Chambers

GLOBAL PRACTICE GUIDE

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

Life Sciences

China: Law & Practice

Alan Zhou, Coco Fan, Samantha He and Felicia Wang
Global Law Office

chambers.com

2020

CHINA

Law and Practice

Contributed by:
Alan Zhou, Coco Fan, Samantha He and Felicia Wang
Global Law Office see p.18

Contents

1. Regulatory Framework

1.1 Legislation and Regulation

Regulatory Framework

The primary statute regulating drugs 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 and clinical trials, manufacturing and distribution as well as administrative measures on drug registration, manufacturing, and distribution, 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 certain products. Some of the above-mentioned regulations and rules are under revision in order to reflect the amendments under the revised DAL.

The Regulations for the Supervision and Administration of Medical Devices (RSAMD) has been enacted to set up a 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 regulated and implemented.

Regulatory Bodies

The State Administration for Market Regulation (SAMR) provides market supervision, administration, and law enforcement for drugs and medical devices, in the areas of anti-monopoly, product quality safety, food safety, IP, fair competition and commercial bribery, issuance of business registrations, certifications and accreditations, among other things. The National Medical Products Administration (NMPA), which is under the supervision of the SAMR, regulates the registration, post-market risk management, administration of safety and quality, formulation of industrial/national standards, as well as the supervision and inspection of drugs and medical devices.

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

The National Healthcare Security Administration (NHSA) is mainly responsible for the implementation of the laws and regulations, policies and standards of medical insurance, the establishment of a mechanism for the prices of medical services with payment from medical insurance funds, the promotion of a market-oriented pricing mechanism for social medical services, and the establishment of a price information monitoring and release system.

1.2 Challenging Decisions of Regulatory Bodies

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.

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 Regulations on the Supervision and Administration of Medical Devices. The challenging party can apply with either the original inspection and agency or the inspection agency at a higher level for re-inspection.

1.3 Different Categories

China classifies drugs as prescription drugs and non-prescription drugs (over-the-counter (OTC)) drugs and regulates them 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.

China 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; their safety and effectiveness should be ensured by strict control and administration.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials of pharmaceuticals are regulated by the NMPA's Administrative Measures for Drug Registration/Administrative Measures for the Registration of Medical Devices, Good Clinical Practice for Drug Trials/ Medical Device Trials (col-

lectively as GCPs) and an array of technical review standards and guidances.

The GCPs provide the general standard for the implementation of clinical trials, including study preparation and prerequisites, patient protection, draft protocols, management of study materials and documentations, study records and reports, data management and statistical analysis, monitoring, and inspection. The GCPs also explicitly define the respective responsibilities of each responsible party in a clinical trial, including independent ethics committees, sponsors, investigators, and monitors.

2.2 Procedure for Securing Authorisation

Clinical trials for drugs are generally required before the sponsor applies for marketing authorisation, unless otherwise excluded by law (in special cases, for example drugs for rare and special diseases or innovative drugs for a serious disease that has no existing effective treatment). Clinical trials must themselves be authorised in advance by the Centre for Drug Evaluation (CDE) of the NMPA. The general steps for securing clinical trial authorisation are:

- all clinical trials of pharmaceuticals shall be reviewed by ethical committee prior to initiation;
- prior to filing with NMPA for clinical trial authorisation of a new drug, a sponsor shall apply for a pre-consultation meeting with the NMPA at which the sponsor is to present relevant data and draft protocols, discuss concerns regarding pharmaceutical development and receive 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 upon acceptance of the application by CDE. Within the 60-day period, the CDE may require the sponsor to submit supplementary documents or not to conduct 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 to recommence the 60-day review period, the sponsor can begin the clinical trial if there are no further objections or requests by the CDE during that period;
- if the CDE issues a notice to the sponsor indicating that it is not allowed to conduct the clinical trial, the sponsor may reply in writing with regard to all raised issues and reapply for approval of the clinical trial. The CDE will further review and determine whether to approve that clinical trial; the sponsor is only allowed to implement the clinical trials upon receipt of the CDE's written approval.

