PRC REGULATIONS

Regulations on Company Establishment and Foreign Investment

The establishment, operation and management of foreign entities in China are mainly governed by the Company Law of the PRC (《中華人民共和國公司法》) and Foreign Investment Law of the PRC (《中華人民共和國外商投資法》). Investment activities in the PRC by foreign investors are also governed by the Special Administrative Measures for the Access of Foreign Investment (Negative List) (2024 Edition) (《外商投資准入特別管理措施(負面清單)(2024年版)》), or the Negative List, which was promulgated by the Ministry of Commerce of the PRC, or the MOFCOM, and the National Development and Reform Commission, or the NDRC, in September 2024 and came into effect in November 2024. The Negative List sets out the restrictive measures in a unified manner, such as the requirements on shareholding percentages. Pursuant to the Negative List, any field not falling under the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment.

The China Securities Regulatory Commission, or the CSRC, the State Administration of Foreign Exchange, or the SAFE, the MOFCOM and three other PRC governmental and regulatory authorities promulgated the Rules on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (《關於外國投資者併購境內企業的規定》), or the M&A Rules, on August 8, 2006, as later amended on June 22, 2009, governing the mergers and acquisitions of domestic enterprises by foreign investors. The M&A Rules, among other things, require that if a domestic company, a domestic enterprise, or a domestic individual, through an overseas company established or controlled by it/him/her, acquires a domestic company which is affiliated with it/him/her, an approval from the MOFCOM is required. The M&A Rules further requires that a special purpose vehicle, that is controlled directly or indirectly by the PRC companies or individuals and that has been formed for overseas listing purposes through acquisitions of PRC domestic interest held by such PRC companies or individuals, shall obtain the approval of the CSRC prior to overseas listing and trading of such SPV's securities on an overseas stock exchange.

Regulations on Pharmaceutical Product

Major Regulatory Authorities

Pharmaceutical products in China are monitored and supervised by the National Medical Products Administration, or the NMPA, the predecessor of which is the China Food and Drug Administration, or the CFDA, on national level. The local provincial medical products administrative authorities are responsible for supervision and administration of drugs within their respective administrative regions. The primary responsibilities of the NMPA mainly include supervising the safety and regulating the registration of drugs (including traditional Chinese medicines and ethno-medicines, the same below), medical devices and cosmetics.

In 2013, the Ministry of Health, or the MOH, and the National Population and Family Planning Commission were integrated into the National Health and Family Planning Commission of the PRC, or the NHFPC. In March 2018, the NHFPC and certain other governmental authorities were consolidated into the National Health Commission, or the NHC. The responsibilities of the NHC include coordinating the formulation of national drug policies, the national essential medicine system and the National Essential Medicines List and drafting the administrative rules for the procurement, distribution and use of national essential medicines.

According to the Decision of the CFDA on Adjusting the Approval Procedures under the Administrative Approval Items for Certain Drugs (《國家食品藥品監督管理總局關於調整部分藥品行政審批事項審批程序的決定》), which came into effect in May 2017, the approval of Investigational New Drug Application, or the IND, should be issued by the Center for Drug Evaluation, or the CDE, in the name of the NMPA.

Drug Regulatory Regime

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》), or the Drug Administration Law, was promulgated by the SCNPC, in September 1984 and last amended in August 2019. The Regulations for the Implementation of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》), or the Regulations for the Implementation of the Drug Administration Law, was promulgated by the State Council in August 2002 and was last amended in December 2024. The Drug Administration Law and the Regulations for the Implementation of the Drug Administration Law have jointly established the legal framework for the administration of pharmaceutical products in China. The Drug Administration Law applies to entities and individuals engaged in the development, production, trade, use, supervision and administration of pharmaceutical products. It regulates and provides for a framework for the administration of drug marketing authorization holders, drug manufacturing enterprises, drug business enterprises and medical institutions, and the relevant development, research, manufacturing, distribution, packaging, pricing and advertising activities. The Regulations for the Implementation of the Drug Administration Law, at the same time, provide the detailed implementation regulations for the Drug Administration Law.

