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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 latest DAL revision has been effective since 1 December 2019. 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. Some of the above-mentioned regulations and rules were updated in 2020, and some are still under revision in order to reflect the amendments under the DAL compared to the previous version.

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 at the end of 2020 (Draft RSAMD 2020), though the official Draft RSAMD 2020 is yet to be released as of the end of February 2021.

The current effective RSAMD entered into effect as of 4 May 2017 ("current RSAMD"), which was amended at the end of 2020 ("RSAMD 2021"). RSAMD 2021 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. RSAMD 2021 is entering into force as of 1 June 2021.

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.

Other items of note

SAMR and NHSA, as government agencies directly under the State Council enjoying independent administrative functions, and NHC, as a constituent department of the State Council performing basic administrative functions thereof, are entitled to promulgate departmental regulations.

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.

In addition, the processes for challenging inspection and test results of pharmaceuticals and medical devices made by the inspection agencies under the NMPA are provided under the DAL and the RSAMD. The challenging party can apply for re-inspection pursuant to the DAL or the RSAMD, as applicable.

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, including competent authorities, qualification for sites, application requirements that sponsors should meet to obtain clinical trial approvals, etc. 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 Administrative Measures for the Registration of Medical Devices and the RSAMD 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 further specifies operation guidance and technical requirements for conducting 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.

- All clinical trials of pharmaceuticals shall be reviewed by an ethical committee prior to initiation.
- Prior to filing with NMPA for the clinical trial authorisation of a new drug, a sponsor may need to apply for a pre-consultation meeting with the NMPA at which the sponsor presents relevant data and draft protocols, discusses concerns regarding pharmaceutical development, and receives guidance.
- 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 when the application fees are paid. Within the 60-day period, the CDE may require the sponsor to submit supplementary documents or to prohibit the clinical trials.
- The 60–day review period begins again after the sponsor submits the supplementary documents required by the CDE. If there is no objection from the CDE, the sponsor

may implement the clinical trial at the conclusion of the 60-day period. Similarly, if the sponsor is required to submit supplementary documents the 60-day review period will be re-calculated.
- 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.

Under current RSAMD, Class I medical devices and certain Class II and III medical devices are exempted from clinical trials. Under RSAMD 2021, when carrying out a clinical evaluation for registration, in the event that existing clinical literature and clinical data are not sufficient for evidencing the safety and effectiveness of a medical device, a clinical trial should be implemented for such a medical device.

With respect to the clinical trial for certain high-risk Class III medical devices, the sponsor may implement a clinical trial for a medical device if it has not received any notice from the Centre for Medical Devices Evaluation of the NMPA (CMDE) within 60 business days from the date when the application fees are paid upon acceptance of the application by CMDE.

2.3 Public Availability of the Conduct of a Clinical Trial

The Drug Clinical Trial Registration and Information Platform hosted by the NMPA is a public database providing detailed information regarding clinical trials of pharmaceuticals for the purpose of registration, including the name of the pharmaceuticals, the name and purpose of the study, information about the sponsor, the standard for recruiting patients, important milestones, investigators, investigating institutes, detailed descriptions of members of the ethical committee, and the current status of the clinical trial. The sponsor shall keep the relevant information updated during and at the end of the clinical trial and could be punished if it fails to provide authentic information.

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.

- Personal information refers to information that can be used independently to identify or be combined with other information to identify a natural person. 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.
- Health data such as medical records are retained and managed by sites, while a copy of certain health data will be entered into the electronic data capture (EDC) system for sponsors' further usage.
- Human genetic resource sample and data (HGR) are governed by the Administrative Regulation on Human Genetic Resources (HGR Regulation). As of April 15, 2021, the Biosecurity Law with a higher legal effect will also focus on and strengthen the HGR administration. 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 in a form of co-operation with a domestic entity, and such co-operation should be filed with (for clinical trial purposes) or approved by (for other purposes) the HGR authority. To clarify, foreign parties refer to foreign individuals or foreign entities that are established by foreign entities/individuals or controlled by them. 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 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 DAL simplifies the list of types of drugs and now only includes traditional Chinese medicines, chemical drugs, and biological products. The CDE evaluates drug marketing-authorisation applications submitted by manufacturers or drug-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 those for drugs. Having said that, it is compulsory to conduct verification and examination on manufacturing sites for biologics, innovative drugs, and improved new drugs 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. Applications for renewal of marketing authorisations should be submitted to the NMPA or provincial MPA (PMPA) six months before expiry. 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 (for the purpose of verification on accuracy and consistency of application documents, manufacturing conditions, compliance and reliability of research data, on-site examination on the manufacturing site, bundling check on active pharmaceutical ingredients (API), pharmaceutical excipients, packaging materials and containers that directly touch the drugs, etc);
- registration inspection (for the purpose of re-checking the drug standard and sample 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.