Class I medical devices and certain Class II and III medical devices are exempted from clinical trials. With respect to Class II and III medical devices that are not exempted from clinical trials, 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 days from the date when the application fees are paid upon acceptance of the application by CDE.

2.3 Public Availability of Databases

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, 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.

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

2.4 Restriction for Using Online Tools

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

Resulting data may contain personal information, including medical records, genetic resources, etc:

- personal information refers to information that can be used independently to identify or be combined with other information to identify a natural person. If resulting data from clinical trials include any personally identifiable information, that data will be regulated as personal data. Unless otherwise permitted by law, the transfer of personal data is subject to consent by the data subject. When transferring personal information outside the PRC, restrictions on cross-border data transfer shall apply;
- any medical records of patients and their copies retained and managed by a hospital shall be kept by such hospital. The hospital shall not share the personal medical records with any third party unless the sharing is for scientific, educational, or research purposes;
- if resulting data include any information generated from human genetic resource materials, the Administrative Regulation on Human Genetic Resources applies. This regulation provides restrictions on and requirements regarding the collection, use, storage or transfer of human genetic

resources in the PRC. Any collection, use, storage or transfer of genetic resources is subject to approval by the ethical committee and consent by data subjects. Stricter rules are applied to foreign entities, including foreign invested or controlled companies in the PRC. Filing with the Ministry of Science and Technology for the transfer of human genetic resources information to foreign entities is required. Utilisation of human genetic resources by a foreign entity must be conducted in collaboration with a domestic entity and is subject to filing or approval by the Ministry of Science and Technology. A foreign entity is prohibited from any storage, collection or transfer of human genetic resources.

2.6 Further Requirements for the Creation of a Database

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.

Specifically:

- if the e-database contains personal information, it will be subject to privacy protection rules and cybersecurity requirements;
- in addition to the restrictions on the transfer of medical records mentioned above, a database that includes medical records obtained from hospitals might be deemed to contain population health information and medical big data which may not be stored in overseas servers. Any use or release of such information must be conducted within the scope of authorisation by the relevant responsible party;
- if the database includes any human genetic resources information, restrictions mentioned in **2.5 Use of Resulting Data** will apply.

3. Marketing Authorisations

3.1 Assessment Process and Criteria

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 indications or primary treatment functions, usage, and dosage are specified. 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.

When a product contains both a drug and a device (ie, a combination product), the CDE, the CMDE, or a joint panel of both, will review and determine whether such a product should be deemed and registered as a drug or a device based upon the product's primary mode of action.

3.2 Granting a Marketing Authorisation

In addition to the general application requirements for a drug market authorisation, applicants for vaccine market authorisations are required to obtain drug manufacturing licences. Given that the revised Administrative Measures for Drug Registration have not been finalised yet, it is uncertain whether any other specific obligations must be fulfilled in relation to the granting of a marketing authorisation for biological medicinal products.

3.3 Period of Validity

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 can suspend or revoke marketing authorisations, if there are (i) serious safety issues (such as serious adverse effects or defective products), (ii) non-compliance of GxP rules by marketing authorisation holders (MAHs), or (iii) other non-compliance issues (such as obtaining a marketing authorisation by fraudulent means). The suspension or revocation of market authorisations will not occur as a result of the manufacturer's failure to place drugs on the Chinese market within a certain time.

3.4 Procedure for Obtaining a Marketing Authorisation

There are five types of registration applications for drugs: new drug applications; generic drug applications; imported drug applications; re-registration applications; and supplemental applications. Under the current Administrative Measures for Drug Registration:

- the first three types of application are required to obtain a new marketing authorisation. Subject to specific requirements under each type of application, the following steps are generally required:
  (a) pre-clinical laboratory study;
  (b) clinical trials;
  (c) submission of a drug registration application;
  (d) regulatory review (such as drug safety and efficiency by the CDE); and
  (e) manufacturing site examination and drug sample testing;
- re-registration is required to renew a valid drug marketing authorisation before expiry;
- supplemental applications enable MAHs to vary their marketing authorisation post-approval. The application will be submitted to either the NMPA or the PMPA for approval or notification, depending on the content of variation;
- if a MAH considers transferring its marketing authorisation to a third party, it was relatively difficult in the past because of the connection between the drug licence and manufacturing licence and lack of clear transfer guidance. It is now explicitly permitted under the DAL. The transferee shall be capable of quality management, risk prevention and control, and providing liability compensation to ensure drug safety, efficacy and quality control. The implementing measures on this matter are under development.

