This section sets forth a summary of the major relevant PRC laws, regulations, rules and policies that may have a significant impact on our business and operations.

MAJOR REGULATORY AUTHORITIES

The major regulatory authorities of the pharmaceutical industry in the PRC include: the National Medical Products Administration (the "**NMPA**"), the National Health Commission (the "**NHC**") and the National Healthcare Security Administration (the "**NHSA**").

The NMPA is subject to the supervision and administration of the State Administration for Market Regulation (the "**SAMR**") and is the primary regulatory authority in the PRC responsible for the supervision and administration of pharmaceuticals and related matters. It regulates almost all key phases of the drug life cycle, including non-clinical research, clinical trials, marketing approval, manufacturing and distribution.

The Center for Drug Evaluation (the "**CDE**") is a directly affiliated unit under the NMPA responsible for the technical review of various drug and biological product applications to assess the safety, efficacy and quality controllability of each drug candidate.

The NHC is the primary regulatory authority responsible for public health. Its main responsibilities include formulating national health policies, supervising and managing public health, medical services and health emergency systems, coordinating the reform of the medical and health system, organizing the formulation of national drug policies and the national essential drug system, carrying out drug use monitoring, comprehensive clinical evaluation and early warning of drug shortages, proposing recommendations on national essential drug pricing policies, and regulating the operation of medical institutions and the practice of medical professionals.

The NHSA is an institution directly under the State Council of the PRC responsible for the administration of the medical security system. Its main responsibilities include formulating and organizing the implementation of policies and standards for medical insurance, maternity insurance, and medical assistance; supervising and managing medical security funds; organizing the formulation of unified medical insurance catalogues and payment standards for drugs, medical consumables and medical services; and formulating and supervising the implementation of bidding and procurement policies for drugs and medical consumables.

PRC LAWS AND REGULATIONS

Laws and Regulations on New Drugs

Administration of Drug Registration

Pursuant to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) promulgated by the SAMR on January 22, 2020 and effective from July 1, 2020, the Administrative Measures for Drug Registration apply to drug development, registration, and supervision and administration activities conducted within the territory of the PRC for the purpose of drug marketing. According to the Administrative Measures for Drug Registration, drug registration refers to activities wherein a drug registration applicant submits applications for drug clinical trials, drug marketing authorization, re-registration, and supplemental applications in accordance with legal procedures and relevant requirements, and the drug regulatory authorities conduct reviews on safety, efficacy, and quality controllability based on laws, regulations, and existing scientific knowledge to decide whether to approve the application. Drug registration is subject to classified registration management for traditional Chinese medicines, chemical drugs, and biological products. Registration of chemical drugs is classified into innovative chemical drugs, improved new chemical drugs, generic drugs, etc. Registration of biological products is classified into innovative biological products, improved new biological products, marketed biological products (including biosimilars), etc. Before applying for drug marketing registration, an applicant shall complete relevant research work such as pharmacy, pharmacology and toxicology, and drug clinical trials. Non-clinical safety evaluation studies of drugs shall be conducted in institutions certified for Good Laboratory Practice and shall comply with the Good Laboratory Practice for Non-Clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) ("**GLP**"). Drug clinical trials are subject to approval, while bioequivalence studies are subject to filing; Drug clinical trials shall be conducted in drug clinical trial institutions that comply with relevant

regulations and shall adhere to the Good Clinical Practice for Drug Clinical Trials (《藥物臨床試驗質量管理規範》) ("**GCP**"). The administration of drug registration follows the principles of openness, fairness, and justice, is oriented by clinical value, encourages the research and creation of new drugs, and actively promotes the development of generic drugs.

A drug registration certificate is valid for five years. During the validity period, the holder of the drug registration certificate shall continuously ensure the safety, efficacy, and quality controllability of the marketed drug, and shall apply for drug re-registration six months before the expiration of the validity period.

Non-clinical Research and Animal Testing

Institutions engaged in non-clinical safety evaluation studies must implement the Good Laboratory Practice for Non-Clinical Laboratory Studies, which was promulgated by the China Food and Drug Administration (the "**CFDA**", the predecessor of the NMPA) on August 6, 2003, last revised on July 27, 2017, and became effective on September 1, 2017. GLP comprises a set of quality system rules and standards related to the organizational processes and conditions for planning, performing, monitoring, recording, achieving, and reporting non-clinical laboratory studies. Other relevant pre-clinical research activities for the purpose of drug registration shall be conducted with reference to GLP. The Administrative Measures for Certification of Good Laboratory Practice for Non-clinical Drug Research (《藥物非臨床研究質量管理規範認證管理辦法》), last revised by the NMPA on January 19, 2023 and effective from July 1, 2023, sets out the requirements for institutions to apply for GLP certification to conduct non-clinical drug research.

Pursuant to the Regulations on the Administration of Laboratory Animals (《實驗動物管理條例》) promulgated by the State Science and Technology Commission on November 14, 1988 and last revised by the State Council on March 1, 2017, the Administrative Measures for the Quality of Laboratory Animals (《實驗動物質量管理辦法》) jointly promulgated and implemented by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision on December 11, 1997, and the Administrative Measures for the Licensing of Laboratory Animals (for Trial Implementation) (《實驗動物許可證管理辦法(試行)》) promulgated by the Ministry of Science and Technology and other regulatory authorities on December 5, 2001 and effective from January 1, 2002, a license for the use of laboratory animals is required for the use of laboratory animals and related products. The license for the use of laboratory animals is valid for five years, and the holder shall apply for re-examination and issuance of the license six months before the expiration of the validity period.

Application and Approval of Clinical Trials

To apply for new drug registration, clinical trials shall be conducted. After completing pre-clinical studies, an applicant must obtain approval from the NMPA before conducting clinical trials. According to the Decision on Adjusting the Approval Procedures for Certain Drug Administrative Approval Matters (《關於調整部分藥品行政審批事項審批程序的決定》), promulgated by the CFDA on March 17, 2017 and effective from May 1, 2017, since May 1, 2017, the approval decisions for drug clinical trials made by the CFDA have been adjusted to be made by the CDE in the name of the CFDA.

According to the Announcement on Certain Policies for Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》), promulgated and implemented by the CFDA on November 11, 2015, a one-time approval system is implemented for clinical trial applications for new drugs, and the method of phased application, review and approval is no longer adopted. The Announcement on Adjusting the Review and Approval Procedures for Drug Clinical Trials (《關於調整藥物臨床試驗審評審批程序的公告》), promulgated and implemented by the NMPA on July 24, 2018, stipulates that if no negative or questioning opinion is received from the CDE within 60 working days from the date of acceptance of payment, the applicant may conduct clinical trials in accordance with the submitted protocol. The Drug Administration Law of the People's Republic of China (《中華人民共和國藥品管理法》) (the "**Drug Administration Law**"), promulgated by the Standing Committee of the National People's Congress (the "**NPC Standing Committee**") on September 20, 1984, last revised on August 26, 2019 and effective from December 1, 2019, further confirms that the drug regulatory department of the State Council shall decide whether to approve and notify the clinical trial sponsor within 60 working days from the date of accepting the clinical trial application. If no notification is given within the time limit, it shall be deemed as approved.

Clinical Trial Registration

According to the Administrative Measures for Drug Registration, after obtaining approval for a clinical trial and before commencing the trial, the sponsor shall register information such as the clinical trial protocol on the Drug Clinical Trial Registration and Information Disclosure Platform. During the drug clinical trial, the sponsor shall continuously update the registration information and register information such as the results of the drug clinical trial after its completion. The registered information is publicly disclosed on the platform, and the sponsor is responsible for the authenticity of the registered information of the drug clinical trial. The Announcement on the Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), issued and effective on September 6, 2013 by the CFDA, provides more detailed regulations, stipulating that all clinical trials approved by the CFDA and conducted within the territory of the PRC shall be published through the Drug Clinical Trial Registration and Information Disclosure Platform. The applicant must complete the pre-registration of the trial within one month after obtaining the approval to acquire a unique trial registration number; complete the subsequent information registration before the enrollment of the first subject, and submit it for the first public disclosure. If the first public disclosure is not completed within one year of obtaining the approval, the applicant must submit an explanation; if the first public disclosure is not completed within three years, the approval will be automatically invalidated.

Phases of Clinical Trials

The Administrative Measures for Drug Registration classify drug clinical trials into Phase I, Phase II, Phase III, and Phase IV clinical trials, as well as bioequivalence studies. According to the characteristics of the drug and the research objectives, the research content includes clinical pharmacology studies, exploratory clinical trials, confirmatory clinical trials, and post-marketing studies.

Pursuant to the Regulations for the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), promulgated by the NMPA and the NHC on November 29, 2019 and effective from December 1, 2019, drug development activities and drug clinical trials approved by the NMPA (including bioequivalence studies conducted after filing) conducted within the territory of the PRC shall be carried out in drug clinical trial institutions. Drug clinical trial institutions are subject to a record-filing administration system.

According to the Drug Administration Law and the Administrative Measures for Drug Registration, conducting drug clinical trials shall be subject to the review and approval of an ethics committee and shall comply with the relevant requirements of GCP. The sponsor shall periodically submit development safety update reports on the website of the CDE. For suspected and unexpected serious adverse reactions and other potential serious safety risk information that occur during a drug clinical trial, the sponsor shall promptly report to the CDE in accordance with relevant requirements. Depending on the severity of the safety risk, the sponsor may be required to take measures to strengthen risk control, and if necessary, may be required to suspend or terminate the drug clinical trial.

According to the Announcement of the National Medical Products Administration on Adjusting the Review and Approval Procedures for Drug Clinical Trials, for an investigational new drug that has been approved for clinical trials, the applicant shall, after completing Phase I and Phase II clinical trials and before commencing Phase III clinical trials, apply to the CDE for a communication meeting to discuss key technical issues, including the design of the Phase III clinical trial protocol, with the CDE. Applicants may also apply for communication meetings on key technical issues at different stages of clinical development.

Regulations on International Multicenter Clinical Trials and Acceptance of Overseas Clinical Trial Data

According to the Circular on the Issuance of the Guideline for International Multicenter Drug Clinical Trials (for Trial Implementation) (《關於發布國際多中心藥物臨床試驗指南（試行）的通告》) (the "**Guideline for Multicenter Clinical Trials**" (《多中心臨床試驗指南》)) (issued by the CFDA on January 30, 2015 and effective from March 1, 2015), applicants for international multicenter clinical trials may conduct clinical trials simultaneously in different centers using the same clinical trial protocol. Applicants planning to conduct international multicenter clinical trials in the PRC shall

comply with relevant laws and regulations such as the Drug Administration Law, the Regulations for the Implementation of the Drug Administration Law of the People's Republic of China (《中華人民共和國藥品管理法實施條例》) promulgated by the State Council in August 2002 and last amended on January 16, 2026 and became effective on May 15, 2026 (the latest version was published on January 16, 2026 and became effective on May 15, 2026), have laid down the legal framework for the establishment and maintenance of pharmaceutical manufacturing and trading enterprises, as well as for the administration of pharmaceutical products including the development and manufacturing of new drugs. The developer and clinical trial applicant of any new drug shall truthfully submit the new drug's manufacturing method, quality specifications, results of pharmacological and toxicological tests and the related data, documents and samples to the NMPA for approval before any clinical trial is conducted.

