Further, the Administrative Measures on the Registration and Record-filing of Medical Devices ("Device Registration Measures") was released to update and specify the regulatory procedure and requirements for medical device registration and filing.

Regulatory Bodies

SAMR

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

NMPA

The National Medical Products Administration (NMPA), as a national bureau operating under the supervision of the SAMR, regulates the registration, post-market risk management, administration of safety and quality, formulation of industrial/national standards, and the supervision and inspection of pharmaceuticals and medical devices.

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

NHC

The National Health Commission (NHC) is a constituent department of the State Council. The NHC is mainly responsible for national health policies, the reform of the medical and health

care system, disease prevention and control, national drug policies, and the national basic drug system. The NHC supervises the National Administration of Traditional Chinese Medicine.

NHSA

The National Healthcare Security Administration (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, which 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, they 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 classifies 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), Pharmaceutical Research Information Guide for phase III Clinical Trials of Innovative Drugs (Chemical Drugs), provide guidance detailing involving parties' obligations, operational procedures, technical requirements, etc.

Likewise, as to 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 con-

ducted, while an array of review standards and guidance such as GCP further specifies operation guidance and technical requirements for conducting clinical trials. As for in vitro diagnosis (IVD) reagents, a special type of medical devices, the NMPA further 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 the drug-related laws). Before the conduct of clinical trials, it must be authorised by the Centre for Drug Evaluation (CDE) of the NMPA. The general steps for securing clinical trial authorisation are the following:

- 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 from 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 upon the receipt of 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. As to Class II and III medical devices, Subject to their safety and effectiveness, a clinical evaluation or even clinical trials could be triggered.

- 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 is 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 for Using Online Tools to Support Clinical Trials

There are no specific restrictions for 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 Resulting Data from the Clinical Trials

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

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

Human genetic resource sample and data (HGR) are governed by the Biosecurity Law, taking effect on 15 April 2021, and 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 Resulting Data 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 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 computer software) that directly or indirectly can be used 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 CMDE, is responsible for the technical evaluation of medical devices.

As to a product containing both a drug and a device (ie, a combination product):

- if its similar products on the market are categorised as a drug or a medical device, such 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 for other drugs, such verification and examination are subject to 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 conduct of clinical trials without pre-approval, use of unapproved package materials or containers, use of unapproved label or instructions, bribery, obtainment of a marketing authorisation by fraudulent means, etc. Conversely, even after obtaining market authorisation, if a product has been approved lacking effectiveness, having material adverse effect or risking human being's health, the NMPA could cancel the market authorisation.

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;
- registration inspection.

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

- registration for drugs with breakthrough effect;
- 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 with public health emergencies.

Re-registration is applicable when renewing a valid drug marketing authorisation before expiry.

Supplemental applications are generally required when there are changes on the drugs with market authorisation, such as material changes on the drug manufacturing, changes related to drug effect and risks on the instructions, change 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 providing liability compensation to ensure drug safety, effect and quality control.

Medical Devices

As to 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 for the quality management system which shall be complied with the GMP;
- submission of registration application documents; and
- regulatory review by the CMDE and the NMPA/provincial MPA.

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

- Registration procedure for an innovative medical device.
- Priority registration procedure for the following specific medical devices:
  (a) those that have obvious clinical advantages for certain diseases or in urgent clinical demand without homogeneous approved medical devices;
  (b) those that are listed in the national key R&D projects; and
  (c) medical devices 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 items variations (eg, change of the MAH's name or address). Currently, both need to be approved by the NMPA/provincial MPA. In addition, 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 authorization 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 application for Class I devices generally requires same materials as those for Class II and III medical devices are administrated by the registration process. Any changes for the filing items of Class I devices, the MAH must apply to the original filing authority.

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.

Under the RSAMD, similar requirement as drug 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:

- 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 executed Good Practice for Pharmacovigilance System provides practical and detailed measures for establishing 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), 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.

For drugs pending for approve, the information containing acceptance number, drug name, drug type, application type, registration category, company's name and accepted date, registration application status, are publicly available. Besides, the public can access granted marketing authorisation information such as approval number, manufacturing enterprise with its production site, approved date, dosage form, specification and relevant database among other information mentioned above. For any refused application information, third parties can access via search function provided by NMPA's official website.

For medical devices, third parties may access relatively less information than with regard 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 search function. Regarding marketing authorisation information for permitted devices contains marketing authorisation number, MAH's name and address, manufacturing site, device's name, type, specifications, structure, components and applicable scope and intended use, approval date, effective date and modified information is publicly available.