Marketing-authorisation applications and variation applications for Class II and III medical devices differ from those for Class I devices:

- Class II and III devices are subject to the registration process 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.
- Changes to these marketing authorisations are divided into licensing items variation (eg, change of product specification or technical requirements) and registration items variation (eg, change of the MAH's name or address). Both need to be approved by the NMPA/PMPA, and changes to licensing items may trigger an additional technical review by the CMDE. Licence transfers for Class II and Class III devices, can be accomplished by changing the MAH's name under the registration items variation.
- Applications for Class I devices are relatively simple. The PMPA (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 Unauthorised Products

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

- the drug is in 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 must be used within the clinical trial site and used on patients outside of the clinical trial setting but with similar conditions.

There is no effective rule for an expanded access programme for investigational medical devices. In August 2019, the NMPA issued a draft rule on this subject for public comments.

3.6 Ongoing Obligations

A drug MAH (and its local MAH deputy, if it is an overseas MAH) is responsible for post-marketing obligations, including:

- making risk-management plans;
- actively carrying out post-marketing studies to affirm further drug safety, efficiency and quality control;
- applying for supplemental registration as needed;
- monitoring, reporting and handling adverse effects, product complaints or other quality issues.

If a drug is approved conditionally, its MAH (and its local deputy) must take corresponding risk-management measures and complete relevant studies as required by authorities within the prescribed time limit. Otherwise, marketing authorisation may be revoked. A medical device MAH is also responsible for post-marketing obligations, such as monitoring of adverse effects and re-evaluation of product safety and efficiency.

3.7 Third-Party Access to Pending Applications

For drugs, the CDE and NMPA's official websites enable third parties to gain access to certain information regarding pending, rejected, and approved marketing authorisations. Available pending marketing authorisation information contains registration application status, the CDE's review summary, report, and result, among others. Compared to drugs, third parties may access less information regarding pending marketing authorisation applications for medical devices on the CMDE and NMPA's official websites. For granted marketing authorisations, third parties can browse information such as approved drug/medical device name, specification, MAH name, approval number and date, etc.

Under the Regulations on Government Information Disclosure and relevant NMPA rules and circulars, the government is prohibited from disclosing any government information involving State secrets, trade secrets or personal privacy, 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 or distribution of counterfeit or substandard drugs and medical devices. The 2019 DAL revision significantly increases administrative penalties for illegal medicines. Penalties include rectification, confiscation of illegal gains, fines, suspension of product production or distribution, or even revocation of licences (such as marketing authorisation, manufacturing licence, distribution licence or business licence). The personnel in charge of the violating entity and the legal representative could also face confiscation of illegal gains, fines, administrative detention, or lifelong prohibition from drug production/distribution activities. Such wrongdoing may also trigger criminal liabilities for the individual and the entity under the Criminal Law, including fines, confiscation of personal property, detention, imprisonment, or even the death penalty.

3.9 Border Measures

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. If a rights-holder discovers infringing drugs or medical devices by itself, it could request the Customs to seize the infringing goods. Further, if a rights-holder voluntarily completes the IP Customs Filing, it would obtain more assistance from the 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 trade marks have been removed.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Manufacturing Plants

Pharmaceutical manufacturing plants require a drug-manufacturing licence issued by the PMPA, which is valid for five years and renewable for another five years. 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 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 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 can be renewed for another five years. 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 on 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 authorisations. 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 PMPA. The PMPA 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 before expiry.

5.2 Different Classifications
For different classifications which apply to pharmaceuticals (such as "available only on prescription"), see **1.3 Different Categories**.

