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China: Law & Practice

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Global Law Office

CHINA

Law and Practice

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Contents

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

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Legislation and Regulations

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

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

The Medical Devices Administration Law was included in the national legislative planning in 2023, and its legal hierarchy is higher than the effective Regulations for the Supervision and Administration of Medical Devices (RSAMD); it aims to better regulate the medical device market by consolidating the responsibilities of related parties. The RSAMD were amended in 2021 to officially incorporate marketing authorisation holder (MAH), conditional approval, emergency use, device unique identification, etc, into the regulatory frameworks. The amendments significantly increased administrative punishment for violation and imposed legal liabilities on the legal representatives and persons in charge of entities violating RSAMD. The development, registration/filing, manufacturing and distribution of medical devices are, like pharmaceuticals, regulated by GxP rules and administrative measures. Product-specific rules and guidelines have also been released and implemented.

Furthermore, the Administrative Measures on the Registration and Record-filing of Medical Devices ("Device Registration Measures") and the Administrative Measures on the Registration and Record-filing of In Vitro Diagnosis (IVD) Reagents were released to update and specify the regulatory procedure and requirements for medical device and IVD reagent registration and filing, respectively.

Regulatory Bodies

State Administration for Market Regulation (SAMR)

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

National Medical Products Administration (NMPA)

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

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

cals and medical devices on the city and county levels.

National Health Commission (NHC)

The NHC is mainly responsible for national health policies, the reform of the medical and healthcare system, disease prevention and control, national drug policies and the national basic drug system. It supervises the National Administration of Traditional Chinese Medicine and the National Disease Control and Prevention Administration.

National Healthcare Security Administration (NHSA)

The NHSA is mainly responsible for the preparation and implementation of regulations and policies related to basic medical insurance (BMI), including policies regarding reimbursement, pricing and procurement for pharmaceuticals and medical services.

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

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

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

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals

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

Medical Devices

The RSAMD classify medical devices into three classes according to their risk levels and expected purposes, structural features, methods of use and other qualities. Class III medical devices have the highest risk level, and their safety and effectiveness should be ensured under strict control.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The DAL and the Administrative Measures for Drug Registration establish the primary principles and statutory requirements for clinical trials. Guidance and technical review standards such as Good Clinical Practice (GCP) for Drug Trials and Pharmaceutical Research Information Guide for Phase III Clinical Trials of Innovative Drugs (Chemical Drugs) provide guidance detailing the obligations of the parties involved, operational procedures, technical requirements, etc. Notably, the newly issued Measures for the Supervision and Inspection of Drug Clinical Trial Institutions (Trial) tailor the rules on supervising compliance with the GCP for Drug Trials

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

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

Likewise, the RSAMD and Device Registration Measures set out the legal framework on whether and how clinical trials of medical devices should be conducted, while an array of review standards and guidance, such as GCP for Medical Devices Trials, further specify operation guidance and technical requirements for conducting clinical trials. For clinical trials for IVD reagents, the NMPA provides special principles with a separate guideline.

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

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Clinical trials for drugs are generally required before the sponsor applies for marketing authorisations, unless otherwise exempted by law (such as certain generic drugs and IVD). A clinical trial must be authorised by the Centre for Drug Evaluation (CDE) of the NMPA before its implementation. The general steps for securing pharmaceutical clinical trial authorisation are as follows:

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

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

- Clinical evaluation – unless otherwise exempt from a list issued by the NMPA, Class II and III medical devices are subject to clinical evaluation conducted by the NMPA.

- Clinical trial – if the existing clinical literature and clinical data are insufficient to demonstrate the safety and effectiveness of a medical device, a clinical trial should be implemented instead.

2.3 Public Availability of the Conduct of a Clinical Trial

The Drug Clinical Trial Registration and Information Platform (www.chinadrugtrials.org.cn) hosted by the NMPA is a public database providing detailed information regarding clinical trials of pharmaceuticals for the purpose of registration. The newly issued Specifications for Drug Clinical Trial Plan Submission and Review reiterate that an applicant shall register the drug clinical trial plan on the platform prior to conducting a drug clinical trial.

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

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no specific restrictions on using online tools to support clinical trials; using such tools is subject to generally applicable laws and regulations concerning personal information protection, online advertising, etc.

2.5 Use of Data Resulting From Clinical Trials

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

The Personal Information Protection Law (PIPL) provides a legal framework for the administration of handling personal information. During clinical trials, sites, principal investigators, sponsor-designated monitors and other third parties may access trial subjects' personal information. However, sponsors will generally only receive anonymised data from the trial. Moreover, the sharing and transferring of personal data are subject to other statutory requirements, such as the receipt of data subjects' consent, restrictions on cross-border data transfer, etc.