In 2017, the drug regulatory system entered a new and significant period of reform. The General Office of the State Council and the General Committee of China Communist Party jointly issued Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on 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》), or the Innovation Opinions, according to which the institutions for drug clinical trials should establish an independent ethics committee and the clinical trial schemes are subject to examination, approval and signing with approval opinions by the ethics committee before implementation, in order to protect the rights and interests of human subjects in clinical trials. For a multi-center clinical trial conducted in the PRC, after ethical review by the leader unit of clinical trial, other member units should recognize the review results of the leader unit and may not conduct repeated review. In addition, the expedited programs, the record-filing system, the prioritized review mechanism, the acceptance of foreign clinical data under the Innovation Opinions and other recent reforms encourage drug marketing authorization holders to seek marketing approval in China first for the development of drugs in highly prioritized therapeutic areas such as oncology or rare disease areas.

Regulations on Clinical Trials and Registration of Drugs

Drug Clinical Trial Application

In January 2020, the SAMR released the amended Administrative Measures for Drug Registration (《藥品註冊管理辦法》), or the Drug Registration Measures, which came into effect in July 2020. According to the Drug Registration Measures, clinical trials of drugs shall be subject to approval from NMPA, carried out by drug clinical trial organizations and consistent with the Good Clinical Trial Practice for Drugs (《藥物臨床試驗質量管理規範》). Prior to applying for drug clinical trial, the applicant shall complete research work pertaining to pharmacy, pharmacology and toxicology, etc.

When applicants submit the application for drug clinical trial, the relevant research materials shall be submitted in accordance with the requirements on declaration materials. Upon form examination, where the declaration materials are found to comply with the requirements, the application shall be accepted. The CDE shall organize pharmacists, medical personnel and other technicians to review the accepted application for drug clinical trials. Within 60 days after the acceptance of and the fees paid for the clinical trial applications, the applicant may conduct the clinical trials for the drug in accordance with the clinical trial protocol submitted, if the applicant has not received any negative or questioning opinion from the CDE.

The CFDA released the Circular Concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》) in November 2015, which further clarified the measures and policies for simplifying and accelerating the approval process of clinical trials.

Drug Clinical Trial Registration

The CFDA released the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) in September 2013, according to which, all clinical trials approved and conducted in China shall publish trial information through the Drug Clinical Trial Information Platform. The applicant shall complete the trial pre-registration within one month after obtaining the approval of the clinical trial approval to obtain the trial's unique registration number and complete registration of certain follow-up information before the first subject's enrollment in the trial. If the registration is not completed within one year after the approval of the IND applications, the applicant shall submit an explanation, and if the first submission is not completed within three years, the approval of the IND applications shall automatically expire. The Drug Registration Measures also require that upon obtaining the approval of the IND applications and before conducting a clinical trial, the sponsor shall register the clinical protocol and other information on the Drug Clinical Trial Registration and Information Platform for clinical trials of drugs. During the clinical trial of drugs, the sponsor shall update registration information continuously, and register the outcome of the clinical trials upon completion. The registration information shall be published on the platform and the sponsor shall be responsible for the veracity of such information.

Phases of Clinical Trials and the Communication with the CDE

According to the Drug Registration Measures, drug clinical trials comprise Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial as well as bioequivalence test. Based on the characteristics of drugs and research objective, the research contents shall include clinical pharmacology research, exploratory clinical trial, confirmatory clinical trial and post-marketing research clinical.

According to the Circular on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》) promulgated by the NMPA in July 2018, where the application for clinical trial of new investigational drug has been approved, upon the completion of Phases I and II clinical trials and prior to Phase III clinical trial, the applicant shall submit the application for Communication Session to CDE to discuss with CDE the key technical questions including the design of Phase III clinical trial protocol.

The Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (《藥物研發與技術審評溝通交流管理辦法》), which was issued by the CDE in December 2020, stipulates that during the research and development periods and in the registration applications of, among others, the innovative drugs, the applicants may propose to conduct communication meetings with the CDE. Communication meetings can be classified into three types. Type I meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are meetings convened for the key research and development stages of drugs, mainly include preclinical trial meetings for new drugs, Phase II clinical trial completion/Pre-phase III clinical trial commencement meetings, pre-marketing authorization meetings of new drugs and Risk assessment and control meetings. Type III meetings refer to meetings not classified as Type I or Type II.

Good Clinical Practices

To improve the quality of clinical trials, the CFDA promulgated the Good Clinical Trial Practice for Drugs in August 2003, or the GCP Rules, which was replaced by the revised Good Clinical Trial Practice for Drugs, or the Revised GCP Rules, promulgated by the NMPA and the NHC in April 2020 and coming into effect in July 2020. The Revised GCP Rules provide comprehensive and substantive requirements on the design and conduct of clinical trials in China. In particular, the Revised GCP Rules enhance the protection for study subjects and tighten the control over bio-samples collected under clinical trials.