According to the Opinions on Deepening the Reform of the Review and Approval System and Encouraging Innovation in Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (issued and implemented by the General Office of the CPC Central Committee and the General Office of the State Council on October 8, 2017), data from international multicenter clinical trials that meet the registration requirements for drugs and medical devices in the PRC can be used for registration applications in the PRC.

According to the Technical Guiding Principles for Accepting Overseas Clinical Trial Data of Drugs (《接受藥品境外臨床試驗數據的技術指導原則》) (issued and implemented by the NMPA on July 6, 2018), the basic principles for accepting overseas clinical trial data include: (1) the applicant shall ensure the authenticity, integrity, accuracy, and traceability of the overseas clinical trial data; (2) the generation process of overseas clinical trial data shall comply with the relevant requirements of ICH-GCP; (3) the applicant shall ensure the scientific nature of the overseas clinical trial design, compliance with the requirements of the clinical trial quality management system, and the accuracy and integrity of data analysis; (4) to ensure the scientific and rational nature of the clinical trial design and data analysis, for drugs that are being developed simultaneously domestically and abroad and are about to undergo clinical trials in the PRC, the applicant may communicate with the CDE before implementing the registration clinical trial to ensure that the design of the registration clinical trial meets the basic technical requirements for drug registration in the PRC. According to the Technical Guiding Principles for Accepting Overseas Clinical Trial Data of Drugs, the integrity of clinical trial data is a basic requirement for accepting a registration application. For overseas clinical trials used for drug registration applications in China, all overseas clinical trial data must be provided in full and may not be provided selectively. Applicants should evaluate early clinical trial data, and clinical trials with complete data can be used to support subsequent clinical trials after communication with the CDE.

New Drug Marketing Application, Registration and Marketing Authorization

According to the Administrative Measures for Drug Registration, after completing research in pharmacy, pharmacology and toxicology, and drug clinical trials, determining quality standards, completing commercial-scale production process validation, and preparing for drug registration inspection and testing, an applicant may submit an application for drug marketing authorization. According to the Administrative Measures for Drug Registration, drug marketing registration applications are divided into three categories: traditional Chinese medicines, chemical drugs, and biological products. The CDE shall organize pharmaceutical, medical, and other technical personnel to conduct a comprehensive review of the safety, efficacy, and quality controllability of drugs. If the comprehensive review conclusion is passed, the drug will be approved for marketing and a drug registration certificate will be issued.

According to the Drug Administration Law, an applicant who has obtained a drug registration certificate shall be confirmed as a marketing authorization holder and shall be responsible for the non-clinical research, clinical trials, production and operation, post-marketing studies, adverse reaction monitoring, reporting and handling of the drug in accordance with the provisions of the Drug Administration Law. A marketing authorization holder may manufacture or distribute the drug itself or entrust a qualified third party to do so.

Marketing Authorization Holder System

Pursuant to the Drug Administration Law and the Administrative Measures for Drug Registration, the state implements the drug marketing authorization holder system for drug management. After obtaining a drug registration certificate, an applicant shall be the drug marketing authorization holder. During the validity period, a holder of a drug registration certificate shall continue to ensure the safety, effectiveness and quality controllability of the marketed drug, and apply for re-registration of the drug six months prior to the expiry of the validity period.

The drug marketing authorization holder shall proactively carry out post-marketing research on drugs, further confirm the safety, effectiveness and quality controllability of drugs, and strengthen the continuous management of marketed drugs. Where a drug registration certificate and its annex require the marketing authorization holder to carry out relevant research work after the drug is marketed, the marketing authorization holder shall complete the research within the prescribed time limit and file a supplementary application, undergo recordation formalities or report as required. After a drug is approved for marketing, the marketing authorization holder shall continue to conduct research on drug safety and effectiveness, undergo recordation formalities in a timely manner or file a supplementary application for revising the instructions according to the relevant data, and continuously update and improve the instructions and labels. According to the duties, the medical products administrative department may require the marketing authorization holder to revise the instructions and labels based on the monitoring of adverse drug reactions and the post- marketing reevaluation results of the drug.

The marketing authorization holder shall apply for re-registration six months prior to the expiry of the validity period of the drug registration certificate. An application for re- registration of a domestically produced drug shall be filed by the marketing authorization holder with the medical products administrative department of the province, autonomous region, or municipality directly under the Central Government, and an application for re-registration of a drug produced overseas shall be filed by the marketing authorization holder with the Center for Drug Evaluation.

Pharmacovigilance

According to the Good Pharmacovigilance Practices《藥物警戒質量管理規範》promulgated by the NMPA on May 7, 2021 and effective from December 1, 2021, marketing authorization holders and drug registration applicants approved to conduct clinical trials of drugs shall establish a pharmacovigilance system to monitor, identify, assess and control adverse drug reactions and other harmful reactions related to drug use through the effective operation and maintenance of the system. Marketing authorization holders shall formulate pharmacovigilance quality objectives and establish a quality assurance system to perform quality management for the pharmacovigilance system and its activities, continuously enhance the operational effectiveness of the pharmacovigilance system, and ensure that pharmacovigilance activities consistently comply with relevant legal and regulatory requirements. The legal representative or principal responsible person of a marketing authorization holder is fully responsible for the pharmacovigilance activities. A marketing authorization holder shall complete information registration in the National Adverse Drug Reaction Monitoring System within 30 days after obtaining the first drug approval certificate.

Approval or Filing Regarding Human Genetic Resources in the PRC

According to the Service Guide for Administrative Licensing Matters of Collection, Gathering, Trading, Export, and Exit of Human Genetic Resources (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》), promulgated and implemented by the Ministry of Science and Technology ("**MOST**") on July 2, 2015, the collection, gathering, or research activities of human genetic resources involving foreign participation fall under the scope of international cooperation and require the Chinese collaborating entity to apply for approval from the Human Genetic Resources Administration Office of China. According to the Notice on Updating the Service Guide for Administrative Licensing of Human Genetic Resources, Filing, and the Scope and Procedures for Prior Reporting (《關於更新人類遺傳資源行政許可事項服務指南、備案以及事先報告範圍和程序的通知》), promulgated and implemented by MOST on July 14, 2023, for the purpose of obtaining drug marketing authorization in the PRC, conducting international cooperative clinical trials using PRC human genetic resources in clinical medical and health institutions without involving the export of human genetic resource materials does not require approval, but certain conditions must be met and the types,

quantities, and uses of the human genetic resources to be used shall be filed with MOST for record before the clinical trial is conducted; the exploratory research part of a clinical trial shall apply for administrative permission for international scientific research cooperation on human genetic resources.

Pursuant to the Regulations of the People's Republic of China on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》), promulgated by the State Council on May 28, 2019, last revised on March 10, 2024 and effective from May 1, 2024, human genetic resources include human genetic resource materials and information. The Regulations of the People's Republic of China on the Administration of Human Genetic Resources further clarify that for the purpose of obtaining drug marketing in the PRC, conducting international cooperative clinical trials using our country's human genetic resources in clinical institutions without involving the export of human genetic resource materials does not require approval, but both collaborating parties shall file the types, quantities, and uses of the human genetic resources to be used with the competent health department of the State Council for record before conducting the clinical trial. Foreign organizations, individuals, and institutions established or actually controlled by them shall not collect or preserve our country's human genetic resources within the territory of the PRC, nor shall they provide our country's human genetic resources to overseas parties.

Implementing Rules for the Administrative Regulation on Human Genetic Resources (《人類遺傳資源管理條例實施細則》), promulgated by MOST on May 26, 2023 and effective from July 1, 2023, further clarify the requirements for administrative licensing, filing, and security review related to the collection, preservation, utilization, and provision to foreign parties of PRC human genetic resources, and detail matters related to supervision, inspection, and administrative penalties.

According to the Biosecurity Law of the People's Republic of China (《中華人民共和國生物安全法》), promulgated by the NPC Standing Committee on October 17, 2020, last revised and effective on April 26, 2024, providing or opening access to PRC human genetic resource information to foreign organizations, individuals, or institutions established or actually controlled by them shall be subject to prior reporting to and submission of an information backup to the competent health department of the State Council. It also stipulates that approval must be obtained for conducting international scientific research cooperation using Chinese biological resources.

Regulations on Drug Manufacturing

Drug Manufacturing License

According to the Drug Administration Law, a drug manufacturer must be approved by the relevant provincial-level department of the NMPA and obtain a drug manufacturing license. According to the Administrative Measures for the Supervision of Drug Manufacturing (《藥品生產監督管理辦法》), promulgated by the SAMR on January 22, 2020 and implemented from July 1, 2020, the validity period of a drug manufacturing license is five years, and the holder of the drug manufacturing license shall apply to the original issuing authority for renewal at least six months before the expiration of the validity period, which shall be approved.

Good Manufacturing Practice for Drugs

The Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) ("**GMP**"), last revised by the Ministry of Health of the PRC (the "**MOH**", now the NHC) on January 17, 2011 and effective from March 1, 2011, systematically regulates aspects of drug manufacturers such as quality management, organization and personnel, premises and facilities, equipment, materials and products, qualification and validation, documentation management, production management, quality control and quality assurance, contract manufacturing and testing, product dispatch and recall, and self-inspection.

Prior to December 1, 2019, drug manufacturers were required to apply for GMP certification and obtain a GMP certificate from the drug regulatory authorities in accordance with relevant regulations. According to the Announcement on Matters Concerning the Implementation of the <Drug Administration Law of the People's Republic of China> (《關於貫徹實施<中華人民共和國藥品管理法>有關事項的公告》), issued and implemented by the NMPA on November 29, 2019, since December 1, 2019, GMP and GSP certifications for drugs have been cancelled, applications for GMP and GSP certifications are no longer accepted, and GMP and GSP certificates for drugs are no longer issued. However, according to the Drug Administration Law, drug manufacturers must still comply with GMP,

establish and improve the GMP system, and ensure that the entire drug manufacturing process always complies with legal requirements. The legal representative and principal responsible persons of a drug manufacturer are fully responsible for the drug manufacturing activities of the enterprise.

On May 24, 2021, the NMPA promulgated the Administrative Measures for Drug Inspection (for Trial Implementation) (《藥品檢查管理辦法(試行)》), which was revised on July 19, 2023, and repealed the Administrative Measures for the Certification of Good Manufacturing Practice for Drugs (《藥品生產質量管理規範認證管理辦法》). The Administrative Measures for Drug Inspection (for Trial Implementation) stipulate that when a drug manufacturer applies for a drug manufacturing license for the first time, an on-site inspection shall be conducted in accordance with the relevant content of GMP. When a drug manufacturer applies for the re-issuance of a drug manufacturing license, a review shall be conducted based on the principles of risk management, taking into account the manufacturer's compliance with drug administration laws and regulations, GMP, and the operation of its quality management system. If necessary, a GMP compliance inspection may be conducted on the drug manufacturer. If a workshop or production line is newly built, rebuilt, or expanded on the original site or at a different location, a GMP compliance inspection shall be conducted.