- Under the current regulations, Class II and III devices are required to be registered with the PMPA (for domestic Class II devices) or the NMPA (for domestic Class III and imported Class II and III devices). The following processes are generally required to obtain a new marketing authorisation:
  (a) submission of technical product requirements;
  (b) product testing for registration by government-certified agents;
  (c) clinical trials if required by law;
  (d) submission of application documents; and
  (e) regulatory review by the CMDE and the NMPA/PMPA.
- Except the above, there are certain special procedures to shorten the time or facilitate the registration review, under relevant regulations and RSAMD 2021, including:
  (a) special review procedure for an innovative medical device;
  (b) registration of medical device treating diseases which are severe but lack effective treatment with additional approval conditions; and
  (c) approval of the medical device for emergency use within certain scope and period of time for the purpose of tackling serious public health emergencies or other serious threats to public health, upon approval of NMPA.
- Changes to these marketing authorisations are divided into licensing item variations (eg, change of product specification or technical requirements) and registration items variations (eg, change of the MAH's name or address). Currently, both need to be approved by the NMPA/PMPA, while under RSAMD 2021, changes may be subject to approval by, record-filing with or notice to the relevant authorities, as applicable. In addition, changes to licensing items may trigger an additional technical review by the CMDE. Transfer of licences for Class II and Class III devices can be accomplished by changing the MAH's name under the registration items variation.
- With respect to the application for Class I devices, the municipal MPA (for domestic devices) or the NMPA (for imported devices) must be notified. Applicants must prepare a description of the product's technical requirements. Product-testing is not required to be conducted by government-certified agents. The applicant can submit a testing report made either by itself or its designated third party. The MAH must apply to the appropriate regulatory authority (with supporting documents) before making changes to marketing authorisations of Class I devices.

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 current RSAMD, there is no effective rule for an expanded access programme for investigational medical devices. The RSAMD 2021 provides statutory requirements for granting patients access to pre-approval to investigational medical devices similar to those applying to drugs.

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, including:
  (a) carrying out post-marketing studies (including phase IV clinical trials);
  (b) monitoring and reporting adverse reactions to drugs; and
  (c) establishing a drug quality assurance system and risk management system.
- Conducting regular post-market launch appraisals.
- Establishing a release process for drug market launches.
- Establishing and implementing a drug tracking system.
- Establishing an annual report system.

The Good Practice for Pharmacovigilance System (draft for comments), established by the NMPA in 2020, provides practical and detailed measures for establishing a pharmacovigilance system.

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

- monitoring and reporting medical device adverse events; and
- re-evaluating the effectiveness and safety of the registered medical device.

Under the RSAMD 2021, a medical device MAH shall also

- establishing a quality management system and maintain its effective operation;
- make plans for post-marketing research and risk management and control and ensure the effective implementation; and
- establish 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 or refused marketing authorisation information containing acceptance number, drug name, drug type, application type, registration category, company's name, accepted date, registration application status, and the CDE's notification, are publicly available. Besides, the public can access granted marketing authorisation information such as approval document references, technical review reports, and pharmaceutical literature among other information mentioned above.

For medical devices, third parties may access relatively less information with regard to medical devices than with regard to drugs. The pending marketing authorisation information is only available to applicants, while third parties may inquire about relevant information only if they know the acceptance number. Refused marketing authorisation information for refused devices including acceptance number, device name, applicant, and agent can be accessed. Regarding marketing authorisation information for permitted devices contains marketing authorisation number, MAH's name and address, device's name, type, model, specifications, structure, components and applicable scope, approval date, and effective date are publicly available.