The Revised GCP Rules also set out the qualifications and requirements, among others, including that the investigators and centers participating in clinical trial shall (i) have professional certification at a clinical trial center, professional knowledge, training experience and capability of clinical trial, and be able to provide the latest resume and relevant qualification documents per request; (ii) be familiar with the trial protocol, investigator's brochure and relevant information of the trial drug provided by the applicant; (iii) be familiar with and comply with the Revised GCP Rules and relevant laws and regulations relating to clinical trials.

The preparation, packaging, labeling and coding of the clinical trial products are also provided strictly in the Revised GCP Rules, which requires that, among others, the preparation of the investigational drug shall conform to the relevant requirements for good manufacturing practice of drugs for clinical trial; the packaging labels of the investigational product shall indicate the information on the use only for clinical trial, clinical trial information and information on the drug for clinical trial; the blinded state shall be kept in blind trials. The packaging of the investigational product shall be able to ensure that the drug is not contaminated or deteriorated during the transportation and storage period.

New Drug Application

According to the Drug Registration Measures, an applicant shall, upon completion of pharmacy, pharmacology and toxicology and drug clinical trial, etc. to support registration of marketing of pharmaceuticals, determination of quality standards, verification of commercial scale manufacturing process, and preparation to undergo examination and inspection for pharmaceutical registration, submit an application for pharmaceutical marketing authorization, and submit the relevant research materials in accordance with the requirements for declaration materials. The CDE shall organize pharmacist, medical and other technical personnel to conduct review for accepted pharmaceutical marketing authorization applications in accordance with the requirements.

Where examination and inspection for pharmaceutical registration is activated due to risks in the review process, the relevant technical agency(ies) shall complete examination and inspection within the stipulated period. The CDE shall, based on the declaration materials for pharmaceutical registration, examination outcome, inspection outcome, etc., conduct a comprehensive review of safety, effectiveness and quality control of the pharmaceuticals. Where the application is cleared after the comprehensive review, the pharmaceuticals shall be approved for marketing and a pharmaceutical registration certificate shall be issued. The pharmaceutical registration certificate shall state the approval document number for the pharmaceuticals, the holder, information of the manufacturing enterprise, etc.

The CFDA promulgated the Administrative Provisions on Special Examination and Approval of Registration of New Drugs (《新藥註冊特殊審批管理規定》) in January 2009, according to which, the CFDA conducts special examination and approval for new drug registration applications when: (1) the effective constituent of drug extracted from plants, animals, minerals, etc., as well as the preparations thereof have never been marketed in China, and the material medicines and the preparations thereof are newly discovered; (2) the chemical raw material medicines as well as the preparations thereof and the biological product have not been approved for marketing at home and abroad; (3) the new drugs have obvious clinical treatment advantages for such diseases as AIDS,

malignant tumors and orphan diseases, etc. or (4) the new drugs treat diseases currently with no effective methods of treatment. It also provides that the applicant may file for special examination and approval at the clinical trial application stage if the product candidate falls within items (1) or (2).

According to the Review Procedures for Breakthrough Therapy Designation (for Trial Implementation) (《突破性治療藥物審評工作程序(試行)》), which was promulgated by the NMPA in July 2020, during the clinical trials of drugs, for innovative drugs or modified new drugs that are used for prevention and treatment of diseases that seriously endanger life or seriously affect the quality of life, for which there are no effective prevention and treatment methods or for which there is sufficient evidence showing obvious clinical advantages as compared with existing treatment methods, applicants may apply for the application of the procedures for breakthrough therapy designation during Phase I or II clinical trials, usually no later than the Phase III clinical trials. In the meantime, according to the Priority Review and Approval Procedures for Drug Marketing Authorizations (for Trial Implementation) (《藥品上市許可優先審評審批工作程序(試行)》), an applicant for drug marketing authorization may apply for priority review and approval procedures for drugs that have been included in the procedures for breakthrough therapy designation.

According to the Announcement on Matters Concerning the Optimization of Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》) jointly issued by the NMPA and the NHC in May 2018 and effective immediately, the CDE will prioritize the allocation of resources for review, inspection, examination and approval of registration applications that have been included in the scope of priority review and approval so as to speed up review and approval.