Contract Manufacturing of Drugs

According to the Drug Administration Law, a marketing authorization holder may manufacture drugs itself or entrust a drug manufacturer to do so. If a marketing authorization holder manufactures drugs itself, it shall obtain a drug manufacturing license; if the holder entrusts a third party with production, it shall entrust a qualified drug manufacturer. The marketing authorization holder and the contract manufacturer shall sign a contract agreement and a quality agreement and strictly perform the obligations stipulated in the agreements. Blood products, narcotic drugs, psychotropic drugs, toxic drugs for medical use, and precursor chemicals for drug production shall not be contract manufactured, unless otherwise stipulated by the drug regulatory department of the State Council.

Pursuant to the Regulations on the Supervision and Administration of Contract Manufacturing of Drugs (《藥品委托生產監督管理規定》), promulgated by the CFDA on August 14, 2014 and effective from October 1, 2014, a drug manufacturer may entrust other domestic drug manufacturers to produce its drugs only when it temporarily lacks the production conditions due to technological upgrades or when its production capacity is insufficient to guarantee market supply. Such contract manufacturing arrangements must be approved by the provincial branch of the CFDA.

According to the Administrative Measures for the Supervision of Drug Manufacturing, a marketing authorization holder that entrusts another party to produce a formulation shall sign a contract agreement and a quality agreement with a qualified drug manufacturer, and submit the relevant agreements and application materials for the actual production site to the drug regulatory department of the province, autonomous region, or municipality directly under the central government where the marketing authorization holder is located, to apply for a drug manufacturing license in accordance with the provisions of these measures.

New Drug Monitoring Period

Pursuant to the Regulations for the Implementation of the Drug Administration Law of the People's Republic of China, based on the requirements for protecting public health, the drug regulatory department of the State Council may establish a monitoring period of no more than 5 years for new drug varieties produced by drug manufacturers; During the monitoring period, other enterprises shall not be approved for production and import.

Pharmaceutical Distribution and the Two-Invoice System

Pursuant to the Implementation Opinions on Implementing the "Two-Invoice System" in Drug Procurement by Public Medical Institutions (for Trial Implementation) (《關於在公立醫療機構藥品採購中推行「兩票制」的實施意見(試行)》) issued on December 26, 2016 (the "**Two-Invoice System Implementation Opinions**"), the "Two-Invoice System" means that one invoice is issued by a drug manufacturer to a distribution enterprise, and another invoice is issued by the distribution enterprise to a medical institution. A wholly-owned or controlled commercial company established by a drug manufacturer or an integrated industry-trade-science group enterprise that exclusively sells drugs of such enterprise (group) (limited to one national commercial company) or the exclusive domestic general

agent of an overseas drug (limited to one national domestic general agent) may be regarded as a drug manufacturer. The internal transfer of drugs by a drug distribution group enterprise to its wholly-owned (controlled) subsidiaries or between such subsidiaries shall not be counted as one invoice, provided that no more than one invoice is permitted. The Two-Invoice System shall be gradually implemented in drug procurement by public medical institutions, and implementation of the system shall be encouraged in drug procurement by other medical institutions. Pilot provinces (autonomous regions and municipalities directly under the Central Government) for comprehensive medical reform and pilot cities for public hospital reform shall take the lead in implementing the Two-Invoice System, and other regions are encouraged to adopt the system with a view to achieving full nationwide implementation by 2018.

In accordance with the Two-Invoice System Implementation Opinions, in regions where the Two-Invoice System is implemented for drug procurement by public medical institutions, centralized procurement agencies shall include compliance with the Two-Invoice System as a mandatory requirement when formulating procurement documents. Drug enterprises participating in centralized drug procurement shall make a commitment to comply with the Two-Invoice System in their bidding documents; failure to do so shall render their bids invalid. For drugs procured through other procurement methods, relevant requirements on the Two-Invoice System shall also be clearly stipulated in the procurement contracts.

Pursuant to Several Opinions of the General Office of the State Council on Further Reforming and Improving Policies for Drug Production, Distribution and Use (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》) issued on January 24, 2017, pilot provinces (autonomous regions and municipalities directly under the Central Government) for comprehensive medical reform and pilot cities for public hospital reform shall take the lead in implementing the Two-Invoice System, other regions are encouraged to adopt the system, and full nationwide implementation shall be strived for by 2018.

Other Laws and Regulations relating to the Pharmaceutical Industry

Basic Medical Insurance Policies

According to the Decision on the Establishment of the Basic Medical Insurance System for Urban Employees (《關於建立城鎮職工基本醫療保險制度的決定》) promulgated and implemented by the State Council on December 14, 1998 and the Interim Measures for the Administration of the Scope of Drugs for Basic Medical Insurance for Urban Employees (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》) issued and implemented by the Ministry of Human Resources and Social Security (formerly the Ministry of Labor and Social Security) on May 12, 1999, all employers in urban areas, including enterprises (state-owned enterprises, collective enterprises, foreign-invested enterprises, private enterprises, etc.), government agencies, public institutions, social organizations, and private non-enterprise units, and their employees, must participate in basic medical insurance. According to the Guiding Opinions on Launching the Pilot Program for Basic Medical Insurance for Urban Residents (《關於開展城鎮居民基本醫療保險試點的指導意見》) promulgated and implemented by the State Council on July 10, 2007, non-employed urban residents in pilot areas may voluntarily participate in the basic medical insurance for urban residents. According to the Opinions of the State Council on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents (《國務院關於整合城鄉居民基本醫療保險制度的意見》) promulgated and implemented by the State Council on January 3, 2016, a unified basic medical insurance system for urban and rural residents shall be established, including all persons who should be insured under the existing urban resident medical insurance and the new rural cooperative medical system, that is, covering all other urban and rural residents except for those who should be insured under the basic medical insurance for employees.

Basic Medical Insurance Drug Catalogue

According to the Interim Measures for the Administration of the Scope of Drugs for Basic Medical Insurance for Urban Employees, the scope of drugs for basic medical insurance is managed through the formulation of the Basic Medical Insurance Drug Catalogue (《基本醫療保險藥品目錄》) (the "**Medical Insurance Drug Catalogue**"). Drugs included in the Medical Insurance Drug Catalogue should be clinically necessary, safe and effective, reasonably priced, convenient to use, and with a guaranteed market supply, and meet one of the following conditions: drugs included in the current edition of the Pharmacopoeia of the People's Republic of China (《中華人民共和國藥典》); drugs that

meet the standards issued by the NMPA; and drugs officially approved for import by the NMPA. The Medical Insurance Drug Catalogue is divided into "Category A Catalogue" and "Category B Catalogue". Patients who purchase drugs included in the "Category A Catalogue" of the Medical Insurance Drug Catalogue are entitled to reimbursement in accordance with the provisions of the basic medical insurance. Patients who purchase drugs included in the "Category B Catalogue" of the Medical Insurance Drug Catalogue must pay a certain percentage of the purchase price, and the remaining purchase price is reimbursed in accordance with the provisions of the basic medical insurance. According to the Opinions of the National Healthcare Security Administration and the Ministry of Finance on Establishing a List System for Medical Security Benefits (《國家醫保局、財政部關於建立醫療保障待遇清單制度的意見》), issued and implemented on January 19, 2021, all localities must strictly implement the Medical Insurance Drug Catalogue and, unless otherwise explicitly stipulated by the state, shall not formulate their own catalogues or use alternative methods to add drugs to the catalogue. After multiple adjustments, the currently effective Medical Insurance Drug Catalogue is the National Basic Medical Insurance, Maternity Insurance and Work-related Injury Insurance Drug Catalogue (2025) (《國家基本醫療保險、生育保險和工傷保險藥品目錄（2025年）》), effective from January 1, 2026.

Drug Pricing

According to the Drug Administration Law, for drugs whose prices are subject to market regulation by law, marketing authorization holders, drug manufacturers, drug distributors, and medical institutions shall set prices in accordance with the principles of fairness, reasonableness, honesty and credit, and consistency between quality and price, to provide users with reasonably priced drugs; and shall comply with the regulations on drug price management stipulated by the competent drug pricing department of the State Council, and formulate and indicate the retail prices of drugs. According to the Notice on Issuing the <Opinions on Promoting Drug Price Reform> (《關於印發＜推進藥品價格改革意見＞的通知》), jointly issued and implemented by the NDRC, the NHC, the Ministry of Human Resources and Social Security, the Ministry of Industry and Information Technology, the Ministry of Finance, the MOFCOM, and the CFDA on May 4, 2015, government-set drug prices were abolished from June 1, 2015, with the exception of narcotic drugs and Category I psychotropic drugs. On December 26, 2023, the NHSA issued and implemented the Notice on Promoting Inter-provincial Price Fairness, Integrity, Transparency, and Balance for Drugs with the Same Generic Name and Manufacturer (《關於促進同通用名同廠牌藥品省際間價格公平誠信、透明均衡的通知》), requiring a comprehensive review and screening of "four-same drugs" (referring to drugs with the same generic name, manufacturer, dosage form, and specification) against the monitored prices formed from statistics of currently online-listed drug prices nationwide, to basically eliminate unfair high prices and discriminatory high prices for "four-same drugs" among provinces by the end of March 2024.

Drug Advertising

According to the Interim Measures for the Administration of Advertising Review for Drugs, Medical Devices, Health Foods, and Foods for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》), issued by the SAMR on December 24, 2019 and implemented on March 1, 2020, advertisements for drugs, medical devices, health foods, and foods for special medical purposes shall be truthful and legal, and shall not contain false or misleading content. The holders of registration certificates or filing vouchers for drugs, medical devices, health foods, and foods for special medical purposes, and the manufacturing or operating enterprises authorized by them, are the advertising applicants ("**Applicants**").

Applicants may entrust an agent to handle the application for advertising review of drugs, medical devices, health foods, and foods for special medical purposes. Applicants may submit applications for advertising of drugs, medical devices, health foods, and foods for special medical purposes at the reception window of the advertising review authority, or through letter, fax, email, or e-government platforms. The advertising review authority shall review the materials submitted by the applicant and complete the review work within ten working days from the date of acceptance.

Upon review, for advertisements that comply with laws, administrative regulations, and the provisions of these measures, a decision of review and approval shall be made, and an advertising approval number shall be issued. The validity period of the advertising approval number for drugs, medical devices, health foods, and foods for special medical purposes is consistent with the shortest

validity period among the product registration certificate, filing voucher, or production license document. If the product registration certificate, filing voucher, or production license document does not specify a validity period, the validity period of the advertising approval number shall be two years.