6. Import and Export of Pharmaceuticals and Medical Devices

6.1 Governing Law and Enforcement Bodies
The major laws that govern the import and export of pharmaceuticals and medical devices are as follows:

- the DAL;
- the DAL Implementing Regulations;
- Administrative Measures for the Import of Drugs;
- the RSAMD;
- Customs Law;
- the Law on Imported and Exported Commodities Inspection.

The SAMR, the NMPA and its designated drug test institutions, Customs, and China Entry-exit Inspection and Quarantine Bureau (CIQ) under China Customs all apply and enforce import regulations (both at the point of entry and afterwards).

6.2 Importer of Record
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
Prior Authorisations for Drug Importation:

- in general, imported pharmaceuticals must obtain market authorisations from the NMPA before importation. An additional special import permit issued by the NMPA is required with regard to narcotic drugs and psychotropic drugs;
- the following are permitted to be imported without market authorisations from the NMPA:
  (a) drug samples for drug-registration purposes; or
  (b) comparator drugs (except narcotic drugs and psychotropic drugs) for the purposes of drug registration or consistency evaluation of generic drugs, if both the market authorisation issued by the country/region where its manufacturer is located and the NMPA's drug import approval have been obtained;
  (c) in exceptional cases, the following drugs that lack market authorisations but have the NMPA's drug-import approval;
    (i) a small amount of drugs to be imported by a hospital and used for specific medical purposes due to urgent clinical needs;
    (ii) new chemical drugs and innovative therapeutic biologicals for clinical trial or drug registration purposes; and
    (iii) drugs that the NMPA considers to be safe, effective and urgently needed;
- in addition, individuals bringing drugs to China for their personal use are exempted from the above authorisations.

Prior Authorisations for Medical Device Importation:

- imported medical devices shall first be filed/registered with the NMPA;
- if the imported medical devices fall into the Catalogue of Products Subject to the Compulsory Product Certification System, the China Compulsory Certification is required;
- any foreign entity that donates medical devices to China must file the identity of the donating entity and the names of donated medical devices with the CIQ.

The Catalogue of Commodities Subject to the Automatic Import Licence Administration lists 11 kinds of medical devices that are

subject to an automatic import licence before customs declaration unless an exemption is permitted by law.

6.4 Non-tariff Regulations and Restrictions

Pharmaceuticals and medical devices sent from voluntary overseas donors to recipients in China that are directly used for charitable purposes are exempt from import tariff and import value-added taxes. A tax-exemption certificate for imported and exported goods issued by the Customs is required for customs clearance. In addition:

- all common drugs are exempted from import tariffs, including cancer drugs, alkaloids used for asthma treatment, raw materials used for the production of new diabetes treatment drugs, actually imported traditional Chinese medicines, etc;
- certain parts, components and raw materials of medical devices under the updated Catalogues Associated with Import Tax Policies for Key Technical Equipment are exempt from import tariffs and value-added tax.

6.5 Provisions on Trade/Regulatory Facilitation

For trade/regulatory facilitation, China has entered into 16 Free Trade Agreements with Australia, Korea, Switzerland, Iceland, Singapore, New Zealand, Chile, Mauritius, the Maldives, Georgia, Costa Rica, Peru, Pakistan, Hong Kong, Macao, and the 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

The pricing of most drugs is not directly controlled by the government, but mainly formed through market competition, while the pricing for narcotic drugs and Class 1 psychotropic drugs is capped by the government under the Catalogue of Pricing by the Central Government.

Though the government aims to establish a market-driven drug pricing system, government policies may have an important effect on drug pricing. For example, (i) the pricing of drugs reimbursed by the basic medical insurance (BMI) fund is established based on reasonable medical reimbursement standards made by the NHSA and other regulatory agents; (ii) the government procurement, which has strong bargaining power, gives a favourable procurement price to public hospitals financially supported by BMI fund; and (iii) the "Two-invoice System" (ie, a maximum of two invoices are allowed between agents of imported products/manufacturers and public hospitals) eliminates multi-tiered distribution to lower the drug prices.