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 non-disclosure will cause 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 in-charge personnel and the legal representative of the violating entity could also face personal liabilities. In addition, 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 (TRIPS Agreement) sets out the provisional measures and special requirements related to border measures and criminal procedures against counterfeited products. China, as a member of the WTO, 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. Further, if a rights-holder voluntarily completes the IP Customs Filing, it would obtain more assistance from Customs; Customs 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 it is counterfeit and provides a bond. The 2020 Economic and Trade Agreement between the PRC and the United States of America (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 get drug manufacturing licences, even for MAHs who lack manufacturing capacity and outsource manufacturing work to other manufacturers. Though such MAHs do not need to build up their own plants, they are still required to establish manufacturing SOPs, designate quality personnel, etc. As to MAHs who need to change the package specification of imported products, they shall appoint a Chinese legal person to submit the sub-packaging filing with the CDE. In the events of outsource manufacture and/or sub-packaging, the manufacturing enterprise that carries out the manufacture and/or sub packaging shall also obtain corresponding manufacturing licence. The manufacturing licence is valid for five years and is renewable for another five years six months before expiry.

Separately, the DAL has abolished the Good Manufacturing Practice (GMP) certificate, but drug manufacturers must still comply with GMP requirements, and the NMPA and its local counterparts will strengthen scrutiny over manufacturing activities.

Types of authorisation for medical device manufacturers are different based upon the classification of devices. A manufacturing filing receipt from the municipal MPA is required for manufacturing Class I devices. The municipal MPA will immediately grant the receipt if all required documents are submitted. For 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 receipt 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 before six months 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

A wholesale drug distributor must maintain a drug distribution licence. The licence is valid for five years and is renewable six months before expiry. The relevant provincial MPA will review the application, conduct on-site examinations, and decide whether to approve the application. The 2019 DAL revision abolished Good Supply Practices (GSP) certificates but that does not mean supervision of drug distribution has been relaxed. On the contrary, drug distributors should pay more attention to compliance with GSP requirements as the NMPA and its local counterparts will strengthen scrutiny over distribution activities.

Class I, II and II Devices

Wholesale distribution of Class I devices does not require authorisation. As to Class II devices, a distributor should maintain a distribution filing receipt from the municipal MPA. The municipal MPA will grant the receipt if all the required documents are submitted. Wholesale distribution of Class III devices requires a distribution licence from the municipal MPA. The municipal MPA 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 six months before expiry.

5.2 Different Classifications Applicable to Pharmaceuticals

For different classifications which 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

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

6.2 Importer of Record of Pharmaceutical and Medical Devices

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

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:

- 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 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;
- comparator drugs (except narcotic drugs and psychotropic drugs) for the purposes of drug registration or consistency evaluation of generic drugs; and
- in addition, individuals bringing drugs to China for their personal use are exempted from the above requirements.

Prior Authorisations for Medical Device Importation:

- 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, China Compulsory Certification is required; and
- if the imported medical devices fall into the Catalogue of Commodities Subject to the Automatic Import License 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 in different rules. Generally, 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 compul-

sory inspection as per their HTS Codes shall be inspected upon the relevant importation.

6.5 Trade Blocs and Free Trade Agreements

For trade/regulatory facilitation, China has entered into 18 Free Trade Agreements, including Free Trade Agreements with Australia, Korea, Switzerland, Iceland, Singapore, New Zealand, Chile, Mauritius, the Maldives, Georgia, Costa Rica, Peru, Pakistan, Hong Kong, Macao, Cambodia, and the Regional Comprehensive Economic Partnership and the Framework Agreement on Comprehensive Economic Cooperation with other members of Association of Southeast Nations (ASEAN), as well as one Preferential Trade Agreement (the Asia-Pacific Trade Agreement).

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.

Though the government aims to leave 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 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);
- 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 "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, pricing of medical devices may be significantly influenced by regulatory factors, such as:

- 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 as aforementioned 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 that the prices of pharmaceuticals and medical devices be bench-

marked 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 2021 (NRDL), which lists the drugs currently covered by the BMI funds. Under the NRDL, pharmaceuticals are classified into Class A and Class B and each class is reimbursed differently by the BMI funds. Patients assume full costs for the drugs excluded from the NRDL.

The latest effective NRDL stipulates that all provincial authorities shall implement the same NRDL before June 30, 2022, 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. The Interim Measures for the Payment Management of medical consumables (draft for comments) sets up the rules specifically regulating BMI reimbursement for medical consumables and draw up a list similar to the NRDL.