Under the Regulations on Government Information Disclosure and relevant NMPA rules and circulars, 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 sub-standard 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, licence revocation, etc. The personnel in charge of the violating entity and the legal representative 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 counter-

feited 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 release the goods if the rights-holder confirms that the shipment is authorised, or 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, such as prohibiting counterfeit products from entering into commerce channels even after their unlawful trademarks have been removed.

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. As to MAHs who lack manufacturing capacity and outsource manufacturing work to other manufacturers, according to the newly issued rules, they are also required for manufacturing licences. Though such MAHs do not need to build up their own plants, they are still required to establish manufacturing SOPs, designate quality personnel, etc. The manufacturing licence is valid for five years and renewable for another five years within 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, by, for example, regular inspections, the frequency of which is determined by the characteristics of the relevant pharmaceuticals.

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 PMPA 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 within six months before 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.

- A wholesale drug distributor must maintain a drug distribution licence. The licence is valid for five years and is renewable within six months before expiry. The relevant PMPA 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.
- 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 immediately 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 on-site examinations, 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 within 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. IMPORT AND EXPORT OF PHARMACEUTICALS AND MEDICAL DEVICES

6.1 Governing Law for the Import and Export 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 Regulations for the Supervision and Administration of Medical Devices, 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.

6.2 Importer of Record of Pharmaceutical and Medical Devices

An importer of record of pharmaceuticals and medical devices is required to register 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 Registration of Customs Declaration Enterprise with Customs.

If the importer of record concurrently acts as the applicant for the NMPA's 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 as domestic medical devices;
- 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. For example, 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.

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 fund are determined by authorities including the NHSA, and prices for certain drugs covered by BMI 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 benchmarked or otherwise be set in reference to the prices of the same products in other countries. However, the NHSA does monitor drug prices at home and abroad for the purpose of making timely warnings of any abnormal changes to drug prices and supply. Prices in other countries might also be used as references during negotiations between the NHSA and suppliers of drugs with respect to BMI 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 2020 (NRDL), which lists the drugs currently covered by the BMI fund. Within the NRDL, pharmaceuticals are classified into Class A and Class B and each class is reimbursed differently by the BMI fund. Class A drugs include drugs that are clinically necessary, widely used, and have good curative effects and relatively low prices.

Expenses for Class A drugs are fully included in the reimbursement scope and shall be reimbursed in the prescribed proportion under the BMI reimbursement policy. Class B drugs include drugs that have good curative effects and relatively higher prices compared with Class A drugs. Expenses for Class B drugs are reimbursed in the prescribed proportion according to the BMI reimbursement policy after deducting patient co-pays. Patients assume full costs for the drugs excluded from the NRDL.

The NHSA withdrew the power previously granted to provincial authorities to adjust the scope of Class B drugs by no more than 15% in their provincial reimbursement drug lists (PRDL) in 2019, and all provincial authorities shall implement the same NRDL after a transitional period of three years, 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. In the future, the NHSA may issue a set of rules specifically regulating BMI reimbursement for medical consumables and may draw up a list similar to the NRDL

with respect to reimbursement of medical consumables by the BMI.

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), are being piloted in multiple cities, 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 incentivized 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 when deciding what to use, and the use of such drugs and medical consumables may be taken into consideration in the performance assessment of public hospitals and medical professionals; therefore, physicians are incentivized to prioritise the prescription of drugs and the use of medical consumables centrally procured, which are much cheaper than drugs and medical consumables that have the same indication or purpose but are not included in the centralised procurement; and
- 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.

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 the Medical Device Software Registration Technical Review Guidelines, the Mobile Medical Device Registration Technical Review Guidelines and the Medical Device Cybersecurity 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.

Under Measures for the Administration of Internet-based Diagnosis and Treatment and Measures for the Administration of Internet Hospitals, physicians can conduct online diagnoses and treatments for patients whose initial appoint-

ment 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 by the Interim Measures for the Administration of Internet Advertising and the Measures for the Administration of Internet Drug Information Services. 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 PMPA.

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 laws or regulations which specifically regulate the use of electronic prescriptions in the PRC. In practice, electronic prescriptions are allowed in online and offline 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 off-line drug distributor. Specific rules for online sales of drugs are under revision by the NMPA.