There is no nationwide regulation or policy specifically and directly controlling the pricing of medical devices. However, the pricing of medical devices is indirectly restricted because national and local rules limit the amount that a non-profit hospital may charge patients for medical services and the cost of medical devices used in such services may be included in that charge. In July 2019, the General Office of the State Council issued the Reform Plan for the Administration of High-value Medical Consumables, which aims to reduce artificially inflated charges for high-value medical consumables in public hospitals.

7.2 Price Comparison

PRC law does not require that the pricing of pharmaceuticals and medical devices be benchmarked or otherwise be set in reference to the pricing of the same products in other countries. But 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.

7.3 Reimbursement from Public Funds

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 all 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 includes drugs that are clinically necessary, widely used, and have good curative effects and a relatively low price. 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 includes 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.

Notably, the NRDL withdraws the previous power of provincial authorities to adjust the scope of Class B drugs by no more than 15% in their provincial reimbursement drug lists (PRDL). Therefore, all provincial authorities will implement the same NRDL after a transitional period of three years.

Medical devices are generally considered to be "diagnosis and treatment items" or parts of such items for BMI reimbursement purposes. Diagnosis and treatment items eligible for BMI reimbursement must be necessary for clinical diagnosis and treatment, safe and effective, with a proper cost, and provided by BMI-designated hospitals. The Scope of Diagnosis and Treatment Items of National Basic Medical Insurance specifies diagnosis and treatment items which the BMI fund will not reimburse, or will only reimburse partially. Provincial authori-

ties may accordingly make their local reimbursement lists for diagnosis and treatment items, respectively. The proportion of reimbursement and cost borne by an individual is locally determined and applicable within districts under BMI overall planning.

7.4 Cost Benefit Analysis

Cost-benefit analysis is not legally required when determining the prices to be paid for pharmaceuticals or medical devices.

Notwithstanding, government authorities do indeed look into the cost and price of drugs to strengthen drug-price supervision and inspection and to maintain orderly drug-pricing. For example, in 2019, the Ministry of Finance and the NHSA jointly conducted an in-depth inspection of the quality of accounting information of 77 pharmaceutical enterprises, in order to understand the costs and profits of drugs throughout the whole chain of manufacturing and distribution, to understand the mechanism of formation of drug prices, and therefore to constrain artificially inflated drug prices.

The result of cost-benefit analysis may influence BMI reimbursement policy with respect to certain drugs. Drugs with a high cost-benefit ratio and proven effectiveness and safety will be prioritised to be included in the National Essential Drugs List (NEDL). A curative drug in NEDL will have priority to be further included in the NRDL and to be re-classified into Class A or B in the NRDL, which will affect reimbursement methods and ratios.

7.5 Prescriptions and Dispensing

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 his or her 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, to avoid wasting medical resources or taking advantage of the BMI fund.

Government policies and measures may affect or guide a physician's prescription decisions, for instance;

- 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 have an incentive to require physicians to consider the BMI budget when prescribing drugs reimbursed by the BMI fund;
- the State's centralised procurement and use of drugs requires that relevant hospitals give priority to drugs centrally procured, and the use of such drugs will be taken into consideration in the performance appraisal of public hospitals and medical professionals. Therefore, physicians have an incentive to prioritise the prescription of drugs centrally procured, which are much cheaper than drugs that have the same indication but are not included in the State's centralised procurement; and
- the Diagnosis-related Groups payment method (DRGs), which will pressure hospitals to control medical expenses, and thus may influence physicians' prescription behaviours, is being explored by NHSA, NHC, the Ministry of Finance, National Administration of Traditional Chinese Medicine.

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, which will be subject to the same approach as that taken by the NMPA to assure safety and effectiveness for other medical devices.

Medical apps which fall within the scope of medical devices must meet 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

Measures for the Administration of Telemedicine (Telemedicine Measures) is a rule specifically applicable to telemedicine. Telemedicine is defined in the Telemedicine Measures to include hospital-to-hospital consultations on diagnoses and treatment by means of modern information and communication technologies.

Other ways of online diagnoses and treatments are regulated by Measures for the Administration of Internet-based Diagnosis and Treatment and Measures for the Administration of Internet Hospitals, which provide that:

- physicians shall conduct online diagnoses and treatments in the hospitals with practising licences covering online diagnoses and treatments' scope; and

- online diagnoses and treatments can only be provided to patients whose initial appointment is at an offline hospital for the same symptoms.