As public hospitals are supported by state financial funds, 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), target to fully implement and expand to all medical institutions at the end of 2025, which measures may significantly affect how drugs, medical consumables, and medical services are reimbursed in the future if finally implemented.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Pharmacoeconomics analysis would be employed when assessing which drugs are to be included in the NRDL and the price for NRDL negotiations. Pharmacoeconomics 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 or 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. 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:

- currently, the BMI fund is subject to budget management and total amount control, and hospitals are responsible for a portion of any over-expenditure. Hospitals thus are incentivised to require physicians to consider the BMI budget when prescribing drugs and use medical consumables reimbursed by the BMI fund;
- hospitals are required to prioritise drugs and medical consumables 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;
- in addition, the DRGs and the DIP, being piloted in multiple cities, will pressure hospitals to control medical expenses, and thus may influence physicians' prescription behaviours;
- the increasingly severe punitive measures to the designated medical institutions and drug retailers contracting with the agencies of the BMI ("Designated Institutions") in the newly published Regulations on the Supervision and Administration of the Use of BMI Funds targets to restraint the fraud actives for the use of BMI Funds, and to strengthen the internal management control of the Designated Intuitions and 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 which fall within the scope of medical devices are subject to the same regulatory requirements for general medical devices while, at the same time, must meet the requirements under the standard of relevant registration technical review guidelines issued by NMPA.

8.2 Rules for Telemedicine

In the PRC, there are separate rules for telemedicine.

Under 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.

The special regulations for encouraging telemedicine services during COVID-19 are introduced in **11.6 Drivers for Digital Health Innovation Due to COVID-19**.

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. The 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. 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

There are no current national laws or regulations which specifically regulate the use of electronic prescriptions in the PRC. In practice, electronic prescriptions are allowed in diagnoses and treatment with the following requirements:

- online – electronic prescriptions are only allowed for common and chronic illnesses and may not include any narcotic drugs or psychotropic drugs. All electronic prescriptions must be issued with a physician's e-signature and must be reviewed by a pharmacist; and
- offline – prescriptions in digital form are widely used by offline hospitals, which are regulated in the same way as a paper prescription, and must be signed by a physician and reviewed by a pharmacist.

8.5 Online Sales of Medicines and Medical Devices

Online sales of drugs are generally permitted, except for drugs subject to special administration, such as vaccines, blood products, narcotic drugs, psychotropic drugs, toxic drugs for medical uses, radioactive drugs, and pharmaceutical precursor chemicals. An online drug distributor should meet the requirements applied to an offline drug distributor. Specific rules for online sales of drugs are under revision by the NMPA. 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 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;
- medical records, 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 is subject to the restrictions under Administrative Regulation on Human Genetic Resources mentioned in **2.5 Use of Resulting Data from the Clinical Trials**; and
- aggregated electronic health records in hospitals may be deemed population health information and medical big data. According to Data Security Law, Guide for Health Data Security, and 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 of 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 satisfies the national standards of data storage, disaster recovery, and back-up and security management.

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 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 (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 of Drug Patent Disputes (for Trial Implementation);
- the Administrative Adjudication Measures for Early Resolution Mechanism of Drug Patent Disputes;
- 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; and
- the Provisions of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Food and Drug Dispute Cases.

Rejection of patent applications for pharmaceuticals and medical devices are the most commonly encountered issues due to lack of:

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

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

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 Economic and Trade Agreement between the PRC and the USA.

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

- inventions or creations in violation of Chinese laws or social morality, or detrimental to public interests;
- inventions or creations 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 which takes 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 Patent Term Extension situations: one is to compensate for unreasonably delay during the patent examination process and is applicable to all types of patents; the other is to compensate for the time spent during review and approval for new drugs. The second situation 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). The decision made by the CNIPA 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, use, offer for sale, sale, or import of the pharmaceutical or medical device containing a patented invention or utility; or
- the use of the patented process of an invention or utility; or
- 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 necessary for 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 the 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 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 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 which 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 neither enjoys 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 fines; and
  - (b) customs – border measures as discussed in **3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices**; and
- 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 upon 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:

- 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, 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 and the Measures for Implementation of the Early Resolution Mechanism for Drug Patent Disputes (Trial) explains the Chinese efficiency-first patent linkage system. The latter stipulates that a MAH shall register its patent information on a Chinese listed drug patent information registration platform, which will be established by NMPA.

To clarify the procedural requirements, the supportive administrative adjudication measures and judicial interpretation further stipulate that, the patentee or the interested party can challenge the declarations before the court (judicial link) or the CNIPA (administrative link) within 45 days after such declaration is published. If they fail to apply for patent rights protection, the generic drug marketing license applicant may file a lawsuit with the patentee or the interested party as the defendant or request an administrative ruling for the confirmation that the drug does not fall within protection scope of patent rights.

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 AMR, MPA, Customs, etc. Also, the administrative authorities may conduct investigations ex officio against counterfeit pharmaceuticals and medical devices. The administrative authorities 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 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 etc.

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 other's commodity which is influential.