Online sales of medical devices are permitted under RSAMD 2021 and Measures for the Administration and Supervision of Online Sales of Medical Devices. 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 online sale of Class II medical devices, which does not require filing with local MPA when sold offline pursuant to RSAMD 2021.

8.6 Electronic Health Records

Electronic health records may contain personal information, medical records, and human genetic resources information. Aggregated electronic health records in hospitals may be deemed population health information and medical big data:

- any collection, use, storage or transfer of records containing personal information is subject to laws and regulations applicable to the protection of personal information. According to the Information Security Technology — Personal Information Security Specification, a recommended national standard and widely accepted practice guideline, health-related information is sensitive personal information. The collection, use, and transfer of sensitive personal information requires express consent by data subjects and are subject to a stricter standard of protection than ordinary personal data;
- electronic health records including medical records of patients are subject to the following regulation:
- the Use and Administration Rules for Electronic Medical Records (for Trial Implementation);
- Provisions on the Administration of Medical Records of Medical Institutions also applies to the management of electronic medical records;
- if electronic health records include any human genetic resources information, restrictions under Administrative Regulation on Human Genetic Resources mentioned in **2.5 Use of Resulting Data from the Clinical Trials** will apply; and
- according to 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 way that satisfies the national standards of data storage, disaster recovery, and back-up and security management. Medical big data must be stored in a reliable server located within the territory of the PRC.

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:

- Patent Law (amended version will be effective on 1 June 2021);
- Rules for the Implementation of the Patent Law;
- Administrative Measures for Prioritised Patent Examination;
- Administrative Measures for Centralised Examination of Patent Applications (for Trial Implementation);
- 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;
- Interpretation (II) of the Supreme People's Court on Several Issues concerning the Application of Law in the Trial of Patent Infringement Dispute Cases; and
- Guidelines for Patent Examination.

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 US. In history, both the China National Intellectual Property Office (CNIPA) and the court adopted a very strict interpretation of whether to consider supplemental data. The Interpretation on Patent Grant and Confirmation explicitly states that the court shall review the supplemental data submitted by the patentee to satisfy the inventiveness and enablement requirement. The Guidelines for Patent Examination were also revised accordingly.

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 amended 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.

The Revision Suggestions on Implementation Rules of the Patent Law (draft for comments) provides detailed instructions on the Patent Term Extension, ie, the application and

determination of Patent Term Extension and the scope of "new drug" invention patents that can apply for patent term extension. Any party can challenge the Patent Term Extension decision before the 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", ie, the disputed intellectual property is on the verge of being disposed of or traded or the disputed intellectual property is being or about to be infringed in time-sensitive occasions such as trade fairs.

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) 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**.
- Civil litigation remedies include preliminary injunctions, permanent injunctions, and monetary damages, the amount of which is based on actual loss, profit made by the infringer, royalties, and statutory damages. The latest amended Patent Law raises the upper limit of statutory compensation to RMB5 million and the lower limit to RMB 30,000.
- 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, among which exclusive licensees, and non-exclusive licensees (together with the patentee or upon specific authorisation by the patentee) can bring proceedings.

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. The court is historically likely to stay the civil litigation and waiting for the result of the invalidation proceeding.

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 latest amended Patent Law established the patent linkage system in China. Also, the NMPA and the CNIPA issued a draft of the Measures for Implementation of the Early Resolution Mechanism for Drug Patent Disputes (Trial) (Daft Measures on Early Resolution Mechanism), which explains in detail the Chinese patent linkage system. Based on the Draft Measures on Early Resolution Mechanism, a MAH shall register its patent information on a Chinese listed drug patent information registration platform, which will be established by NMPA. Similar to the USA Hatch-Waxman Act, the generic drug applicant shall make one of four types of declaration regarding each patent listed on the registration platform. The four types of declarations are:

- Type I – there is no patent related to the generic drug according to the platform;
- Type II – the patents related to the generic drug have been terminated or declared invalid;
- Type III – there are patents related to the generic drug according to the platform and the applicant will not market the generic drug until the expiration of the relevant patents; and
- Type IV – the patents related to the generic drug are invalid or the generic drug does not fall within the protection scope of the patents.