Drug Inserts, Labels, and Packaging

According to the Provisions for the Administration of Drug Inserts and Labels (《藥品説明書和標簽管理規定》), issued by the CFDA on March 15, 2006 and implemented on June 1, 2006, drug inserts and labels shall be approved by the CFDA. The drug insert shall contain important scientific data, conclusions, and information on the safety and efficacy of the drug to guide its safe and rational use. The inner label of a drug shall contain information such as the generic name, indications or functions, specifications, usage and dosage, production date, product batch number, validity period, and manufacturer; The outer label of a drug shall indicate information such as the generic name, ingredients, characteristics, indications or functions, specifications, usage and dosage, adverse reactions, contraindications, precautions, storage, production date, product batch number, validity period, approval number, and manufacturer. According to the Administrative Measures for Drug Packaging (《藥品包裝管理辦法》), effective from September 1, 1988, drug packaging must comply with the provisions of national and professional standards. In the absence of the above standards, the enterprise shall formulate drug packaging standards, which shall be implemented after approval by the provincial food and drug administration department and the standards bureau. If the packaging standards need to be changed, the enterprise must re-submit them to the relevant departments for approval. Drugs without packaging standards shall not be released from the factory or distributed (except for drugs for special military needs).

Drug Technology Transfer

Drug technology transfer refers to the process whereby the owner of drug technology transfers the drug production technology to a transferee drug manufacturer in accordance with the requirements of relevant laws and regulations on drug technology transfer, and the transferee drug manufacturer applies for drug registration. The registration process for drug technology transfer, including the application, review, approval, and supervision and administration of drug technology transfer registration, is regulated by the Administrative Measures for Drug Registration and the Provisions for the Administration of Drug Technology Transfer Registration (《藥品技術轉讓註冊管理規定》), promulgated and implemented by the CFDA on August 19, 2009. According to the above regulations, drug technology transfer is divided into new drug technology transfer and drug production technology transfer. An application for drug technology transfer shall be submitted to the provincial drug regulatory department, and the final approval decision shall be made by the CFDA based on the comprehensive opinion of the CDE. If the requirements are met, a "Drug Supplementary Application Approval Document" and a drug approval number will be issued.

Management of Pathogenic Microorganism Laboratories

Pursuant to the Regulations on the Biosafety Management of Pathogenic Microorganism Laboratories (《病原微生物實驗室生物安全管理條例》), promulgated by the State Council on November 12, 2004, most recently revised on December 6, 2024, and effective from January 20, 2025, pathogenic microorganism laboratories are classified into four levels according to national biosafety standards for laboratories, namely Level I, Level II, Level III, and Level IV. Level I or Level II laboratories shall not engage in experimental activities with highly pathogenic microorganisms. The new construction, reconstruction, or expansion of Level I or Level II laboratories shall be reported to the competent health department of the municipal people's government of the districted city for filing. The establishing unit of a laboratory shall formulate scientific and strict management systems, regularly inspect the implementation of relevant biosafety regulations, and periodically inspect, maintain, and update laboratory facilities, equipment, and materials to ensure they comply with national standards. Level III or Level IV laboratories shall obtain national laboratory accreditation. If a laboratory passes accreditation, a biosafety laboratory certificate of the corresponding level will be issued. The certificate is valid for five years.

Disinfection Products

Pursuant to the Measures for the Administration of Disinfection (《消毒管理辦法》) which was promulgated by the former State Health and Family Planning Committee on September 18, 1987 and amended on August 31, 1992, March 28, 2002 and December 26, 2017, as well as the Regulations on Sanitation and Safety Evaluation of Disinfection Products (《消毒產品衛生安全評價規定》) which was promulgated and became effective on June 27, 2014, when the first and second types of disinfection products are first launched on the market, the entity responsible for such products shall submit the sanitation and safety evaluation report to the competent provincial health administrative department for filing. The manufacturing enterprise, or the entrusted enterprise shall be responsible for the quality of the disinfection products.

Regulations on Company Establishment and Foreign Investment

The establishment, operation, and management of corporate entities in China are governed by the Company Law of the People's Republic of China (《中華人民共和國公司法》) (the "**Company Law**"), promulgated by the NPC Standing Committee on December 29, 1993, most recently revised on December 29, 2023, and implemented on July 1, 2024. The Company Law also applies to foreign-invested companies limited by shares.

Investment activities of foreign investors in the PRC are governed by the Provisions on Guiding the Direction of Foreign Investment (《指導外商投資方向規定》) (promulgated by the State Council on February 11, 2002 and implemented on April 1, 2002), the Special Administrative Measures for Foreign Investment Access (Negative List) (2024 Edition) (《外商投資准入特別管理措施(負面清單)(2024年版)》) (the "**Negative List**") (issued by the NDRC and MOFCOM on September 6, 2024 and implemented on November 1, 2024), and the Catalogue of Industries for Encouraging Foreign Investment (2025 Edition) (《鼓勵外商投資產業目錄（2025年版）》) (the "**Encouraged Catalogue**") (issued by the NDRC and MOFCOM on December 15, 2025 and implemented on February 1, 2026). The Provisions on Guiding the Direction of Foreign Investment classify foreign investment projects into four categories: "encouraged," "permitted," "restricted," and "prohibited". The Encouraged Catalogue lists the encouraged foreign investment projects, the Negative List lists the restricted and prohibited foreign investment projects, and foreign investment projects that are not encouraged, restricted, or prohibited are classified as permitted. The Negative List uniformly lists the restrictive measures for foreign investment access, such as requirements for shareholding ratios and corporate governance, as well as industries where foreign investment is prohibited. The Negative List covers 11 industries, and areas outside the Negative List are managed under the principle of equal treatment for domestic and foreign investment.

The Foreign Investment Law of the People's Republic of China (《中華人民共和國外商投資法》) (the "**Foreign Investment Law**"), promulgated by the National People's Congress ("**NPC**") on March 15, 2019, came into effect on January 1, 2020, upon which the Wholly Foreign-owned Enterprise Law of the People's Republic of China (《中華人民共和國外資企業法》), the Sino-foreign Equity Joint Venture Enterprise Law of the People's Republic of China (《中華人民共和國中外合資經營企業法》), and the Sino-foreign Cooperative Joint Venture Enterprise Law of the People's Republic of China (《中華人民共和國中外合作經營企業法》) were repealed. Investment activities conducted directly or indirectly within the territory of China by foreign natural persons, enterprises, or other organizations (collectively, "**foreign investors**") shall comply with and be governed by the Foreign Investment Law.

While strengthening investment promotion and protection, the Foreign Investment Law further standardizes the administration of foreign investment by proposing the establishment of a foreign investment information reporting system to replace the previous approval and filing system of the MOFCOM for foreign-invested enterprises. The reporting of foreign investment information is governed by the Measures for Foreign Investment Information Reporting (《外商投資信息報告辦法》), which were jointly formulated by the MOFCOM and the SAMR and came into effect on January 1, 2020.

The Measures for the Security Review of Foreign Investment (《外商投資安全審查辦法》), promulgated by the NDRC and MOFCOM on December 19, 2020 and implemented on January 18, 2021, set out provisions concerning the security review mechanism for foreign investment, including the types of investment subject to review, the scope of review, and the review procedures.

Regulations on Real Estate Leasing

According to the Civil Code of the People's Republic of China (《中華人民共和國民法典》) (the "**Civil Code**"), a lease contract generally includes clauses on the name, quantity, and use of the leased property, lease term, rent, payment term and method, and maintenance of the leased property. With the consent of the lessor, the lessee of a lease may sublease the leased property to a third party.

According to the Administrative Measures for Commodity Housing Leasing (《商品房屋租賃管理辦法》), issued by the Ministry of Housing and Urban-Rural Development of the People's Republic of China ("**MHURD**") on December 1, 2010 and implemented on February 1, 2011, a commodity housing lease contract shall be registered and filed with the competent construction (real estate) department of the people's government of the municipality, city, or county where the leased premises are located within 30 days of its conclusion.

Regulations on Construction Projects

Construction Project Planning Permit

According to the Urban and Rural Planning Law of the People's Republic of China (《中華人民共和國城鄉規劃法》), promulgated by the NPC Standing Committee on October 28, 2007, most recently revised and implemented on April 23, 2019, for construction projects within urban or town planning areas, the relevant construction entity shall apply to the competent administrative authority for urban and rural planning for a construction project planning permit.

Construction Work Permit

According to the Construction Law of the People's Republic of China (《中華人民共和國建築法》), promulgated by the NPC Standing Committee on November 1, 1997, most recently revised and implemented on April 23, 2019, before commencing a construction project, the construction entity shall apply to the competent construction administrative department for a construction work permit, but certain small projects that meet the requirements and conditions stipulated by the competent construction administrative department may be exempted from obtaining a construction work permit.

According to the Administrative Measures for Construction Work Permits for Construction Projects (《建築工程施工許可管理辦法》), promulgated by the MHURD on October 15, 1999, most recently revised and implemented on March 30, 2021, any entity in the PRC engaged in the construction, renovation, and decoration of buildings and their ancillary facilities, the installation of their supporting lines, pipelines, or equipment, and municipal infrastructure projects shall apply for a construction work permit before commencement. Construction projects with an investment of less than RMB300,000 or a construction area of less than 300 square meters are not required to obtain a construction work permit.

Completion Acceptance

According to the Administrative Measures for the Filing of Completion Acceptance of Housing Construction and Municipal Infrastructure Projects (《房屋建築和市政基礎設施工程竣工驗收備案管理辦法》), promulgated and implemented by the MHURD on October 19, 2009, entities engaged in the new construction, expansion, or reconstruction of various types of housing construction or municipal infrastructure projects within the PRC shall file with the competent construction administrative department of the local people's government at or above the county level where the project is located within 15 days from the date of passing the completion acceptance.

Regulations on Environmental Protection, Health, and Safety

Environmental Protection

The Environmental Protection Law of the People's Republic of China (《中華人民共和國環境保護法》), promulgated by the NPC Standing Committee on December 26, 1989, most recently revised on April 24, 2014, and implemented on January 1, 2015, outlines the rights and responsibilities of environmental protection regulatory authorities. The competent environmental protection department of the State Council (now the Ministry of Ecology and Environment ("**MEE**")) is authorized to issue

national environmental quality standards and emission standards. Meanwhile, local environmental protection departments may formulate local standards that are stricter than national standards, in which case the relevant companies must comply with both national and local standards.

Environmental Impact Assessment

Pursuant to the Regulations on the Environmental Protection Management of Construction Projects (《建設項目環境保護管理條例》), promulgated by the State Council on November 29, 1998, most recently revised on July 16, 2017, and effective from October 1, 2017, a construction entity shall, based on the degree of environmental impact of the construction project, submit an environmental impact report, an environmental impact report form, or fill out a registration form (as applicable). For construction projects that require the preparation of an environmental impact report or an environmental impact report form, the construction entity shall submit the environmental impact report and environmental impact report form to the competent administrative department of environmental protection for approval before commencing construction. If the environmental impact assessment documents of a construction project have not been reviewed by the competent administrative department in accordance with the law or have not been approved after review, the construction entity shall not commence the construction project. The environmental protection facilities required for a construction project must be designed, constructed, and put into operation simultaneously with the main project.