The Drug Registration Measures provide more detailed standards, procedures and policy supports regarding different kinds of accelerated drug marketing registration, which include breakthrough therapy designation, conditional approval, prioritized review and approval and special examination and approval. For example, an innovative drug or improved new drug used for prevention and treatment of life-threatening illnesses or illnesses which have a serious impact on quality of life and for which there is no other effective prevention and treatment method or there is adequate evidence to prove that the said innovative drug or improved new drug has obvious clinical advantages over existing treatment approach(es), the applicant may apply for breakthrough therapy designation.

Marketing Authorization Holder System

Pursuant to the Drug Administration Law, drug marketing authorization holder refers to an enterprise or a drug development institution that has obtained the drug registration certificate. The drug marketing authorization holder shall be responsible for non-clinical research, clinical trials, production and operation, post-marketing research, adverse reaction monitoring, reporting and processing of drugs in accordance with the provisions of the law. Other units and individuals engaged in drug development, production, operation, storage, transportation, use and other activities shall bear corresponding responsibilities pursuant to the law.

Trial Exemptions and Acceptance of Foreign Data

The NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data (《接受藥品境外臨床試驗數據的技術指導原則》) in July 2018, which provides that overseas clinical data can be submitted for the drug registration applications in China. According to the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data, sponsors may use the data of foreign clinical trials to support drug registration in China, provided that, among others, sponsors must ensure the authenticity, completeness, accuracy and traceability of foreign clinical trial data and such data must be obtained consistent with the relevant requirements under the Good Clinical Trial Practice of the International Conference on Harmonization of Technical Requirements

for Registration of Pharmaceuticals for Human Use (《人用藥物註冊技術要求國際協調會臨床試驗管理規範》), or the ICH-GCP. Sponsors must also comply with other relevant sections of the Drug Registration Measures when applying for drug registrations in China using foreign clinical trial data.

International Multi-Center Clinical Trials

The International Multi-Center Clinical Trial Guidelines (Trial) (《國際多中心藥物臨床試驗指南(試行)》), or the Multi-Center Clinical Trial Guidelines, which was promulgated by the CFDA in January 2015 and came into effect in March 2015, provided guidance on the implementation of international Multi-Center Clinical Trials, or the MCCT, in China. According to the Multi-Center Clinical Trial Guidelines, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicants plan to implement the international MCCTs in the PRC, the applicants shall comply with relevant laws and regulations, such as the Drug Administration Law, the Regulations for the Implementation of the Drug Administration Law and the Drug Registration Measures, execute the GCP Rules, make reference to universal international principles such as the ICH-GCP and comply with the laws and regulations of the countries involved in the international MCCTs. Where the applicants plan to use the data derived from the international multi-center clinical trials for approval of a drug registration in the PRC, it shall involve at least two countries, including China, and shall satisfy the requirements for clinical trials set forth in the Multi-Center Clinical Trial Guidelines, Drug Registration Measures and other related laws and regulations.

Data derived from international MCCTs can be used for the NDAs with the NMPA. When using international MCCT data to support NDAs in China, applicants shall submit the completed global clinical trial report, statistical analysis report and database, along with relevant supporting data in accordance with the content and format requirements under the International Conference on Harmonization-Common Technical Document; subgroup research results summary and comparative analysis shall also be conducted concurrently.

Approval of Human Genetic Resources

The Regulations of the PRC on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》), or the HGR Regulation, which was promulgated by the State Council in May 2019, amended in March 2024 and came into effect in May 2024, further stipulates that, to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China's human genetic resources at clinical institutions without export of human genetic resource materials. However, the type, quantity and usage of the human genetic resource to be used shall be filed with the department of health and wellness under the State Council before clinical trials, otherwise, the Department of Health and Wellness under the State Council shall order cooperative parties to stop the illegal acts, confiscate the human genetic resources illegally collected and preserved as well as illegal gains, and impose a fine of not less than RMB500,000 but not more than RMB5,000,000. If the illegal gains reach more than RMB1,000,000, the fine shall be more than five times and less than ten times the illegal gains.

In October 2020, the SCNPC promulgated the Biosecurity Law of the PRC (《中華人民共和國生物安全法》), which was further amended and became effective in April 2024. The Biosecurity Law of the PRC reaffirms the regulatory requirements stipulated by the HGR Regulation while potentially increasing the administrative sanctions significantly in cases where China's human genetic resources are collected, preserved, exported or used in international cooperation for scientific research in violation of applicable laws.

During the Track Record Period and up to the Latest Practicable Date, our Group conducted clinical trials at various clinical institutions in China using China's human genetic resources to obtain the marketing authorization for our drug candidates in the PRC. We have complied with the necessary procedures as required under the HGR Regulation for these activities. As advised by our PRC Legal Adviser, during the Track Record Period and up to the Latest Practicable Date, we had complied with the HGR Regulation and other relevant regulations on the use of China's human genetic resources in the above activities in all material respects.