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 onsite diagnoses and treatment:

- for common and chronic illnesses. Electronic prescriptions 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;
- by offline hospitals in digital form, 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

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 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.

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:
  (a) copies of these records must be retained and managed within the corresponding hospitals. Hospitals shall not share personal medical records with third parties except other hospitals for the purpose of science, education or research;
  (b) the establishment, recording, modification, use, preservation, management and all other aspects of electronic medical records of hospitals are governed by the Use and Administration Rules for Electronic Medical Records (for Trial Implementation);
- if electronic health records include any human genetic resources information, restrictions under Administrative Regulation on Human Genetic Resources mentioned in Section 2.5 will apply;
- 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 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. Other entities may use or release medical big data upon authorisation by hospitals.

9. Licensing

9.1 Customary Deal Structures

Typical collaboration arrangements to develop and/or commercialise products include traditional licensing agreements, co-development, and co-promotion, among others:

- licensing deals can be made at almost any stage of product development, different phases of trials, registration or after-launch. Typically, the licensee will make up-front payments to the licensor to acquire the exclusive right to use or market the licensed products;
- co-development arrangements usually involve both parties' contributions regarding IP, personnel, capital, and other assets. This type of arrangement will be formalised under a co-development contract;
- co-promotion arrangements are normally structured for a product in a later development stage. Terms such as market segments and royalties need to be specifically negotiated by the parties.

The promulgation of an array of new laws and regulations has produced some new trends in the deal structures of licensing transactions in the PRC:

- wide acceptance of the licensing model for the MAHs to authorise others to manufacture and commercialise products. Other technology transfer models that have complicated approval requirements are unlikely to be used;
- with the NMPA's increase in incentives for drug innovation, an increasing number of PRC companies plan to license new drugs at an early stage of development; and
- because of the NMPA's recent acceptance of overseas clinical trial data, more domestic companies license products from foreign companies at the clinical trial stage.

9.2 Dispute Resolution Provisions

A joint steering committee (JSC) composed of representatives from both parties to a licence agreement always takes the responsibility of resolving potential disputes between parties. If a JSC cannot resolve the disputes, they are referred to the designated management teams of both parties.

Any disputes that cannot be resolved internally between two parties will be submitted to a court or an arbitration centre, in which case technical arbitrators may be designated for any technical issues.

9.3 Diligence Obligations Provisions

"Commercially reasonable efforts" or "best efforts" are not legally defined terms under PRC law. In practice, the court always looks into the Good Faith Doctrine under PRC Contract Law instead of differentiating between these two terms.

The following diligence obligations are always imposed on the following activities of a licensee under the development plan and commercialisation plan provided in the licence agreement:

- development activities: the development plan will always set up certain milestones for development, including obtaining authorisation of clinical trials, recruitment of the first patient in a clinical trial and/or completion of phase I/II/III clinical trials;
- regulatory application: the estimated timeline for obtaining regulatory approval and launch of the licensed product is always stated expressly in a regulatory application;
- commercialisation: the commercialisation plan provides the minimum purchase or sale requirements to be satisfied by the licensee.

9.4 Change of Control

License agreements usually address and allocate risks associated with changes of control, which typically occur as a result of mergers, sales of shares or assets, and similar transactions. A non-Affected Party (one who is not party to the change of control) typically has the following rights in the case of a change of control:

- right of termination; and/or
- right of renegotiation at the non-Affected Party's discretion.

An Affected Party (one who is the party to the change of control) is always obliged to ensure that the licence agreement will be binding upon their successor.

9.5 Termination

The following consequences of termination typically are included in the licence agreement:

- termination of any licensed activities by the licensee;
- return of confidential information, materials and samples, including development data;
- sale, return or destruction of stocks of licensed products upon termination;
- transfer of regulatory approval of licensed products to the licensor;
- the right of IP generated by each party belongs to the developing party, and the grant of a licence to the other party is subject to negotiation;
- termination or transfer of any ongoing clinical trial; and
- payment of payable royalties and indemnifications.