According to the Environmental Impact Assessment Law of the People's Republic of China (《中華人民共和國環境影響評價法》), promulgated by the NPC Standing Committee on October 28, 2002, most recently revised and implemented on December 29, 2018, for construction projects that have an impact on the environment, the enterprise shall, according to the severity of the potential environmental impact of the project, prepare an environmental impact report, an environmental impact report form, or fill out an environmental impact registration form.

Completion Acceptance

Pursuant to the Regulations on the Environmental Protection Management of Construction Projects, after the completion of a construction project for which an environmental impact report or an environmental impact report form has been prepared, the construction entity shall, in accordance with the standards and procedures prescribed by the competent environmental protection administrative department of the State Council, conduct an acceptance inspection of the supporting environmental protection facilities and prepare an acceptance report. The Interim Measures for the Environmental Protection Acceptance of Completed Construction Projects (《建設項目竣工環境保護驗收暫行辦法》), promulgated and implemented by the Ministry of Environmental Protection (abolished) on November 20, 2017, regulate the environmental protection acceptance procedures and standards for construction entities after the completion of construction projects.

Pollutant Discharge

Pursuant to the Administrative Measures for Pollutant Discharge Permits (《排污許可管理辦法》), promulgated by the MEE on April 1, 2024 and implemented on July 1, 2024, enterprises, public institutions, and other producers and operators subject to pollutant discharge permit management shall apply for a pollutant discharge permit and discharge pollutants in accordance with the requirements of the permit; No pollutants may be discharged without obtaining a pollutant discharge permit.

According to the Classified Administration Catalogue of Pollutant Discharge Permits for Fixed Pollution Sources (2019 Edition) (《固定污染源排污許可分類管理名錄(2019年版)》), issued and implemented by the MEE on December 20, 2019, key management, simplified management, and registration management for pollutant discharge permits are implemented based on factors such as the amount of pollutants generated, the amount of pollutants discharged, and the degree of environmental impact. Pollutant discharging units subject to registration management are not required to apply for a pollutant discharge permit, but shall fill in a pollutant discharge registration form on the national pollutant discharge permit management information platform.

Pursuant to the Regulations on Urban Drainage and Wastewater Treatment (《城鎮排水與污水處理條例》), promulgated by the State Council on October 2, 2013 and implemented on January 1, 2014, drainage units and individuals within the coverage of urban drainage facilities shall discharge

wastewater into urban drainage facilities in accordance with the law. Companies or other entities engaged in medical activities that discharge wastewater into urban drainage facilities shall apply for a permit to discharge wastewater into the drainage network. Drainage units and individuals shall pay wastewater treatment fees in accordance with the law.

According to the Administrative Measures for the Environmental Management of Biosafety in Pathogenic Microorganism Laboratories (《病原微生物實驗室生物安全環境管理辦法》), promulgated by the State Environmental Protection Administration (abolished) on March 8, 2006 and effective from May 1, 2006, laboratories that discharge wastewater and waste gas shall implement the pollutant discharge declaration and registration system in accordance with the relevant regulations of the State Environmental Protection Administration.

Work Safety

According to the Work Safety Law of the People's Republic of China (《中華人民共和國安全生產法》), promulgated by the NPC Standing Committee on June 29, 2002, most recently revised on June 10, 2021, and implemented on September 1, 2021, any entity whose work safety conditions do not meet the requirements shall not engage in production and business operation activities. Production and business operation entities shall provide work safety education and training to their employees, employees who have not passed work safety education and training shall not be assigned to their posts to carry out work. The safety facilities of a new construction, reconstruction, or expansion project (a "**construction project**") shall be designed, constructed, and put into use simultaneously with the main project. The investment in safety facilities shall be included in the budget of the construction project.

Pursuant to the Regulations on the Administration of Precursor Chemicals (《易制毒化學品管理條例》), promulgated by the State Council on August 26, 2005, most recently revised and implemented on September 18, 2018, a classified management and licensing system is implemented for the production, distribution, purchase, transportation, import, and export of precursor chemicals. When an enterprise purchases Category II and Category III precursor chemicals, it shall file the types and quantities to be purchased with the competent public security bureau before the purchase.

According to the Administrative Measures for the Public Security of Precursor Hazardous Chemicals (《易制爆危險化學品治安管理辦法》), promulgated by the Ministry of Public Security on July 6, 2019 and implemented on August 10, 2019, enterprises that have legally obtained a hazardous chemical safe production license, a hazardous chemical safe use license, or a hazardous chemical business license may purchase precursor hazardous chemicals with the corresponding permits. Other units purchasing precursor hazardous chemicals shall present relevant materials to the selling unit. The selling and purchasing units of precursor hazardous chemicals shall, within five days after the sale or purchase, file the type, quantity, and flow information of the sold or purchased precursor hazardous chemicals with the local county-level public security organ for record through the precursor hazardous chemicals information system.

The Regulations on the Safe Management of Hazardous Chemicals (《危險化學品安全管理條例》) (the "**Hazardous Chemicals Regulations**"), promulgated by the State Council on January 26, 2002, most recently revised and implemented on December 7, 2013. The Hazardous Chemicals Regulations stipulate the regulatory requirements for the safe production, storage, use, operation, and transportation of hazardous chemicals.

Fire Control

According to the Fire Control Law of the People's Republic of China (《中華人民共和國消防法》), promulgated by the NPC Standing Committee on April 29, 1998, most recently revised and implemented on April 29, 2021, the design and construction of fire protection facilities for a construction project must comply with national technical standards for fire protection in engineering. The development, design, construction, and engineering supervision units of a construction project are legally responsible for the design and construction quality of the project's fire protection facilities. Where a special development project has not undergone fire safety design examination or the fire safety design does not pass examination, the developer and the builder shall not carry out construction. Where

a development project which is required by law to undergo fire safety inspection and acceptance does not undergo fire safety inspection and acceptance, or does not pass fire safety inspection and acceptance, the project shall not be put into use.

Regulations on Product Liability

The Product Quality Law of the People's Republic of China (《中華人民共和國產品質量法》) (the "**Product Quality Law**"), promulgated by the NPC Standing Committee on February 22, 1993 and most recently revised and implemented on December 29, 2018, is the primary law concerning the supervision and administration of product quality. The Product Quality Law specifies the responsibilities of producers and sellers. Producers shall be responsible for the quality of the products they produce, while sellers shall take measures to ensure the quality of the products they sell.

Where a defective product causes personal injury or damage to property other than the defective product itself, the producer shall be liable for compensation. A producer shall not be liable for compensation if it can prove any of the following circumstances: (1) the product has not been put into circulation; (2) the defect causing the personal injury or property damage did not exist when the product was put into circulation; or (3) the level of science and technology at the time the product was put into circulation was not sufficient to discover the existence of the defect. If a product defect is caused by the fault of the seller, resulting in personal injury or damage to the property of others, the seller shall be liable for compensation. If the seller cannot identify the producer of the defective product nor its supplier, the seller shall be liable for compensation. If a defective product causes personal injury or property damage, the victim may claim compensation from the producer or seller of the product.

According to the Civil Code and the Product Quality Law, if a patient suffers harm due to a defective drug, they may claim compensation from the Marketing Authorization Holder, the producer, or the medical institution. If the patient claims compensation from the medical institution, the medical institution, after making compensation, has the right to seek recourse from the responsible Marketing Authorization Holder.

Regulations on Information Security and Data Protection

Personal Information Protection

According to the Civil Code, personal information is protected by law. Any organization or individual that needs to obtain the personal information of others shall obtain it in accordance with the law and ensure information security, and shall not illegally collect, use, process, or transmit the personal information of others, nor illegally trade, provide, or disclose the personal information of others. In addition, the processing of personal information shall follow the principles of legality, legitimacy, and necessity.

The Personal Information Protection Law of the People's Republic of China (《中華人民共和國個人信息保護法》) (the "**Personal Information Protection Law**"), promulgated by the NPC Standing Committee on August 20, 2021 and implemented on November 1, 2021, stipulates that the processing of personal information shall have a clear and reasonable purpose, be limited to the minimum scope necessary to achieve the processing purpose, and be conducted in a manner that has the least impact on personal rights and interests, and personal information irrelevant to the processing purpose shall not be processed.

The Interpretation of the Supreme People's Court and the Supreme People's Procuratorate on Several Issues Concerning the Application of Law in Handling Criminal Cases of Infringing on Citizens' Personal Information (《最高人民法院、最高人民檢察院關於辦理侵犯公民個人信息刑事案件適用法律若干問題的解釋》) was issued on May 8, 2017 and implemented on June 1, 2017. This interpretation clarifies certain concepts related to the crime of "infringing on citizens' personal information" as stipulated in Article 253-1 of the Criminal Law of the People's Republic of China, including "citizens' personal information," "violating relevant state regulations," "providing citizens' personal information," and "illegally obtaining citizens' personal information by other methods." In addition, the interpretation provides the criteria for determining whether this crime constitutes "serious circumstances" and "particularly serious circumstances".

Information Security and Review

On June 10, 2021, the NPC Standing Committee promulgated the Data Security Law of the People's Republic of China (《中華人民共和國數據安全法》) (the "**Data Security Law**"), which was implemented on September 1, 2021. The Data Security Law sets out the regulatory framework for supervising data security and the responsibilities of relevant administrative agencies. The Data Security Law stipulates that the central government shall establish a central data security work coordination mechanism, which shall coordinate relevant departments covering different industries to formulate a catalogue of key data and shall take special measures to protect the security of key data.

The Cybersecurity Law of the People's Republic of China (《中華人民共和國網絡安全法》) (the "**Cybersecurity Law**"), promulgated by the NPC Standing Committee on November 7, 2016, most recently revised on October 28, 2025 and implemented on January 1, 2026, stipulates that network operators shall fulfill cybersecurity protection obligations when conducting business and service activities. Providers of services via networks shall, in accordance with laws, administrative regulations and mandatory requirements of national standards, take technical measures and other necessary measures to ensure the secure and stable operation of the network, effectively respond to cybersecurity incidents, prevent illegal and criminal activities on the network, and maintain the integrity, confidentiality, and availability of network data. Network operators shall not collect personal information irrelevant to the services they provide, and shall not collect or use personal information in violation of the provisions of laws, administrative regulations, and their agreements with users. Personal information and important data collected and generated by operators of critical information infrastructure during their operations within the PRC shall be stored within the territory. The procurement of network products and services that may affect national security shall be subject to a national security review organized by the national cyberspace administration department in conjunction with relevant departments of the State Council.

On July 30, 2021, the State Council promulgated the Regulations on the Security Protection of Critical Information Infrastructure (《關鍵信息基礎設施安全保護條例》), which was implemented on September 1, 2021. Pursuant to the Regulations on the Security Protection of Critical Information Infrastructure, "critical information infrastructure" refers to important network facilities and information systems in important industries such as public communication and information services, among others, as well as other important network facilities and information systems that, if destroyed, lose function, or suffer data leakage, could seriously endanger national security, the national economy and people's livelihood, or public interests.