Regulations on Drug Manufacturing and Distribution

Drug Manufacturing

According to the Drug Administration Law and the Regulations for the Implementation of the Drug Administration Law, all facilities that manufacture drugs in China must obtain a Drug Manufacturing License with an appropriate "scope of manufacturing" from the local drug regulatory authority. This license must be renewed every five years.

Good Manufacturing Practices (GMP)

Pursuant to the Norms on Good Manufacturing Practices (《藥品生產質量管理規範》) last amended on 17 January 2011 and effective from 1 March 2011, sets out the basic standard for the manufacture of pharmaceuticals products, which includes the production facilities, the qualification of the management personnel, production plant and facilities, documentation, material packaging and labelling, inspection, production management, sales and return of products and customers' complaints.

Contract Manufacturing of Drug

The Drug Administration Law specifies that a holder of drug sales approval may produce drugs by itself or may entrust other drug manufacturers. A holder of drug sales approval that intends to manufacture drugs on its own shall obtain a drug manufacturing permit, or if the holder intends to entrust a third-party to manufacture, it shall entrust a qualified drug manufacturer. The holder of drug sales approval and the commissioned manufacturer shall enter into an entrustment agreement and a quality agreement, and strictly perform the obligations pursuant to such agreements. Blood products, anesthetics, psychotropic pharmaceuticals, toxic pharmaceuticals for medical treatment, and pharmaceutical precursor chemicals may not be produced through entrustment, except as otherwise prescribed by the drug administrative department of the State Council.

Drug Distribution

In September 2023, SAMR promulgated the Measures for Supervision and Administration of the Quality of Drug Operation and Use (《藥品經營和使用質量監督管理辦法》), or the Measures, which came into effect in January 2024. When the Measures came into effect, the Measures for the Supervision and Administration of Circulation of Pharmaceuticals (《藥品流通監督管理辦法》) and the Measures for the Administration of Pharmaceutical Operation Certificate (《藥品經營許可證管理辦法》) were repealed simultaneously. Pursuant to the Measures, pharmaceutical enterprises shall be responsible for the quality of the pharmaceuticals that they manufacture, operate, use, purchase, sell, transport, or store. And a Medicine Operation Certificate is valid for five years. Each holder of the Medicine Operation Certificate must apply for an extension of its permit within two months to six months before such expiration.

Drug Advertisements

According to the Advertising Law of the PRC (《中華人民共和國廣告法》), which was promulgated by the SCNPC in October, 1994 and last amended in April, 2021, certain contents such as statement on cure rate or efficiency shall not be included in the advertisement of drugs.

According to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food, and Formula Food 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 in December, 2019 and came into effect in March, 2020, the advertisements for drugs shall not be released without being reviewed and the contents of a drug advertisement shall be based on the drug instructions approved by the drug administration departments.

Regulations on Intellectual Property Rights

Patents

According to the Patent Law of the PRC (《中華人民共和國專利法》) and its last amended on October 17, 2020 implementing rules, the duration of a patent right shall be 20 years for inventions, 10 years for utility models and 15 years for designs, all commencing from their respective application date. For the purpose of compensating for the time taken to evaluate and get a new drug approved and marketed, the patent administrative department under the State Council would grant compensation for duration of patent rights for invention of a new drug approved to be put on market in China upon request of the patentee. The compensation period shall not exceed five years, and the total validity period of patent rights for a new drug after being approved for market shall not exceed 14 years.

Trademarks

According to the Trademark Law of the PRC (《中華人民共和國商標法》) last amended in April 2019, the validity period for each renewal of registration is ten years, commencing on the day immediately after the expiry of the preceding period of validity for the trademark.

Regulations on Anti-Unfair Competition

Pursuant to the Regulations on the Establishment of Adverse Records with Respect to Commercial Briberies in the Medicine Purchase and Sales Industry (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》) (2013 revision) enforced on March 1, 2014 by the NHFPC, the enterprises manufacturing and operating drugs, medical equipment and medical supplies, and the agencies as well as individuals thereof, which bribe the employee(s) of the medical and health institutions procuring and using their drugs, medical equipment or medical supplies with property or other benefits, shall be included into the Adverse Records of Commercial Bribery if they satisfy any of the circumstances as described the above- mentioned regulation. If medical production and operation enterprises be listed into the Adverse Records of Commercial Bribery more than once in five years, their products shall not be purchased by all public medical institutions and medical and health institutions receiving financial subsidies nationwide for two years since publication of the record.

