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China: Law & Practice

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CHINA

Law and Practice

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Contents

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The primary statute regulating pharmaceuticals in the People's Republic of China (the *"PRC"*) is the Drug Administration Law (the *"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, good practice (GxP) 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 draft Medical Devices Administration Law (the *"MDAL Draft"*) was released for public comment on 28 August 2024. The MDAL Draft introduces chapters related to medical device standards and classification, R&D, import and export and use to emphasise the life cycle management of medical devices. It is noteworthy that the content of the MDAL Draft is subject to further revisions and reviews and upon the official release of the final document, the Medical Devices Administration Law (the *"MDAL"*) will be the first basic law in the PRC to regulate medical devices, with its legal hierarchy higher than the effective Regulations for the Supervision and Administration of Medical Devices (the *"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 (the *"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 others.

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 (the *"AMR"*) are in charge of certain permit issuance and law enforcement on pharmaceu-

ticals and medical devices at city and county levels.

National Health Commission (NHC)
The NHC is mainly responsible for national health policies, 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 pharmaceuticals and medical devices regulations 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 a 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 can be sought.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals

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

Medical Devices

The RSAMD classifies medical devices into 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 through strict controls.

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 the Good Clinical Practice (GCP) for Drug Trials and the 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.

In June 2024, the Centre for Drug Evaluation (the *"CDE"*) released the Technical Guidelines for the

Evaluation of Adverse Event Relatedness in Drug Clinical Trials (*"Trial Implementation"*) to provide a reference for sponsors, investigators, regulatory agencies and other relevant personnel in conducting surveillance, identification, assessment and control of adverse reactions in drug clinical trials. For clinical trial institutions, the 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.

The Administrative 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. Notably, the NMPA issued new regulations in 2024 to optimise the review and approval procedures for clinical trials of innovative drugs, including reducing the standard review period to 30 days, and launched pilot programmes in Beijing and Shanghai.

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 the 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 operational guidance and technical requirements for conducting clinical trials. For clinical trial institutions, in line with the regulatory approach for drug clinical trials, the NMPA issued regulations on the supervision and inspection of medical device clinical trial institutions in June 2024. For clinical trials for IVD reagents, the NMPA provides special principles with a separate guideline.

The Trial Measures for the Review of Sci-tech Ethics Clinical requires that entities engaged in the life sciences, medicine and other scitech activities set up a scitech ethics review committee to assess the scitech 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 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. For pilot projects that meet the requirements, the CDE will complete the review and approval process within 30 days after receiving the application and will notify the applicants of the approval or rejection decision through its website. Applicants must wait for this notification before proceeding with subsequent work.
- If there is no objection from the CDE, the sponsor may implement the clinical trial after

the 60-day period, which will be recalculated if supplementary documents are required.
- 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. The MDAL Draft proposes shortening the approval period for medical device clinical trials from 60 days to 30 days.

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 Specifications for Drug Clinical Trial Plan Submission and Review reiterate that an applicant 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 the PRC.

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 these 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 (the *"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 is subject to other statutory requirements, such as the receipt of data subjects' consent, restrictions on cross-border data transfer, etc. In March 2024, the Cyberspace Administration of China issued the Provisions on Promoting and Regulating Cross-border Data Flow, which refines the specific requirements for cross-border data transfer.

Human genetic resource (HGR) samples and data are governed by the Biosecurity Law and the Administrative Regulation on Human Genetic Resources (the *"HGR Regulation"*). Foreign parties are currently 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 the filing/approval may result in administrative liabilities or even criminal liabilities. The 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 from the scope 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 *"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 only serve auxiliary functions).

The Center for Medical Device Evaluation (the *"CMDE"*) of the NMPA is responsible for the technical evaluation of medical devices. The NMPA has released the Announcement on Standardising the Identification of the Classification of Medical Device Products, outlining procedures to apply for the classification of newly developed medical devices which have never been classified before or where provincial MPA finds it hard to identify the device. The NMPA has issued and been constantly updating the Medical Device Classification Catalogue, 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).

- Applicants should apply for its registration as a drug if the product mainly acts as a drug, and as a medical device if the product mainly acts as a medical device.
- If the major utility of a combination product cannot be easily identified, the applicant will 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 outlined in **3.1 Product Classification: Pharmaceuticals or Medical Devices**. Having said that, it is compulsory to conduct verification and examination on manufacturing sites and pre-market GMP inspections for biologic medicinal products being registered, while the verification and examination of other drugs is 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 conducting of clinical trials without pre-approval;
- the use of unapproved package materials or containers; and
- 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 poses risks to 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.