On December 28, 2021, the Cyberspace Administration of China ("**CAC**") jointly promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) with 12 other administrative agencies, which was implemented on February 15, 2022. According to the Measures for Cybersecurity Review, where operators of critical information infrastructure procure network products and services, and network platform operators carry out data processing activities that affect or may affect national security, they shall undergo a cybersecurity review in accordance with these measures. In addition, network platform operators possessing the personal information of more than one million users must apply for a cybersecurity review before listing abroad. If the competent authorities believe that an operator's network products or services or data processing activities affect or may affect national security, the competent authorities may also initiate a cybersecurity review of the operator.

On July 7, 2022, the CAC promulgated the Measures for Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》), which was implemented on September 1, 2022. The Measures for Security Assessment of Cross-border Data Transfer stipulate that a data processor providing data overseas shall, under any of the following circumstances, apply to the competent authorities for a security assessment of the cross-border data transfer: (1) the data processor provides important data overseas; (2) a critical information infrastructure operator and a data processor processing the personal information of more than one million individuals provides personal information overseas; (3) a data processor that has cumulatively provided the personal information of 100,000 individuals or the sensitive personal information of 10,000 individuals overseas since January 1 of the preceding year provides personal information overseas; (4) other circumstances requiring an application for security assessment of cross-border data transfer as stipulated by the CAC. In addition, the CAC promulgated the Measures on the Standard Contract for the Cross-border Transfer of Personal

Information (《個人信息出境標準合同辦法》) (the "**Standard Contract Measures**") on February 22, 2023, which was implemented on June 1, 2023. The Standard Contract Measures provide a prescribed template for the standard contract for the cross-border transfer of personal information, which can be used as an optional solution to meet the conditions for cross-border transfer of personal information as stipulated in Article 38 of the Personal Information Protection Law.

According to the Provisions on Promoting and Regulating Cross-Border Data Flows (《促進和規範數據跨境流動規定》), issued and implemented by the CAC on March 22, 2024, data processors that are not operators of critical information infrastructure will be exempted from applying for a security assessment for data export, signing a standard contract with the overseas recipient, or undergoing personal information protection certification if they cumulatively transfer the ordinary personal information of no more than 100,000 individuals overseas since January 1 of the current year.

On September 24, 2024, the State Council issued the Regulations on the Administration of Network Data Security (《網絡數據安全管理條例》), which will be implemented from January 1, 2025. The Regulations on the Administration of Network Data Security are not only the first regulations at the administrative level specifically targeting network data security, but also comprehensive implementing regulations for the compliance requirements set out in the Cybersecurity Law, the Data Security Law, and the Personal Information Protection Law. The Regulations on the Administration of Network Data Security introduce several key responsibilities, including requiring network data processors to specify the purpose and manner of processing personal information, as well as the types of personal information involved, before processing any personal information. The regulations also clarify the definition of important data, outline the responsibilities of important data processors, establish broader contractual requirements for data sharing between data processors, and introduce new exemptions for regulatory responsibilities regarding cross-border data transfer.

Regulations on Intellectual Property

The PRC is a party to several international intellectual property conventions, including but not limited to the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Paris Convention for the Protection of Industrial Property, the Patent Cooperation Treaty, the Berne Convention for the Protection of Literary and Artistic Works, the Universal Copyright Convention, and the Madrid Agreement Concerning the International Registration of Marks.

Trademarks

Trademarks are protected by the Trademark Law of the People's Republic of China (《中華人民共和國商標法》), promulgated by the NPC Standing Committee on August 23, 1982, most recently revised on April 23, 2019 and implemented on November 1, 2019, and the Regulations for the Implementation of the Trademark Law of the People's Republic of China (《中華人民共和國商標法實施條例》), promulgated by the State Council on August 3, 2002, most recently revised on April 29, 2014 and implemented on May 1, 2014. A trademark registrant intending to continue using the trademark after the expiry of the validity period shall undergo renewal procedures in accordance with relevant regulations within 12 months prior to the expiration. If the procedures are not completed on time, the trademark registrant may have a grace period of six months. The validity period of each renewal is ten years, calculated from the day after the expiration of the previous validity period. If the renewal procedures are still not completed within the grace period, the trademark registration will be cancelled. The administrative department for industry and commerce under the State Council has the authority to investigate any act of infringing the exclusive right to use a registered trademark. If a crime is suspected, the administrative department for industry and commerce shall promptly transfer the case to the judicial department for handling in accordance with the law.

Patents

Patents are protected by the Patent Law of the People's Republic of China (《中華人民共和國專利法》) (the "**Patent Law**"), promulgated by the NPC Standing Committee on March 12, 1984, most recently revised on October 17, 2020 and implemented on June 1, 2021, and the Implementing Regulations of the Patent Law of the People's Republic of China (《中華人民共和國專利法實施細則》), promulgated by the State Council on June 15, 2001, most recently revised on December 11, 2023 and implemented on January 20, 2024. The Patent Office of the China National Intellectual Property

Administration is responsible for patent work nationwide, while provincial patent work offices are responsible for patent administration within their respective administrative regions. An invention or utility model for which a patent right is granted shall possess novelty, inventiveness and utility. Calculated from their respective application dates, the term of protection for an invention patent is 20 years, for a utility model patent is 10 years, and for a design patent is 15 years. Any entity or individual intending to exploit the patent of another shall conclude a license contract for exploitation with the patentee and pay the patentee a royalty. Exploitation of a patent without the permission of the patent owner constitutes an infringement of the patent right. According to the Patent Law, for the purpose of public health, the patent administration department under the State Council may grant a compulsory license for a patented drug to manufacture and export it to countries or regions that conform to the relevant international treaties to which China is a party.

The Patent Law provides for patent term extension for new drug patents marketed in the PRC, and stipulates that the patent administration department under the State Council shall, at the request of the patentee, extend the patent term of an invention patent related to a new drug approved for marketing in the PRC to compensate for the time spent on the review and approval for marketing of the new drug. The compensation period shall not exceed five years, and the total effective patent term after the new drug is approved for marketing shall not exceed fourteen years.

Copyrights

Copyright in the PRC is primarily protected by the Copyright Law of the People's Republic of China (《中華人民共和國著作權法》), promulgated by the NPC Standing Committee on September 7, 1990, most recently revised on November 11, 2020 and implemented on June 1, 2021, and the Regulations for the Implementation of the Copyright Law of the People's Republic of China (《中華人民共和國著作權法實施條例》), promulgated by the State Council on August 2, 2002, most recently revised on January 30, 2013 and implemented on March 1, 2013. These laws and regulations provide for the classification of works and the acquisition and protection of copyright.

Domain Names

Domain names are protected by the Measures for the Administration of Internet Domain Names in China (《中國互聯網絡域名管理辦法》), issued on November 5, 2004 by the Ministry of Information Industry of the People's Republic of China (which has been integrated into the Ministry of Industry and Information Technology of the People's Republic of China ("**MIIT**")). This regulation was replaced by the Measures for the Administration of Internet Domain Names (《互聯網域名管理辦法》), issued by the MIIT on August 24, 2017 and implemented on November 1, 2017. The MIIT is the primary regulatory authority responsible for the administration of internet domain names in China. Domain name registration is handled by domain name service agencies established in accordance with relevant regulations, following the "first-to-file, first-to-register" principle. Domain name registration applicants shall provide true, accurate, and complete domain name information to the domain name registration service agency.

Trade Secrets

According to the Anti-Unfair Competition Law of the People's Republic of China (《中華人民共和國反不正當競爭法》) (promulgated by the NPC Standing Committee on September 2, 1993, most recently revised on June 27, 2025 and effective from October 15, 2025), "trade secrets" refer to technical information, operational information, and other commercial information that is not known to the public, has commercial value, and for which the rights holder has taken corresponding confidentiality measures. Business operators shall not engage in the following acts of infringing on trade secrets: (i) obtaining the trade secrets of a rights holder by theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (ii) disclosing, using, or allowing others to use the trade secrets of a rights holder obtained through the aforementioned means; (iii) disclosing, using, or allowing others to use trade secrets in their possession in breach of a confidentiality obligation or in violation of the rights holder's requirements for maintaining the secrecy of such trade secrets; (iv) instigating, luring, or assisting others to violate a confidentiality obligation or to violate a rights holder's requirements for maintaining secrecy to obtain, disclose, use, or allow others to use the rights holder's trade secrets. A natural person, legal person, or unincorporated organization that engages in the aforementioned illegal acts is deemed to have infringed on trade secrets. If a third party knows or

should have known that an employee or former employee of the trade secret rights holder, or any other entity or individual, has committed the acts described above, and still obtains, discloses, uses, or allows others to use the trade secret, that third party will be deemed to have infringed on the trade secret. A party whose trade secrets have been infringed may apply for administrative remedies, and the supervision and inspection department shall order the cessation of the illegal act and impose a fine on the infringing party.

Regulations on Taxation

PRC Enterprise Income Tax

According to the Enterprise Income Tax Law of the People's Republic of China (《中華人民共和國企業所得稅法》) (the "**EIT Law**"), promulgated by the NPC on March 16, 2007, most recently revised and implemented by the NPC Standing Committee on December 29, 2018, and its implementing regulations, the EIT Law generally imposes a unified income tax rate of 25% on all resident enterprises in the PRC (including foreign-invested enterprises). The EIT Law and its implementing regulations allow enterprises qualified as "High and New Technology Enterprises" to enjoy a reduced enterprise income tax rate of 15%.

PRC Value-added Tax

Pursuant to the Value-added Tax Law of the People's Republic of China (《中華人民共和國增值稅法》), issued on December 25, 2024 and implemented on January 1, 2026, and the Regulations for the Implementation of the Value-added Tax Law of the People's Republic of China (《中華人民共和國增值稅法實施條例》), issued on December 25, 2025 and implemented on January 1, 2026, unless otherwise stipulated, taxpayers selling goods, providing processing, repair, and replacement services, leasing tangible movable property, and importing goods shall pay value-added tax at a rate of 13%; selling transportation, postal, basic telecommunication, construction, and real estate leasing services, selling real estate, and transferring land use rights shall be subject to value-added tax at a rate of 9%; and unless otherwise stipulated, selling services and intangible assets shall be subject to value-added tax at a rate of 6%.

According to the Notice on Adjusting Value-Added Tax Rates (《財政部、稅務總局關於調整增值稅稅率的通知》), issued by the Ministry of Finance and the State Administration of Taxation on April 4, 2018 and implemented on May 1, 2018, from May 1, 2018, where taxpayers engage in VAT-taxable sales activities or import goods, the previously applicable rates of 17% and 11% were adjusted to 16% and 10%, respectively.

According to the Announcement on Policies for Deepening Value-Added Tax Reform (《關於深化增值稅改革有關政策的公告》), issued on March 20, 2019 and implemented on April 1, 2019, where general VAT taxpayers engage in VAT-taxable sales activities or import goods, the previously applicable rate of 16% was adjusted to 13%; the previously applicable rate of 10% was adjusted to 9%.