Regulations on Environment Protection and Fire Prevention

Pursuant to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) effective in January 2015 and its related laws and regulations, the environmental impact assessment and acceptance must be conducted on any construction project before its construction and use to analyze its impact on the environment based on the Catalog of Administration of Environmental Impact Assessment for Construction Projects (《建設項目環境影響評價分類管理名錄》) promulgated by ecological environment department under the State Council.

According to the Measures for Pollutant Discharge Permitting Administration (《排污許可管理辦法》), promulgated by the Ministry of Ecology and Environment in 2024, enterprises, institutions and other producers and operators, or the pollutant discharge enterprises, that have been included in the Classification Management List for Fixed Source Pollution Permits (2019 Edition) (《固定污染源排污許可分類管理名錄(2019年版)》) shall apply for and obtain a discharge permit in accordance with the prescribed time limit. Pursuant to the Regulations on Urban Drainage and

Sewage Disposal (《城鎮排水與污水處理條例》), which was promulgated in October 2013 and came into effect in January 2014, and the Measures for the Administration of Permits for the Discharge of Urban Sewage into the Drainage Network (《城鎮污水排入排水管網許可管理辦法》), which was promulgated in January 2015 and further amended in December 2022, drainage entities covered by urban drainage facilities shall discharge sewage into urban drainage facilities in accordance with the relevant provisions of the PRC. Where a drainage entity needs to discharge sewage into urban drainage facilities, it shall apply for a drainage license in accordance with the provisions of these Measures.

The Fire Prevention Law of the PRC (《中華人民共和國消防法》) most recently amended on April 29, 2021 and its related laws and regulations provide that fire safety design examination and acceptance system shall be implemented for development projects which are required to have fire safety design in accordance with the national fire protection technical standards for project construction.

Regulations on Foreign Exchange and Dividend Distribution

On January 29, 1996, the State Council promulgated the Administrative Regulations on Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) which became effective on April 1, 1996 and was amended on January 14, 1997 and August 5, 2008. Foreign exchange payments under current account items shall, pursuant to the administrative provisions of the foreign exchange control department of the State Council, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in conversion and sale of foreign currencies by presenting the valid document. Domestic entities and domestic individuals making overseas direct investments or engaging in issuance and trading of overseas securities and derivatives shall process registration formalities pursuant to the provisions of the foreign exchange control department of the State Council.

Pursuant to the Circular of the SAFE on Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign 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》), the State Administration of Foreign Exchange on Reforming the Management Mode of Foreign Exchange Capital Settlement of Foreign Investment Enterprises (國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》) and related policies, foreign exchange capital accounts and guarantee accounts, the reinvestment of RMB proceeds derived by foreign investors in the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of SAFE. Foreign-invested enterprises could settle their foreign exchange capital on a discretionary basis according to the actual needs of their business operations with certain exceptions. The Notice of the SAFE on Further Promoting Cross-border Trade and Investment Facilitation (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》) further stipulated that non-investing foreign-funded enterprises are permitted to legally make domestic equity investments with their capital funds under the premise that the existing Negative List, are not violated and domestic invested projects are true and compliant.

Pursuant to the Circular of the SAFE on Relevant Issues Concerning Foreign Exchange Administration for Domestic Residents Conducting Overseas Investment and Financing and Round-Trip Investments Through Special Purpose Vehicles (《國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) and its amendents, which was promulgated by the SAFE and became effective on July 4, 2014, a PRC resident shall register with the eligible banks before he or she contributes assets or equity interests in an overseas special purpose vehicle (the "Overseas SPV"), that is directly established or controlled by the PRC resident for the purpose of conducting investment or financing. Following the initial registration, if there is any change in the basic information of the Overseas SPV, such as the PRC resident individual shareholder, name, term of business, or a significant change such as increase or reduction of capital contribution, equity transfer or exchange by the PRC resident individual, merger or division, foreign exchange registration change formalities shall be promptly completed with the foreign exchange bureau.