Re-Registration

This is applicable when renewing a valid drug marketing authorisation before expiry. The NMPA has promulgated detailed application procedures and documents for re-registration of drugs.

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 marketing authorisation holder (the *"MAH"*), registration standards, 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 the 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.

In 2024, the General Office of the State Council promulgated certain opinions, requiring relevant authorities to improve the quality and efficiency of the review and approval of drugs and medical devices, such as shorter review and approval time, less inspection quantity and batches. Detailed measures are to be issued by the NMPA.

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 will comply with good manufacturing practices;
- submission of the registration application documents; and
- regulatory review by the CMDE and the NMPA/provincial MPA.

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). Both currently 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. Having said that, the MDAL Draft expressly allows the medical device registrant, namely the MAH, to transfer the registration certificate upon approval by the competent MPA, provided that the transferee is capable of quality management and risk prevention and control. It remains uncertain whether the transfer will also be allowed in the final version.

Regarding the application for Class I devices, the provincial MPA (for domestic devices) or the NMPA (for imported devices) will be provided with the filing materials, which are generally the 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 these procedures, the NMPA has required registration applications for drugs and certain medical devices to be conducted via the electronic system since 2022. In order to facilitate applicants, the CDE continues to optimise and update the software for the production of electronic application materials.

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

In addition to these 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 grounds, such as approval for expanded clinical trials and submission of the marketing authorisation application to the CDE for these drugs.

The RSAMD also has similar requirements for an expanded access programme for investigational medical devices. Moreover, the 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 relevant regulations:

- 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 a MAH, the NMPA subsequently issued Provisions on the Supervision and Administration of Drug Marketing Authorisation Holder Implementation of the Main Responsibility of Drug Quality and Safety in 2023 to 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.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

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

- 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.

Likewise, there are certain special procedures to shorten the time or facilitate the registration review of medical devices, under relevant regulations, including the following.

- 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.
- An emergency registration procedure for medical devices required in public health emergencies.

4.2 Regulatory Reliance

In terms of medical products that have obtained authorisations in other jurisdictions, China has introduced special rules for the registration of these medical products to strengthen international exchanges and co-operation.

For drugs that have been authorised to market from internationally recognised jurisdictions, supporting documents (with notarised instruments and Chinese translations) proving the overseas permits for marketing should be submitted for the application for market authorisation in the PRC. Drugs that have already been marketed overseas are classified into different categories (ie, Class 5 for chemical drugs, and Class 3.1 and 3.2 for prophylactic/therapeutic biologics), and applications are submitted based on different registration classifications and declaration documents.

Overseas research information and data could be used to support drug registration in the PRC if the sources, research institutions or laboratory conditions, quality system requirements, and other management conditions are in line with the prevailing principles of the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (the *"ICHR"*), and comply with the relevant requirements for the administration of drug registration in the PRC. Compared with the general review time limit of 200 days, the review time limit for rare disease drugs with urgent clinical needs that have been marketed overseas but are yet to be marketed in the PRC would be shortened to no more than 70 days.

An application for imported medical devices is required to be submitted to the NMPA for the filing (Class I)/application for review (Class II and Class III). Supporting documents are also of the essence when submitting the application to prove that competent authorities permit the marketing of these medical devices. In terms of the timeframe for acceptance, technical review, verification and approval of registration, there is no specific process for accelerated approval for the filing/registration of imported medical devices.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 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 capac-

ity 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 also has to obtain the corresponding manufacturing licence, which is valid for five years and is renewable for another five years and six months before it expires.

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. In recent years, the NMPA continuously issued drafts for comments in the regulations to supervise the manufacturing of exported drugs, outlining the fundamental compliance requirements for the manufacturing of exported drugs.

Medical Devices

In line 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 will conduct a filing with the provincial 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. To ensure the quality and safety of contract manufacturing of medical devices, the NMPA has established detailed requirements for quality management and supervision of contract manufacturing of medical devices since June 2024, which aims to fully implement the responsibilities of medical device registrants.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

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, and the NMPA issued the Announcement on Further Improving the Supervision and Administration of Pharmaceutical Distribution in April 2024. These measures further clarify the conditions, procedures and quality management requirements for obtaining a drug distribution licence.

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 distribution licence. The licence is valid for five years and can be renewed two to six months before expiry. The relevant provincial MPA will review the application, conduct on-site examinations and decide whether to approve it.

An application for changes to licensed matters of a drug distribution licence must be submitted to the issuing authority, which will make its decision within 15 days from the date of receiv-

ing the change application. In addition, a wholesale drug distributor must have a self-operated warehouse that is appropriate for its range of products and scale of operations.