Regulations on Foreign Exchange

The Regulations of the People's Republic of China on Foreign Exchange Administration (《中華人民共和國外匯管理條例》), promulgated by the State Council on January 29, 1996 and most recently revised and implemented on August 5, 2008, established the regulatory framework for foreign exchange administration in China. Pursuant to the Regulations of the People's Republic of China on Foreign Exchange Administration, payments in foreign currency for current account items (such as trade, services, profits or current transfer-related transactions) are not subject to prior approval from the State Administration of Foreign Exchange of the People's Republic of China ("**SAFE**"), provided that certain procedural requirements are satisfied. Conversely, the conversion of Renminbi into foreign currency for capital account items to be remitted out of China, such as repaying foreign currency-denominated loans, or the remittance of foreign currency into China under capital accounts, such as capital increases or foreign currency loans provided by foreign entities to Chinese entities, is subject to approval or registration with the appropriate administrative authorities.

The Provisions on the Foreign Exchange Administration of Domestic Direct Investment by Foreign Investors (《外國投資者境內直接投資外匯管理規定》), promulgated by SAFE on May 10, 2013 and most recently revised and implemented on December 30, 2019, regulate and clarify the foreign

exchange administration for direct investment by foreign investors, and stipulate that SAFE or its local branches shall manage direct investment by foreign investors in the PRC through registration, and banks shall handle foreign exchange business related to direct investment in the PRC based on the information recorded by SAFE and its branches.

According to the Circular of the SAFE on Further Improving and Adjusting the Foreign Exchange Administration Policies for Direct Investment (《國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知》) and its annexes, promulgated by SAFE in November 2012 and revised in May 2015, October 2018, and December 2019, foreign exchange procedures were further simplified. SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies for Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) in February 2015 (effective in June 2015 and further revised in December 2019), which stipulates that banks may directly handle foreign exchange registration for outbound direct investment on behalf of SAFE, while SAFE and its branches indirectly supervise the foreign exchange registration for outbound direct investment through banks. On April 3, 2024, SAFE promulgated the Guidelines for Foreign Exchange Business under the Capital Account (2024 Edition) (《資本項目外匯業務指引(2024年版)》), which was implemented on May 6, 2024, providing guidance for foreign exchange business under the capital account.

According to the Circular on Reforming the Management Method of Foreign Exchange Capital Settlement of Foreign-Invested Enterprises (《關於改革外商投資企業外匯資本金結匯管理方式的通知》), promulgated by SAFE in March 2015 and revised in December 2019 and March 2023, and the Circular of the SAFE on Reforming and Regulating the Management Policies for the Settlement of Foreign Exchange under the Capital Account (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》), issued and implemented on June 9, 2016 and revised in December 2023, discretionary settlement of foreign exchange income under the capital account refers to foreign exchange income under the capital account for which discretionary settlement has been explicitly implemented by relevant policies (including foreign exchange capital, foreign debt funds, and funds repatriated from overseas listings), which can be settled at a bank according to the actual business needs of the domestic institution. The discretionary settlement ratio for foreign exchange income under the capital account of domestic institutions is provisionally set at 100%, and SAFE may adjust the aforementioned ratio in a timely manner based on the balance of payments situation. The Circular of the SAFE on Further Deepening Reform and Promoting the Facilitation of Cross-Border Trade and Investment (《國家外匯管理局關於進一步深化改革促進跨境貿易投資便利化的通知》), issued and implemented by SAFE on December 4, 2023, further facilitates the payment and use of funds raised by foreign-invested enterprises from overseas listings. The capital account asset realization account is adjusted to a capital account settlement account. Foreign exchange funds raised by domestic enterprises from overseas listings can be directly remitted to the capital account settlement account. Funds in the capital account settlement account can be settled and used at the discretion of the enterprise.

According to the Circular on Optimizing Foreign Exchange Administration to Support the Development of Foreign-related Business (《關於優化外匯管理支持涉外業務發展的通知》), issued and implemented by SAFE on April 10, 2020, eligible enterprises are allowed to use capital account income, such as capital, foreign debt, and proceeds from overseas listings, for domestic payments without providing authenticity-proving materials for such payments to the bank in advance, provided that the use of funds is authentic, compliant, and in line with the current administrative regulations on the use of capital account income. The relevant banks must conduct post-event random inspections, and the local branches of SAFE must strengthen supervision and analysis as well as interim and post-event supervision in accordance with relevant regulations.

On April 28, 2013, SAFE issued the Administrative Measures for Foreign Debt Registration (《外債登記管理辦法》), which was implemented on May 13, 2013, and parts of which were revised in accordance with the Circular of the SAFE on Annulling and Amending Relevant Normative Documents Concerning the Reform of the Registered Capital Registration System (《國家外匯管理局關於廢止和修改涉及注冊資本登記制度改革相關規範性文件的通知》). The Administrative Measures for Foreign Debt Registration stipulate that after borrowing foreign debt in accordance with regulations, the debtor shall register with or report to the local foreign exchange bureau information on the signing, drawdown, repayment, and settlement/sale of foreign exchange for the foreign debt in the prescribed manner.

According to the Notice of the People's Bank of China and the State Administration of Foreign Exchange on Issues Concerning the Administration of Funds Raised by Domestic Enterprises Listed Overseas (《中國人民銀行國家外匯管理局關於境內企業境外上市資金管理有關問題的通知》), promulgated by the People's Bank of China and the SAFE on December 24, 2025, effective on April 1, 2026, a domestic enterprise that conducts an overseas listing shall, within 30 working days from the first trading day of the overseas listing or the completion of the over-allotment option, apply to a bank within the province or the separately-listed municipality where it is registered for overseas listing registration. In principle, funds raised by domestic enterprises through overseas listings shall be remitted back to the territory in a timely manner. Where such funds are retained overseas for the conduct of overseas direct investment, overseas securities investment, overseas lending and other businesses, the domestic enterprise shall obtain the approval or filing documents from the business competent authorities before the date of completion of the overseas issuance or the over- allotment option, and shall comply with relevant cross-border funds administration provisions.

Regulations on Labor, Social Insurance and Housing Provident Fund

According to the Labor Law of the People's Republic of China (《中華人民共和國勞動法》), promulgated by the NPC Standing Committee in July 1994 and most recently revised and became effective in December 2018, the Labor Contract Law of the People's Republic of China (《中華人民共和國勞動合同法》), promulgated by the NPC Standing Committee in June 2007, revised in December 2012 and became effective in July 2013, and the Regulations on the Implementation of the Labor Contract Law of the People's Republic of China (《中華人民共和國勞動合同法實施條例》), promulgated and became effective by the State Council in September 2008, an employer shall enter into a written labor contract with an employee when establishing a labor relationship. Wages shall not be lower than the local minimum wage standards. Employers must establish a labor safety and health system, strictly comply with national regulations and standards, provide labor safety and health education to employees, provide labor safety and health conditions and necessary labor protection articles that comply with national regulations, and arrange regular health checks for employees engaged in operations with occupational hazards.

According to the Social Insurance Law of the People's Republic of China (《中華人民共和國社會保險法》), promulgated by the NPC Standing Committee in October 2010 and most recently revised and became effective in December 2018, the Interim Regulations on the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》), promulgated by the State Council in January 1999 and most recently revised in March 2019, and the Regulations on the Management of Housing Provident Fund (《住房公積金管理條例》), promulgated by the State Council in April 1999 and most recently revised in March 2019, employers are required to make contributions on behalf of their employees to certain social insurance funds (including basic pension insurance fund, unemployment insurance fund, basic medical insurance fund, work-related injury insurance fund and maternity insurance fund) and housing provident fund.

Pursuant to the Interpretation (II) of the Supreme People's Court on Issues Concerning the Application of Law in the Trial of Labor Dispute Cases (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)》), promulgated on July 31, 2025, and effective as of September 1, 2025, where the employer and the laborer agree, or the laborer promises the employer, that there is no need to pay social insurance premiums, the people's court shall determine that such agreement or promise is invalid. Where the employer fails to pay social insurance premiums in accordance with the law, and the laborer requests to terminate the labor contract and for the employer to pay economic compensation in accordance with item (3), Article 38 of the Labor Contract Law of the People's Republic of China, the people's court shall support such claim in accordance with the law. Where the circumstances in the preceding provisions exist, and the employer, after making up the social insurance premiums in accordance with the law, requests the laborer to return the social insurance compensation already paid, the people's court shall support such claim in accordance with the law.

Laws and Regulations Relating to Outbound Investment

The Administrative Measures for Outbound Investment (《境外投資管理辦法》) were promulgated by MOFCOM on September 6, 2014 and implemented on October 6, 2014. According to these measures, outbound investment refers to the act of an enterprise legally established within the territory of the People's Republic of China owning a non-financial enterprise or acquiring the ownership,

control, management rights and other interests of an existing non-financial enterprise outside the PRC through new establishment, merger and acquisition and other means. Outbound investment by an enterprise involving sensitive countries and regions or sensitive industries is subject to approval and administration by MOFCOM and the provincial-level competent commerce departments. Outbound investment by an enterprise in other circumstances is subject to filing and administration by MOFCOM and the provincial-level competent commerce departments. MOFCOM and the provincial-level competent commerce departments issue an "Enterprise Outbound Investment Certificate" to enterprises that have obtained filing or approval.

The Administrative Measures for Enterprise Outbound Investment (《企業境外投資管理辦法》) were promulgated by the NDRC on December 26, 2017 and implemented on March 1, 2018. According to these measures, outbound investment refers to investment activities whereby an enterprise within the territory of the People's Republic of China, directly or through its controlled overseas enterprises, acquires overseas ownership, control, management rights and other related interests by means of investing assets, equity, or providing financing, guarantees, etc. When an investing entity carries out outbound investment, if the investment project involves sensitive countries and regions or sensitive industries, it must be reported to the NDRC for approval; if the investment project does not involve sensitive countries and regions or sensitive industries and is classified as a non-sensitive project, the investing entity shall file the relevant materials with the NDRC or its provincial-level counterpart department. The Catalogue of Sensitive Industries for Outbound Investment (2018 Version) (《境外投資敏感行業目錄(2018版)》), promulgated by the NDRC on January 31, 2018 and implemented on March 1, 2018, contains a detailed list of the aforementioned sensitive industries.

Regulations on Overseas Listing

Regulations on Overseas Issuance of Securities and Listing by Domestic Enterprises

Pursuant to the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the "**Overseas Listing Trial Measures**"), promulgated by the CSRC on February 17, 2023 and effective from March 31, 2023, a domestic enterprise conducting an initial public offering or listing overseas shall file with the CSRC within three working days after submitting its application documents for overseas issuance and listing.

According to the Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》), jointly promulgated by the CSRC and other departments on February 24, 2023 and implemented on March 31, 2023, domestic enterprises in their overseas issuance and listing activities, as well as the securities companies and securities service institutions providing corresponding services for them, shall strictly abide by the relevant PRC laws and regulations and the requirements of these provisions, enhance their legal awareness of protecting state secrets and strengthening archives management, establish and improve confidentiality and archives work systems, take necessary measures to implement confidentiality and archives management responsibilities, shall not leak state secrets and work secrets of state organs, and shall not harm national and public interests. Where a domestic enterprise provides or publicly discloses, or provides or publicly discloses through its overseas listed entity, documents or materials involving state secrets or work secrets of state organs to relevant securities companies, securities service institutions, overseas regulatory authorities and other entities and individuals, it shall, in accordance with the law, report to the competent authority with approval power for approval and file with the confidentiality administrative department at the same level for record.