Regulations on Labor

According to the Social Insurance Law of the PRC, which was promulgated by the SCNPC in October 2010 and further amended in December 2018, the Interim Regulations on the Collection and Payment of Social Security Funds (《社會保險費徵繳暫行條例》), which was promulgated by the State Council in January 1999 and amended in March 2019, the Regulation on Work-Related Injury Insurance (《工傷保險條例》), which was issued by the State Council on April 27, 2003, came into effect on January 1, 2004 and revised on December 20, 2010, the Regulations on Unemployment Insurance (《失業保險條例》), which was issued by the State Council on January 22, 1999 and came into effect on the same day, the Trial Measures on Employee Maternity Insurance of Enterprises (《企業職工生育保險試行辦法》), which issued by the Ministry of Labor on December 14, 1994 and came into effect on January 1, 1995 and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), which was promulgated by the State Council in April 1999 and amended in March 2002 and March 2019, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance, maternity insurance and housing provident funds.

Regulations on Taxation

Enterprise Income Tax

According to the Enterprise Income Tax Law (《中華人民共和國企業所得税法》) last amended December 2018 and its implementation rules, other than a few exceptions, the income tax rate for both domestic enterprises and foreign-invested enterprises is 25%. Besides enterprises established within the PRC, enterprises established outside China whose "de facto management bodies" are located in China are considered "resident enterprises" and subject to the uniform 25% enterprise income tax rate for their global income.

Value Added Tax

According to the Provisional Regulations of the PRC on Value-Added Tax (《中華人民共和國增值税暫行條例》), effective in January 1994 and further amended in November 2008, February 2016, and November 2017, and its implementation rule (《中華人民共和國增值税暫行條例實施細則》) was effected in December 1993 and amended in December 2008 and October 2011, except stipulated otherwise, taxpayers who sell goods, labor services or tangible personal property leasing services or import goods shall be subject to a 17% tax rate; taxpayers who sell transport services, postal services, basic telecommunications services, construction services, or real property leasing services, sell real property, transfer the land use right shall be subject to an 11% tax rate, and taxpayers who sell services or intangible assets, unless otherwise provided, shall be subject to a 6% tax rate.

Regulations on Securities Offering and Listing Outside of the PRC

On July 6, 2021, the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council jointly promulgated the Opinions on Strictly Combating Illegal Securities Activities in accordance with the Law (《關於依法從嚴打擊證券違法活動的意見》), or the Opinions on Securities Activities. The Opinions on Securities Activities emphasize the need to strengthen the management of securities activities and the supervision of overseas listing of listed companies, both domestic and foreign, and propose effective measures, such as the promotion of the construction of a phase-by-phase supervisory system, to deal with the risks and events faced by listed companies in the PRC outside the PRC.

On February 17, 2023, the CSRC promulgated the Trial Measures for the Administration of Offshore Issuance and Listing of Securities by Domestic Enterprises (《境內企業境外發行證券和上市管理試行辦法》), or the Trial Measures for Administration, which became effective on March 31, 2023, and five related guidelines. Pursuant to the Trial Measures for Administration, a domestic enterprise that directly or indirectly issues and lists securities overseas shall file a record with the CSRC and report the relevant information. Under the Trial Measures for Administration, an issuer shall be deemed to have filed with the CSRC for indirect overseas issuance and listing if the issuer meets the following circumstances: (i) the operating revenues, total profits, total assets or net assets of the domestic enterprise in the most recent fiscal year, with any one of the indicators accounting for more than 50% of the relevant data in the issuer's audited consolidated financial statements for the same period; (ii) the major aspects of the operating activities are carried out in the territory or the principal place of business is located in the territory, or the majority of the senior management in charge of the operation and management are Chinese citizens or have their usual place of residence in the territory. If an issuer submits an application for an initial public offering to a foreign regulatory body, it shall file the application with the CSRC within three working days after the application is made.

On February 24, 2023, the CSRC jointly with other authorities, promulgated the Provisions on Strengthening Confidentiality and File Management Related to Overseas Issuance and Listing of Securities by Domestic Enterprises or the Confidentiality Provisions (《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》), which came into effect on March 31, 2023. Pursuant to the Confidentiality Provisions, domestic joint stock companies that directly issue shares to be listed overseas and domestic operating organizations of enterprises listed overseas through indirect share issuance shall submit for approval and comply with other regulations, before filing prior to publicly disclosing or providing to securities companies, securities service providers, overseas regulatory bodies and other entities and individuals any documents or information that involves state secrets, the working secrets of state organs, or documents and information that, if divulged, would jeopardize national security or public interests.

U.S. REGULATION

Regulations on Drug and Biological Products

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations, and biologics under the FDCA and the Public Health Service Act (the "PHSA") and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative actions or judicial sanctions. These actions and sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, the market acceptance of our products and our reputation.