The patented design of pharmaceuticals and medical devices can be protected under the Patent Law. In addition, 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 trademark 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 that 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, distribution of medicines and medical devices are still subject to distribution permits, which is discussed in **5. Distribution of Pharmaceutical and Medical Devices**. China issued special regulations to severely crack down on the illegal manufacture and dis-

tribution 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.

11.2 Special Measures Relating to Clinical Trials

To ensure the effectiveness of safety management of clinical trials during COVID-19, the CDE published relevant Guidelines which is 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

There have been two regulatory pathways since before the outbreak of COVID-19 applicable for emergency approvals of pharmaceuticals or medical devices in China, ie, emergency approvals and conditional approvals.

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

The other regulatory pathway is to obtain market authorisation for pharmaceuticals (including vaccines) or medical devices upon additional approval conditions. Conditional approvals often occur when pharmaceuticals (including vaccines) or medical devices used for the treatment of rare diseases or serious life-threatening diseases that cannot be treated in an effective manner, or those urgently needed in response to public health events.

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

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

For vaccines, if a vaccine MAH lacks sufficient capacity to produce, subject to NMPA's case-by-case review, such MAH could apply to NMPA to designate a CMO to produce vaccines.

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, 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 "blacklist,", as well as requiring the exporting enterprise when making customs declarations to provide a written or electronic statement undertaking that the exported products have obtained marketing authorisations of medical devices in China and meet the quality standard requirements of the importing countries (regions).

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, and specially proposes to actively develop telemedicine services and 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, which is 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 requisition or conversion of manufacturing sites are allowed due to the outbreak of public health emergencies, 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.

Global Law Office (GLO) has become one of the largest and leading Chinese law firms, with more than 500 lawyers practising in its Beijing, Shanghai, Shenzhen, and Chengdu offices. Its life sciences and healthcare (L&H) practice group is one of the earliest L&H teams in China, having provided "one-stop" legal services for every area of the L&H 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 L&H 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. GLO's L&H Team deeply participates in the formulation of local codes of conduct and benchmark policies/rules. GLO's L&H Team also has close cooperation with associations such as the CPIA, the RDPAC and the ACCP.

AUTHORS

Alan Zhou is the leading partner of the life sciences and healthcare (L&H) practice group at Global Law Office, with a strong background in L&H practice. Mr Zhou has routinely represented multinational corporations, well-known Chinese state-owned and private enterprises, private equity/venture capital funds in the L&H area. As a participant or an external counsel, Mr Zhou has been engaged by local authorities and industrial associations for advising on legislation and industrial standards in the L&H industry, including guidelines on compliance, e-healthcare, medical insurance reform, and medical representative administration. Mr Zhou has been recognised for his expertise in the L&H area. Mr Zhou has been widely published both at home and abroad.

Coco Fan is a partner of the life sciences and healthcare (L&H) practice group at Global Law Office. She specialises in corporate, compliance, private equity and venture capital, and M&A. Her experience includes prescription medicine, over-the-counter medicine, contract research organisations, medical devices, bio-pharmaceuticals, health foods, clinical supply, vaccines, animal health, and hospitals. Ms Fan has advised multinational and private companies, and investors with respect to risk-assessment or health checks, tailored compliance training including anti-corruption, anti-trust and promotion. Ms Fan also advises on the establishment of industrial compliance management standards of pharmaceuticals and medical devices.

Samantha He is of counsel of the life sciences and healthcare (L&H) practice group at Global Law Office. Ms He focuses on the life sciences industry and has represented a number of major life sciences companies on compliance and regulatory matters and corporate issues. Through significant experience in the life sciences industry, Ms He has acquired insight into the evolving legal and regulatory landscape in China. She advises clients on NMPA regulatory matters across a range of sectors, including drugs and biologics, medical devices, and e-health products and services. Ms He also counsels' clients on transactions, including M&A, venture capital, licensing, and strategic collaboration.

Kelly Cao is a partner of the life sciences and healthcare (L&H) practice group at Global Law Office. Her main practice areas encompass dispute resolution, compliance and risk control, as well as labour and employment. Ms Cao has advised major life sciences companies in general compliance and dispute resolution, and assists multinational enterprises and well-known domestic enterprises with their disputes in litigation and arbitration. Ms Cao also provides legal services to multinational pharmaceutical corporations regarding establishing compliance systems and internal compliance investigations.

Global Law Office

36th Floor
Shanghai One ICC
No.999 Middle Huai Hai Road
Xuhui District
Shanghai 200031
China

Tel: +86 21 2310 8200
Fax: +86 21 2310 8299
Email: Alanzhou@glo.com.cn
Web: www.glo.com.cn

环球律师事务所
GLOBAL LAW OFFICE

Chambers Guides to the Legal Profession

Chambers Directories are research-based, assessing law firms and individuals through thousands of interviews with clients and lawyers. The guides are objective and independent.

practiceguides.chambers.com