Regulations on H-Share "Full Circulation"

According to the Guidelines on the Application for "Full Circulation" of Domestically Unlisted Shares of H-Share Companies (《H股公司境內未上市股份申請「全流通」業務指引》), promulgated by the CSRC on November 14, 2019 and revised on August 10, 2023, "full circulation" refers to the **[REDACTED]** and circulation on the Hong Kong Stock Exchange of the unlisted domestic shares of H-share listed companies (including unlisted domestic shares held by domestic shareholders before overseas listing, unlisted domestic shares issued domestically after overseas listing, and unlisted shares held by foreign shareholders). Provided that relevant laws and regulations, as well as policy requirements for state-owned asset management, foreign investment, and industry supervision are met,

shareholders of unlisted domestic shares may voluntarily negotiate and determine the number and proportion of shares to apply for circulation, and entrust the corresponding H-share listed company to file for registration with the CSRC. A domestic joint stock limited company that is not yet listed may, at the time of its initial public offering and listing overseas, also file for "full circulation" with the CSRC.

LAWS AND REGULATIONS OF THE UNITED STATES

Laws and Regulations of New Drug Developments

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the "**FDCA**"), its implementing regulations, and biologics under the FDCA, the Public Health Service Act (the "**PHSA**"), and their respective implementing regulations. Both drugs and biologics are also subject to other federal, state, and local statutes and regulations, including those related to competition. The process of securing regulatory approvals and subsequent compliance with applicable federal, state, and local statutes and regulations entails the expenditure of significant time and financial resources. Failure to comply with applicable U.S. requirements at any stage of product development, the approval process, or post-approval may expose an applicant to administrative actions or judicial sanctions. Such actions and sanctions may include, but are not limited to, the FDA's refusal to approve pending applications, withdrawal of an existing approval, revocation of a license, imposition of a clinical hold, issuance of untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, denial of government contracts, restitution, disgorgement, and civil or criminal fines or penalties.

Once a product candidate is identified for development, it enters preclinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Preclinical testing is conducted in accordance with the FDA's Good Laboratory Practice regulations. A sponsor of an IND must submit the results of preclinical testing, manufacturing information, analytical data, the clinical trial protocol, and any available clinical data or literature to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions and places the trial on a clinical hold within that 30-day period. The FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance. An IND applicant may proceed with a clinical investigation once notified by the FDA, typically through a "study may proceed" letter with or without non-holding comments, that the investigation may proceed, or after 30 days if the IND is not placed on clinical hold, which is an order issued by the FDA to the sponsor of an IND application to delay a proposed clinical investigation or suspend an ongoing investigation.

All clinical trials, which involve the administration of the investigational product to humans, must be conducted under the supervision of one or more qualified investigators in accordance with the Good Clinical Practice regulations, including the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board ("**IRB**") must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to subjects. Clinical trials generally are conducted in three sequential phases, known as Phase I, Phase II and Phase III, and may overlap. Phase I clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect, tolerability and safety of the product candidate. Phase II clinical trials involve studies on disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted. Phase III clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than 7 calendar days after the sponsor's initial receipt of the information. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, which is publicly available at **www.clinicaltrials.gov**.

Concurrent with clinical trials, companies usually complete additional animal studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions.

Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA or a BLA. Unless deferred or waived, NDAs or BLAs, or supplements must contain data adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The submission of an NDA or a BLA is subject to the payment of a substantial user fee and an annual prescription drug product program fee.

Within 60 days of its receipt, the FDA reviews the NDA/BLA to ensure that it is sufficiently complete for substantive review before it accepts the NDA/BLA for filing. After accepting the NDA/BLA filing, the FDA begins an in-depth substantive review to determine, among other things, whether a product is safe and effective for its intended use. The FDA also evaluates whether the product's manufacturing is GMP-compliant to assure the product's identity, strength, quality and purity. Before approving the NDA/BLA, the FDA typically will inspect whether the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA/BLA to an advisory committee, a panel of experts, for review whether the application should be approved and under what conditions and considers such recommendations when making decisions.

The FDA may refuse to approve the NDA/BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. The FDA will issue a complete response letter describing all of the specific deficiencies that the FDA identified in the NDA/BLA that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. The applicant may either resubmit the NDA/BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

The regulatory approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including Phase IV clinical trials, to further assess a product's safety and effectiveness after NDA/BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

FDA Acceptance of Foreign Clinical Studies

Pursuant to Title 21 of the Code of Federal Regulations ("**21 CFR**") 312.120 and 314, FDA acknowledges that sponsors may elect to conduct multinational clinical studies under a range of scenarios. Such multinational studies may include U.S. sites conducted under an IND, foreign sites conducted under an IND, and/or foreign sites not conducted under an IND. Some sponsors may even

seek to rely exclusively on foreign clinical data to support an IND or an application for marketing approval in the United States. An application based solely on foreign clinical data that satisfies U.S. criteria for marketing approval may be approved if: (1) the foreign data are relevant to the U.S. population and U.S. clinical practice; (2) the studies were conducted by duly qualified clinical investigators; and (3) the data may be regarded as valid without an on-site inspection by the FDA, or, if the FDA deems such an inspection necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. If an application fails to satisfy any of these criteria, it cannot be approved on the basis of the foreign data alone. The FDA will apply this policy flexibly based on the nature of the drug and the data under review.

U.S. BIOSECURE Act

On December 18, 2025, the BIOSECURE Act (the "**BIOSECURE Act**") was enacted as Section 851 of the National Defense Authorization Act for Fiscal Year 2026 (the "**FY2026 National Defense Authorization Act**"). The BIOSECURE Act prohibits, after the applicable effective date and subject to statutory exceptions and waivers, U.S. executive agencies from (1) procuring or obtaining biotechnology equipment or services produced or provided by a biotechnology company of concern; (2) entering into, renewing or extending certain contracts where such equipment or services are used in the performance of the relevant federal contract; and (3) using federal loan or grant funds, or permitting recipients to use such funds, to procure, obtain or use such equipment or services.

The BIOSECURE Act identifies biotechnology companies of concern by reference to, among others, entities included on the Department of Defense Section 1260H list and involved in biotechnology equipment or services, entities designated by the Office of Management and Budget ("**OMB**"), and certain qualifying parents, subsidiaries and successors of such entities. OMB is required to publish its initial list within one year following enactment of the BIOSECURE Act, followed by implementing guidance and revisions to the Federal Acquisition Regulation ("**FAR**"). The relevant prohibitions will become effective 60 or 90 days after the applicable FAR revisions, depending on the relevant designation pathway.

LAWS AND REGULATIONS OF AUSTRALIA

Laws and Regulations of Clinical Development

Clinical trials conducted in Australia are regulated by the Therapeutic Goods Administration ("**TGA**"). Clinical trials must comply with a number of Australian laws and regulations at Commonwealth and State/Territory levels, including the *Therapeutic Goods Act 1989* (Cth) and the *Therapeutic Goods Regulations 1990* (Cth). Clinical trials must also comply with the ICH Guidelines for Good Clinical Practice, as adopted and annotated by the TGA (the "**ICH GCP Guidelines**"), and the National Statement on Ethical Conduct in Human Research (the "**National Statement**").

There are two approval schemes for clinical trials in Australia: the Clinical Trial Notification ("**CTN**") scheme and the Clinical Trial Approval ("**CTA**") scheme. The CTN scheme involves notifying the TGA of the clinical trial without the TGA undertaking any evaluation of the trial. The CTA scheme involves notifying the TGA of the clinical trial and requires the TGA to conduct an evaluation and assessment prior to trial commencement. The CTN scheme is generally used for early-phase studies where adequate preclinical data regarding the product, particularly its safety profile, are available. The CTA scheme is generally used for high-risk or novel treatments where limited or no safety information on the product exists. The decision as to which scheme to follow generally rests with the trial sponsor and the applicable Human Research Ethics Committee ("**HREC**"), although the CTA scheme is

mandatory for certain types of biological medicines. Clinical trials in Australia require approval from the research institute conducting the trial, following review by its HREC prior to initiation. HRECs are also responsible for overseeing the conduct of clinical trials.

Clinical trials conducted in Australia must have an Australian company as the trial sponsor. A foreign corporation may engage an Australian company to act as the trial sponsor, often referred to as the Local Sponsor. In such circumstances, the foreign corporation itself is not required to obtain any licenses or authorizations in relation to the clinical trial. The Australian trial sponsor is responsible for the initiation, management and financing (or arrangement of financing) of the clinical trial, and is legally liable for the conduct of the trial, including obtaining all necessary licenses or authorizations. The trial sponsor is not required to be the manufacturer of the product under trial. The product manufacturer may rely on the trial results when seeking registration of the product on the Australian Register of Therapeutic Goods.

Clinical trials in Australia must comply with the ICH GCP Guidelines as annotated by the TGA. The TGA's annotations provide additional guidance on compliance with the National Statement, obtaining informed consent in special circumstances, responsibilities for trial conduct (including trial management, data handling and record keeping), the manufacturing, packaging, labelling and coding of investigational products, and adverse drug reaction reporting. Approval of a clinical trial in Australia is conditional on compliance with the ICH GCP Guidelines as annotated by the TGA.

Clinical trials in Australia must also comply with the National Statement, which establishes Australian ethical standards for the review of all human research, including clinical trials. Approval of a clinical trial in Australia is conditional on compliance with the National Statement.

With respect to safety reporting requirements, clinical trials conducted in Australia must follow the Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95), as annotated by the TGA, and the National Health and Medical Research Council ("**NHMRC**") Guidance: Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods.

In addition, under the ICH GCP Guidelines as annotated by the TGA, products used in clinical trials must comply with applicable good manufacturing practices ("**GMP**"). For investigational products manufactured in Australia, the relevant manufacturing standards are set out in the *Therapeutic Goods (Manufacturing Principles) Determination 2020* (Cth). Generally, therapeutic goods (other than blood, blood components, haematopoietic progenitor cells and biologicals that do not comprise or contain live animal cells, tissues or organs) must be manufactured in accordance with the Guide to Good Manufacturing Practice of Medicinal Products (PE 009-15, 1 May 2021) published by PIC/S.

Under both the CTN and CTA schemes, the clinical trial sponsor for a trial involving medicines or biological products must provide the TGA with information regarding the proposed dosage form, route of administration, formulation, dosage and frequency of administration of the product, among other information, prior to trial commencement. If a dosage change is proposed following completion of a Phase I clinical trial, such change must either be notified to the TGA (for trials under the CTN scheme) or approved by the TGA (for trials under the CTA scheme). The proposed change will also require review and approval by the HREC overseeing the trial.