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 FDA's Good Laboratory Practice regulations. A sponsor of an IND must submit the results of the preclinical tests, 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. FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance.

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 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 (the "**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 in 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.

Specifically for oncology drugs and biologics, in August 2018, the FDA, together with other U.S. competent authorities, introduced a draft guidance paper "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics Guidance for Industry" (the "**Guidance**"), which was formally adopted in March 2022. This guidance paper acknowledges a new clinical trial design, which the FDA calls the first-in-human ("**FIH**") multiple expansion cohort trial. These are trial designs that have a single protocol with an initial dose escalation phase for the initial determination of a tolerated dose and multiple concurrently accruing expansion cohorts with assessments that are more typical of phase 2 trials (i.e., to estimate anti-tumor activity). The new trial design is intended to efficiently expedite the clinical development of oncology drugs, including biological products, through multiple expansion cohort trial designs.

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 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 cGMP 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.

Regulations on Drug 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 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 cGMP-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 cGMP 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.

In the United States, products composed of components that would normally be regulated by different centers at the FDA are known as combination products. Typically, the FDA's Office of Combination Products assigns a combination product to a specific Agency Center as the lead reviewer. The FDA determines which Center will lead a product's review based upon the product's primary mode of action. Depending on the type of combination product, its approval, clearance or licensure may usually be obtained through the submission of a single marketing application. However, the FDA sometimes will require separate marketing applications for individual constituent parts of the combination product which may require additional time, effort, and information. Even when a single marketing application is required for a combination product, the relevant Centers may participate in the review. An applicant will also need to discuss with the Agency how to apply certain pre-market requirements and post-marketing regulatory requirements, including conduct of clinical trials, adverse event reporting and good manufacturing practices, to their combination product.

Regulations on Post-approval Requirements

Rigorous and extensive FDA regulation of biologic products continues after approval, particularly with respect to cGMP requirements. Manufacturers are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biologic products include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information and complying with electronic record and signature requirements.

The FDA may also require testing and surveillance programs to monitor the product after commercialization. For biologics, such testing may include official lot release, which requires the manufacturer to perform certain tests on each lot of the product before it is released for distribution. The manufacturer then typically must submit samples of each lot of the product to the FDA, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products itself, before releasing the lots for distribution by the manufacturer.

After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are often subject to further testing requirements and FDA review and approval, depending on of the change that is made. The FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if issues arise after the product reaches the marketplace. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-approval studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions under a risk evaluation and mitigation strategy (REMS) program.

The distribution of biologic products is subject to the Drug Supply Chain Security Act (the "**DSCSA**"), which requires manufacturers and other stakeholders to comply with product identification, tracing, verification, detection and response, notification and licensing requirements. In addition, the Prescription Drug Marketing Act (the "**PDMA**"), and its implementing regulations, and certain state laws limit the distribution of prescription pharmaceutical product samples, and the DSCSA imposes requirements to ensure accountability in distribution and to identify and remove prescription drug and biological products that may be counterfeit, stolen, contaminated, or otherwise harmful from the market.

BIOSECURE Act

On December 18, 2025, the U.S. legislation titled the BIOSECURE Act (the "BIOSECURE Act") was signed by President Trump. The enacted BIOSECURE Act prohibits federal agencies from contracting with or funding companies that are designated "biotechnology companies of concern." The BIOSECURE Act's final definition of "biotechnology companies of concern" includes (A) entities on the Department of Defense's section 1260H list of Chinese military companies operating in the United States (known as the "1260H List"), and (B) entities that will be named through a process headed by the Office of Management and Budget ("OMB"), who must supplement the list of biotechnology companies of concern within one year of enactment. Prohibitions in the BIOSECURE Act will not take effect until the OMB issues implementing guidance and relevant federal regulations are finalized.

The OMB must publish the initial list of "biotechnology companies of concern" within one year of the FY2026 NDAA's enactment (i.e., by December 2026). Within 180 days of publishing this list, OMB must issue implementation guidance for the BIOSECURE Act's requirements. The Federal Acquisition Regulation ("FAR") Council must then update the FAR within one year. Prohibitions for 1260H List entities take effect 60 days after the FAR revision, while prohibitions for companies newly named by the OMB take effect 90 days after the FAR revision. A grandfathering period applies for up to five years after the FAR revision, where the prohibitions do not apply to biotechnology equipment or services produced or provided under contracts or agreements (including previously negotiated contract options) entered into before the applicable effective date.