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

Medical Devices

The wholesale distribution of Class I devices does not require authorisation. For Class II devices, a distributor should maintain a distribution filing receipt from the provincial MPA, which will grant receipt if all the required documents are submitted. The wholesale distribution of Class III devices requires a distribution licence from the provincial MPA, which will review the application, conduct examinations when necessary and decide whether to approve the application.

A filing receipt for Class II devices does not specify a validity period, while a distribution licence for Class III devices is valid for five years and can be renewed for another five years, subject to an application for renewal within 30 to 90 working days before expiry.

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

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

6.2 Different Classifications Applicable to Pharmaceuticals

For the different classifications that apply to pharmaceuticals (such as *"available only on prescription"*), see **1.3 Different Categories of Pharmaceuticals and Medical Devices**. Additionally, a drug retailer will not offer free prescription drugs or Class A OTC drugs for purchase or commodity.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The import and export of pharmaceuticals and medical devices are subject to the Customs Law of the PRC, the DAL and various relevant regulations.

The SAMR, the NMPA, the NMPA's designated drug test institutions, the Ministry of Commerce of the PRC (the *"MOFCOM"*) and China Customs all have the power to enforce relevant laws and regulations. The NMPA and its local counterparts govern the administration of the use of imported pharmaceuticals and medical devices.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

An importer of record of pharmaceuticals and medical devices is required to conduct a filing with China Customs as the customs declaration enterprise (either as a customs broker or as a consignee of imported/exported goods).

If the importer of record concurrently acts as the applicant for the NMPA's import filing (see **7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices**) and port inspection for imported pharmaceuticals, it must maintain a drug distribution licence or a drug manufacturing licence (for active pharmaceutical ingredients and intermediate agents).

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

Prior Authorisations for Importation of Pharmaceuticals

The following require prior authorisation:

- in general, imported pharmaceuticals must obtain marketing authorisations from the NMPA prior to importation. An additional import permit issued by the NMPA is required for narcotic drugs and psychotropic drugs;
- in exceptional cases, pharmaceuticals can be imported by means of a special approval from the NMPA;
- a small number of drugs to be imported by a hospital and used for specific medical purposes due to urgent clinical needs;
- drug samples for drug registration purposes; and
- comparator drugs (except narcotic drugs and psychotropic drugs) for the purposes of drug registration or consistency evaluation of generic drugs.

Individuals bringing drugs to China for their personal use are exempted from these requirements.

Prior Authorisations for Importation of Medical Devices

The following applies:

- imported medical devices will first be filed/registered with the NMPA and obtain marketing authorisations;
- if the imported medical devices fall into the Catalogue of Products Subject to the Compulsory Product Certification System, a Chinese compulsory certification is required;
- if the imported medical devices fall into the Catalogue of Commodities Subject to the Automatic Import Licence Administration, an automatic import licence is required; and
- if medical devices are imported for emergency use, an approval from expert evaluation organised by the CMDE of the NMPA is required.

To meet peoples' needs for pharmaceuticals and medical devices, more and more policies have been issued by local governments to optimise import approval procedures for designated medical institutions to apply for drugs and medical devices in urgent clinical needs, such as nine cities in the Guangdong Province-Hong Kong-Macao Greater Bay Area, Beijing and Hainan Boao Lecheng International Medical Tourism Pilot Zone. A tax exemption is also applicable.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

The importation of drugs or medical devices is subject to registrations/permits, compulsory national or industrial standards and specific regulations. To guarantee the public's safe use of pharmaceuticals and medical devices, the laws

and regulations specify several reasons for prohibiting importing, including but not limited to:

- uncertain curative effect;
- serious adverse reaction;
- harm to the human body;
- expired;
- invalid;
- obsolete; or
- used.

7.5 Trade Blocs and Free Trade Agreements

China has signed and acceded to various trade blocs and free trade agreements, including the Regional Comprehensive Economic Partnership, the Framework Agreement on Comprehensive Economic Cooperation with ten members of the Association of South-East Asian Nations, the Preferential Trade Agreement (the Asia-Pacific Trade Agreement) and 18 bilateral free trade agreements (FTAs). Based on the official website of the China FTA Network, several other FTAs are also being negotiated and considered.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

Pharmaceuticals

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

Nonetheless, government policies may have a significant effect on the pricing of drugs. For example:

- prices for drugs reimbursed by the BMI funds are determined by authorities, including the NHSA, and prices for certain drugs covered by the BMI funds are fixed through negotiations between the NHSA and suppliers thereof;
- the government centralised procurement, which offers strong bargaining power to the procuring side, gives a favourable procurement price to hospitals and drug stores participating in centralised procurement, and may set pricing rules for manufacturers and wholesalers;
- the *"two-invoice system"* eliminates multi-tiered distribution channels and lowers drug prices; and
- the enforcement of *"zero mark-up policy"* means that public hospitals may not add any mark-up when selling drugs to patients.