Human genetic resource samples and data (HGR) are governed by the Biosecurity Law and the Administrative Regulation on Human Genetic Resources ("HGR Regulation"). Currently, foreign parties are only permitted to use Chinese HGR upon filing/approval by the HGR authority and are strictly prohibited from collecting or storing Chinese HGR in the PRC and transferring the Chinese HGR overseas. Failure to obtain such filing/approval may result in administrative liabilities or even criminal liabilities. The newly issued Implementation Rules on the HGR Regulation provide specific guidance on determining foreign parties and a more specific scope of HGR, excluding clinical data, imaging data, protein data and metabolic data on the top of the HGR Regulation.

2.6 Databases Containing Personal or Sensitive Data

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

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

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

The term "medical devices" refers to instruments, equipment, appliances, IVD reagents and calibrators, materials and other similar or related articles (including computer software) that can be used directly or indirectly with human bodies to achieve specified purposes (such as diagnosis, prevention and monitoring) and whose effectiveness is primarily achieved by physical or other similar means rather than by pharmacological, immunological or metabolic means (or under circumstances where these latter means serve only auxiliary functions).

The Center for Medical Device Evaluation (CMDE) of the NMPA is responsible for the technical evaluation of medical devices. The NMPA released Opinions on Further Strengthening and Improving Medical Device Classification Management in 2023, outlining critical tasks concerning medical device classification, including improving classification principles and catalogue and proposing to modify the classification-related rules. The NMPA has updated the Medical Device Classification Catalogue accordingly, indicating its commitment to maintaining the regulatory environment with the rapid development of medical device technologies and the industry.

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

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

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

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

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

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

The NMPA can revoke a marketing authorisation for reasons such as the conduct of clinical trials without pre-approval, the use of unapproved package materials or containers, the

use of unapproved labels or instructions, bribery, obtainment of a marketing authorisation by fraudulent means, etc. Conversely, the NMPA could cancel the marketing authorisation if an approved product lacks effectiveness, has material adverse effects or risks human health.

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

There are three types of registration applications for drugs:

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

Drug Registration

The following steps are generally required in a drug registration:

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

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

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

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

Re-registration

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

Supplemental Applications

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

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

Medical Devices

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

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

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

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

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

Changes to these marketing authorisations are divided into modification registration item variations (eg, change of product specification or technical requirements) and filing item variations (eg, change of the MAH's name or address). Currently, both need to be approved by the NMPA/provincial MPA. Changes to modification registration items may trigger an additional technical review by the CMDE. There is no definitive regulation to permit the transfer of the marketing authorisation of medical devices.

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

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

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

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

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

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

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

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

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

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

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

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

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

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

- establishing and maintaining a quality management system;
- setting up and implementing the post-marketing research and risk management and control plan;
- monitoring and re-evaluating medical device adverse events; and
- establishing a tracking and recall system.

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

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

Pharmaceuticals

For drugs pending approval, information such as acceptance number, drug name, drug type, application type, registration category, company name, accepted date and registration application status is publicly available on the CDE's official website. The public can also access granted

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

Medical Devices

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

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

3.8 Rules Against Illegal Medicines and/or Medical Devices

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

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

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

3.9 Border Measures to Tackle Counterfeit Pharmaceuticals and Medical Devices

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

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

Customs will seize counterfeit goods if the rights-holder confirms and provides a bond. Besides, Customs is authorised to suspend imports or exports of counterfeit goods and to impose fines accordingly. Such wrongdoing may trigger criminal liability. The 2020 Economic and Trade Agreement between the PRC and the United States of America (the "China–US Trade Agreement") further strengthens China's obligation to implement border measures.

4. Manufacturing of Pharmaceuticals and Medical Devices

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

Pharmaceuticals

Pharmaceutical manufacturing plants are required to obtain drug manufacturing licences, even for MAHs that lack manufacturing capacity and outsource manufacturing work to other manufacturers. In the event of outsourcing the manufacturing and/or sub-packaging, the manufacturing enterprise that carries out the manufacture and/or sub-packaging shall also obtain the corresponding manufacturing licence, which is valid for five years and is renewable for another five years six months before expiry.

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

Medical Devices

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

- Class I devices: the manufacturer shall conduct a filing with the municipal MPA for the manufacturing of Class I devices.
- Class II and III devices: a manufacturing licence will be granted by the provincial MPA following the result of the review and on-site examination.

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

5. Distribution of Pharmaceuticals and Medical Devices

5.1 Wholesale of Pharmaceuticals and Medical Devices

Drug Distribution Licence

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

Generally, a wholesale drug distributor must maintain a drug distribution licence, with an exception for drug MAHs that sell their drugs as a wholesaler without obtaining a drug distribu-