10. Patents

10.1 Applicable Laws

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

- Patent Law;
- Rules for the Implementation of the Patent Law;
- Guidelines for Patent Examination;
- Administrative Measures for Prioritised Patent Examination; and
- Administrative Measures for Centralised Examination of Patent Applications (for Trial Implementation).

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

- inventiveness;
- sufficient disclosure of specifications; or
- specifications' support on claims.

To be patentable, an invention or utility model must possess:

- novelty: it is not an existing technology, nor has another patent application been filed in China before the filing date and published in a patent document after the filing date;
- inventiveness: an invention has prominent and substantive features, and represents notable progress over existing technology, or a utility model possesses substantive features and represents notable progress over an existing technology; and
- usefulness: it has practical applications and may produce positive results.

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; or
- methods for diagnosing or treating diseases.

10.2 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 permission of the patent-owner, may constitute an infringement of second and subsequent patents of pharmaceutical products.

10.3 Patent Term Extension

The Patent Law does not provide a special mechanism by which to extend the 20-year invention patent term for drugs. However, PRC legislators and regulators are exploring IP regulatory incentives in this regard. Patent terms for innovative drugs may be extended by no more than five years, and the total span of valid patent rights post-marketing can be extended to 14 years under the revised draft of Patent Law and the China-US Trade Agreement.

10.4 Patent Infringement

Without the permission of the patent-owner, 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
- to utilise, 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.

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

If a patent right-holder 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 right-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.

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

- the factual and legal basis, including 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; and
- whether the injunction would harm public interests.

An applicant is required to provide a sufficient surety bond for a preliminary injunction.

To be actionable, such a threat of infringement is required to be "imminent".

10.5 Defences to Patent Infringement

The specific defences to patent infringement in relation to pharmaceuticals and medical devices include Administrative Approval Exemption (see **10.4 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.

10.6 Bringing Proceedings

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

- administrative actions
  - (a) taken by the State Intellectual Property Office (SIPO) (and its local counterparts) (remedies include ordering the infringers to cease the infringement, seizing/destroying infringing items, and fines); or
  - (b) taken by Customs (seizing infringing items).
- civil litigation (remedies include evidence or property preservation orders, 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); 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, among which exclusive licensees, and non-exclusive licensees (together with the patentee or upon specific authorisation by the patentee) can bring proceedings.

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 Patent Review Board (PRB) under the SIPO;
- 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 SIPO or its local counterparts;

- the SIPO 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 SIPO or its local counterparts issues a decision; and
- either party may choose to appeal the decision by filing an administrative lawsuit with the court.

Any party, including the defendant to a patent infringement suit, can file an invalidation application with the PRB under the SIPO in order to invalidate a granted patent. Any such applicant or patentee can file a lawsuit to a court to appeal the review decision of PRB within three months from the date of receipt of the decision.

10.7 Available Procedures

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.

Currently, clearing the way is not a requirement for generic market entry. Only a simple non-infringement statement is required when making drug approval applications and the applicant can hardly be held liable for the authenticity and accuracy of the statement. However, the NMPA has proposed a patent linkage system for drugs in a draft policy for comment in 2017 and the General Office of the State Council further confirmed the necessity of such a system in the Opinion on Strengthening Protection of Intellectual Property in 2019. However, the details and regulation of a patent linkage system have yet to be officially published by the NMPA.

11. IP Other Than Patents

11.1 Counterfeit Pharmaceuticals and Medical Devices

When discovering counterfeit pharmaceuticals and medical devices, a rights-holder can take self-help actions such as negotiating directly with the infringer. Alternatively, the rights-holder could take external action to battle by using the following channels:

- administrative channels are widely viewed as a quicker and less expensive way. To start, a rights-holder must file an infringement complaint with supporting evidence to the administrative authority, such as the local AMR, MPA, Customs, etc. The local authorities may issue a ruling after a formal regulatory investigation and may impose administrative penalties when infringement is affirmed. The unsatisfied rights-holder or the infringer can bring an administrative suit to the court regarding the local authority's ruling;
- judicial channels include civil and criminal procedures. Specialised IP courts will hear civil cases. Criminal cases will be investigated by public security bureaus and prosecutors and then be heard by courts with competent jurisdiction.