Medical Devices

There is no nationwide regulation or policy specifically and directly controlling the pricing of all medical devices. However, the pricing of medical devices may be significantly influenced by the following regulatory factors:

- the pricing of certain medical devices is indirectly restricted because national and local rules limit the amount that a public hospital may charge patients for medical services, and the cost of medical devices used in these services may be included in those charges;
- the procurement of certain costly medical devices by hospitals is strictly controlled by planning at the central and provincial levels; and
- centralised procurement, the *"two-invoice system"* and the *"zero mark-up policy"* may also be applied to the procurement of certain high-value medical consumables by public hospitals, etc.

8.2 Price Levels of Pharmaceuticals or Medical Devices

PRC law does not require the prices of pharmaceuticals and medical devices to be benchmarked or otherwise set in reference to the prices of the same products in other countries. However, the NHSA does monitor drug prices at home and abroad for the purpose of making timely warnings of any abnormal changes to drug prices and supply. Prices in other countries might also be used as reference points during negotiations between the NHSA and drug suppliers with respect to BMI funds coverage.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Pharmaceuticals

The NHSA and the Ministry of Human Resources and Social Security (the *"MOHRSS"*) jointly issued the latest version of the National Reimbursement Drug List (the *"NRDL"*) in 2024. Under the NRDL, pharmaceuticals are classified into Class A and Class B, with each class being reimbursed differently by the BMI funds. Patients assume full costs for drugs excluded from the NRDL.

The latest effective NRDL, officially implemented on 1 January 2025, reiterates that all provincial authorities will implement the same NRDL with limited exceptions, including ethnic medicines, preparations of medical institutions and Chinese medicine tablets.

Medical Devices

Medical consumables may be considered *"diagnosis and treatment items"* or parts of these items for BMI funds reimbursement purposes. Certain local healthcare security administrations at the provincial level have promulgated effective lists of medical consumables that local BMI funds can reimburse.

At the end of 2024, the General Office of the State Council issued the Opinions on Comprehensively Deepening the Reformation of Pharmaceuticals and Medical Devices Supervision and Promoting the High-Quality Development of the Pharmaceutical Industry, providing guidance on studying and standardising the lists of medical consumables and medical service for medical insurance, and incorporating eligible innovative drugs and medical devices into the medical insurance coverage.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Pharmaco-economic analysis would be employed when assessing which drugs are to be included in the NRDL and the price for NRDL negotiations. Pharmaco-economic materials may be required to be submitted by applicants to add a drug into the NRDL or to adjust its reimbursement coverage.

A cost-benefit analysis would also be considered when assessing which medical consumables are to be covered by BMI funds.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

Physicians and pharmacists must follow the principles of safety, effectiveness and economy when issuing or dispensing prescriptions.

A physician may decide what drugs are to be prescribed based on the physician's professional judgement that the prescription is rational and appropriate to a patient's condition. In no event will the prescription be formulated by artificial intelligence (AI). The quantity of drugs a physician may prescribe is specifically limited for each

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

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

- The BMI funds indirectly require physicians to consider the BMI budget when prescribing drugs and to use medical consumables reimbursed by the BMI funds.
- Hospitals are required to prioritise drugs and medical consumables that are centrally procured.
- Diagnosis-related group (DRG) payment methods and the big data diagnosis-intervention package (DIP) are aimed to be fully implemented and expanded to all medical institutions by the end of 2025 and will pressure hospitals to control medical expenses so may influence physicians' prescription behaviours. The NHSA is building an intelligent monitoring system for BMI fund supervision of the DRGs and DIP payment methods.
- Local authorities of the NHSA, along with other departments, conduct examinations of the use of BMI funds through diverse inspections, such as daily supervision, special inspections, joint inspections, unannounced inspections and inspections based on whistle-blowing. The increasingly severe punitive measures imposed on designated medical institutions and drug retailers contracting with the agencies of the BMI, as well as the mechanism and rewards for reporting incompliant use of BMI funds, aim to restrain fraudulent activities in the use of BMI funds. The special rectification campaign to crack down on BMI fund fraud led by the NHSA focuses on acts of obtaining insurance benefits in a deceptive manner and monitors how the BMI funds are reimbursed on key drugs and medical consumables with top billing.

A pharmacist will dispense prescription drugs according to a physician's prescription. The examination of a prescription by an eligible pharmacist focuses on the appropriateness, rationality and correctness of a drug's use, rather than economic considerations.

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