The patentee and the interested party can challenge the aforementioned declarations before the court and the CNIPA within 45 days after such declaration is published. It is worth noting that a market exclusivity period up to 12 months will be granted to the first chemical generic drug that successfully challenged the drug patent and obtained market approval.

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 proceedings – an administrative proceeding could be initiated by the rights-holder or the administrative authority. 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 constitute violations of the Criminal Law of the PRC. Criminal cases in relation to counterfeit pharmaceuticals will be prosecuted by prosecutors and then be heard by courts with competent jurisdiction.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Trade marks used for drugs and medical devices are subject to general requirements of the Trademark Law (such as prohibitions on using the name or logo of the Red Cross or containing fraudulent content). In addition, the NMPA places special restrictions on trade marks to be used for drugs and medical devices. For example, drugs' generic names cannot be registered as trade marks, trade marks appearing on drug labels must be printed at the label's corner, and the font size of each character of trade marks on drug labels may not be larger than a quarter of the font size of the generic drug name.

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 drugs, not for medical devices. PRC law provides six-year protection (which aligns with China's WTO commitment) that prohibits unauthorised third parties from using undisclosed trial data and other data to apply for manufacturing or distribution approval of new chemical drugs. The protection term starts from the date of the marketing authorisation.

In 2018, the NMPA released the draft of Pharmaceutical Trial Data Exclusivity Implementing Rules (provisional). The draft proposes six-year data protection for innovative new drugs, orphan drugs, and pediatric drugs. Twelve-year data protection is available for innovative therapeutic biologics. Data protection terms may be reduced to one to five years if international multi-centre clinical trials for drugs are conducted in China but the drug is introduced into the China market later than other countries/districts. Furthermore, the data exclusivity advantage will not apply if the aforementioned drug is introduced into the Chinese market six years later than in other countries/districts.

The draft is not effective yet, but it appears to be a positive signal to encourage multi-national corporations (MNCs) to introduce new drugs into China.

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 Device** s. China issued special regulations to severely crack down on the illegal manufacture and distribution of counterfeit and inferior drugs, medical devices, and hygienic materials, especially for drugs 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 the Guidelines for the Administration of Clinical Trials of Medicines during COVID-19 Epidemic (Guidelines). Section 2 under the Guidelines provides measures with respect to the clinical trials of COVID-19 treatments and vaccines.

The aim of the Guidelines 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, special approvals and conditional approvals.

Regulatory pathways of special approvals are mainly provided in the Procedures of the State Food and Drug Administration for the Special Examination and Approval of Drugs and the Procedures for the Emergent Examination and Approval of Medical Devices, which greatly reduces the required time for approval of drugs and medical devices due to public health emergency.

The other regulatory pathway is to obtain market authorisation for drugs (including vaccines) upon additional approval conditions. For instance, a vaccine meeting any of the following requirements may apply for such regulatory pathway:

- used for diseases that threaten life but lack effective treatment;
- urgently needed for public health;
- urgently needed as determined by NHC; or
- urgently needed for prevention and control of infectious diseases where an extraordinarily serious public health crisis occurs.

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 PMPA, and a simplified filing with the municipal MPA is sufficient.

For drug manufacturing certification, there are no similar flexible measures due to COVID-19.

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 drugs, 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 (effective from 2007) and the Prevention and Treatment of Infectious Diseases Law (effective from 2013) 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 drugs and medical devices to prevent and treat COVID-19 from certain suppliers directly.

Global Law Office was one of the first law firms in the People's Republic of China (PRC) and is one of the largest, with more than 465 lawyers practising in its Beijing, Shanghai, Shenzhen, and Chengdu offices. Its life sciences and healthcare (L&H) practice group is one of the leading advisers in China, having provided "one-stop" legal services for every area of the L&H industry, including drug R&D, clinical research organisations, pharmaceuticals, biotechnology, medical devices, supply producers and distributors, hospitals and other healthcare provider and investment funds. Global advises clients on challenging L&H legal issues, such as regulatory compliance, structuring transactions and contractual arrangements, realisation of pipeline and geographic expansions, capital-raising and project-financing, M&A, re-organisations, IP protection, licensing and distribution arrangements, settlement of disputes involving adverse effects in clinical trials and medical treatment. The firm has close links to industrial associations and makes recommendations on industry codes of conduct and compliance management standards.

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