11.2 Restrictions on Trade Marks

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.

Furthermore, the Trademark Law is silent on restrictions on the importation or distribution of non-counterfeit, genuine products from other markets, regions, or countries (ie, parallel imports). In practice, different courts may hold different views on whether parallel imports would constitute trade-mark infringement. Therefore, each individual occurrence needs to be analysed on a case-by-case basis. For example, parallel imports could establish trade-mark infringement should the reputation of the trade mark-owner be damaged in some precedents.

11.3 IP Protection for Trade Dress or Design

IP protection is available for the trade dress or design of drugs and medical devices, as well as their packaging, under various PRC laws. The visual appearance is protected as trade dress under the Revised Anti-unfair Competition Law, as a design under the Patent Law, as a copyrightable industrial design under the Copyright Law and as a two-dimensional/three-dimensional trade mark under the Trademark Law.

11.4 Data Exclusivity

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 market authorisation.

In 2018, the NMPA released the draft of Pharmaceutical Data Exclusivity Implementing Rules (provisional). The draft proposes six-year data protection for innovative new drugs, orphan drugs, and pediatric drugs. 12-year data protection is available for innovative therapeutic biologics (the previous term in the

NMPA's circular was ten years). Data protection terms may be reduced to one to five years if a drug applying the data from multi-regional clinical trials conducted in China is introduced into the China market late. The draft is not effective yet, but it appears to be a positive signal to encourage multi-national corporations (MNCs) to introduce new drugs in China.

Global Law Office was the first law firm in the People's Republic of China (PRC) and is one of the largest PRC law firms, 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, life sciences, biotechnology, medical devices, supply producers and distributors, hospitals and other healthcare providers, as well as various investment funds in the L&H sector. 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.

Authors

Alan Zhou is the leading partner of the L&H practice group at Global Law Office, with his strong background in L&H practice. He focuses on M&A, private equity/venture capital, regulatory compliance and general corporate. Mr Zhou has routinely represented multinational corporations, such as Sanofi, Siemens, AstraZeneca, GSK, Boehringer Ingelheim, and Novartis, as well as local Life Science and Healthcare companies. As a participant or external counsel, he has been engaged by local authorities and industrial associations to advise on legislation and industry standards in the L&H industry, including such topics as online hospital, digital marketing, medical insurance reform, medical representative management and other compliance topics.

Coco Fan is a partner at Global Law Office. She specialises in corporate, compliance, private equity (PE) and venture capital (VC), and M&A. Ms Fan has rich experience in the L&H practice. This includes prescription medicine, over-the-counter medicine (OTC), contract research organisations (CROs), medical devices, bio-pharmaceuticals, health foods, clinical supply, vaccines, animal health and hospitals. Ms Fan has advised many multinational companies, private companies and investors, including Siemens, Sanofi, MSD, Aspen, Boehringer Ingelheim, Abbott, GSK, Novartis, Eli Lilly, Tencent, Catalent, Allergan, Gensci Schlumberger, and Shanghai Jiaotong University School of Medicine.

Samantha He is of counsel at Global Law Office. Ms He's practice is primarily focused on the life sciences industry, and she 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 insights 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 mergers and acquisitions, venture capital, licensing, and strategic collaboration.

Felicia Wang is of counsel at Global Law office. Her main practice areas encompass M&A, private equity (PE) and venture capital (VC), compliance and general corporate. Ms Wang is dedicated to providing services to pharmaceutical, bioscience, and other healthcare industry clients. Ms Wang regularly assists reputable multinational and domestic companies with the legal aspects of drugs, medical devices, digital health and data protection, etc. She also provides professional legal opinions to her clients in the area of medical AI. A shortlist of her clients includes GSK, Tencent, MSD, Boehringer Ingelheim, Eli Lily, BeiGene and Sanofi.

Global Law Office

26 Floor
5 Corporate Avenue
150 Hubin Road,
Huangpu District
Shanghai 200021
China

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