We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section summarizes the principal PRC laws, rules and regulations that we believe are relevant to our business and operations.

## REGULATORY AUTHORITIES

In the PRC, the National Medical Products Administration, or the NMPA, which was previously known as China Food and Drug Administration, is the primary regulatory agency for pharmaceutical products and their businesses and regulates almost all of the key stages of the life-cycle of pharmaceutical products, including non-clinical studies, clinical trials, marketing licensure manufacturing, advertising and promotion, distribution, and pharmacovigilance (*i.e.* post-marketing safety reporting obligations). The Center for Drug Evaluation, or the CDE, which is a subsidiary under the NMPA, conducts the technical evaluation on each drug and biologic application to assess the safety and efficacy of each candidate.

The National Health Commission, or the NHC (formerly known by names of the Ministry of Health and National Health and Family Planning Commission), is the primary healthcare regulatory agency in China. It is responsible for overseeing the operation of medical institutions, some of which also serve as clinical trial sites.

Also, the Ministry of Commerce, or the MOFCOM, and the State Administration for Market Regulation, or the SAMR, are the main regulatory authorities on our PRC subsidiaries with regard to the foreign investment activities and business supervision.

## REGULATIONS RELATING TO DRUGS

### Introduction

The National People's Congress, or the NPC and the NMPA have been revising the fundamental laws, regulations and rules regulating pharmaceutical products and the industry, which include the framework law known as the PRC Drug Administration Law (《中華人民共和國藥品管理法》), or the Drug Administration Law. The Drug Administration Law was promulgated by the Standing Committee of the NPC, or the SCNPC, on September 20, 1984 and latest amended on August 26, 2019 and took effect as of December 1, 2019. The State Council issued the Regulations for 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》), which was promulgated on August 4, 2002 and latest amended on December 6, 2024 and took effect as of January 20, 2025 to further implement the Drug Administration Law. The NMPA also set up a series of regulations to further implement the Drug Administration Law. Among them, the most important primary management measures regulating clinical trial applications, licensures, post-approval changes and renewals are called the Drug Registration Regulation (《藥品註冊管理辦法》), or the Drug Registration Regulation, which was amended by the SAMR on January 22, 2020 and effective from July 1, 2020.

### Non-clinical Studies

The NMPA requires preclinical data to support registration applications for imported and domestic drugs. According to the Drug Registration Regulation, non-clinical safety studies shall be carried out in an institution that has passed the certification of the Good Laboratories Practice of Non-clinical Laboratory and comply with the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory (《藥物非臨床研究質量管理規範》), or the GLP, which was issued by NMPA on July 27, 2017. The GLP has been promulgated to improve the quality of non-clinical safety evaluation studies.

### Clinical Trial Approval

Before registering a new drug, a sponsor shall complete clinical trials according to the Drug Registration Regulation. To start the clinical trial, a sponsor needs to apply for clinical trial approval first, and the Administrative Regulations of Quality of Drug Clinical Practice (《藥物臨床試驗質量管理規範》), or the GCP, has been promulgated to further promote the research into good practice for clinical trials of drugs and enhance the quality thereof. The GCP was promulgated by NMPA on August 6, 2003 and amended by NMPA and NHC which came into effect on July 1, 2020. All clinical trials to be conducted in China for new drug registration purposes must be approved and conducted at pharmaceutical clinical trial institutions filed according to the Regulations on the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》) promulgated by NMPA and NHC on November 29, 2019.

According to the Announcement of Several Policies on the Evaluation and Examination for Drug Registration (《關於藥品註冊審評審批若干政策的公告》) promulgated by NMPA on November 11, 2015, an umbrella approval would be issued by NMPA for all phases of a new drug clinical trial, instead of approvals phase by phase. Provided by the Announcement of the Adjustment of Procedures of the Evaluation and Examination for Drug Clinical Trial (《關於調整藥物臨床試驗審評審批程序的公告》) issued by NMPA on July 24, 2018, applicants could proceed with their clinical trials if they have not received any objection or query from the CDE within 60 days after the application has been accepted and the relevant application fees have been paid. The newly revised Drug Administration Law further confirms that the drug administrative department under the State Council shall, within 60 working days from the date on which the application for a clinical trial is accepted, decide on whether to approve it and then notify the clinical trial applicant. In the case of failure to notify the applicant within the prescribed time limit, it shall be deemed approved.

**Overseas Clinical Trial**

On January 30, 2015, the NMPA promulgated the Guidelines for International Multi-Center Clinical Trials of Drugs (for Trial Implementation) (《國際多中心藥物臨床試驗指南(試行)》) to guide the application, implementation and administration of international multi-center drug clinical trials in China.

Pursuant to the Innovation Opinion, the clinical trial data obtained from overseas centers may be used to apply for drug registration in China if they meet the relevant requirements for the drug registration in China. For drugs first applied for NDA in China, registration applicants should provide clinical trial data on whether there are racial differences, if any.

According to the Announcement on Promulgation of the Guiding Technical Principles for the Acceptance of Overseas Clinical Trial Data of Drugs (《關於發佈接受藥品境外臨床試驗數據的技術指導原則的通告》) issued by NMPA on July 6, 2018, if drug registration applicants use overseas clinical trials for drug registration applications in China, all overseas clinical trial data shall be provided, rather than selectively.

**Drug Clinical Trial Registration**

Pursuant to the Drug Registration Regulation, upon obtaining the clinical trial approval and before commencing a clinical trial, the sponsor shall register the scheme on the clinical trial and other information on the Drug Clinical Trial Registration and Information Platform (藥物臨床試驗登記與信息公示平台) for clinical trials of drugs. More details are provided in the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) released by the NMPA on September 6, 2013, providing that the applicant shall complete trial pre-registration within one month after obtaining the clinical trial approval to obtain the trial's unique registration number and shall complete certain follow-up information and first submission for publication before the first subject's enrollment in the trial.

**Human Genetic Resources Approval and Registration**

On March 10, 2024, the State Council of PRC revised the PRC Administrative Regulations on Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》), or the Human Genetic Resource Regulation, which became effective on May 1, 2024. According to the Human Genetic Resource Regulation, human genetic resource includes human genetic resource materials and information. Human genetic resource materials refer to organs, tissues, cells and other genetic materials containing human genome, genes and other genetic materials. Human genetic resource information refers to information, such as data, generated by human genetic resources materials. The Human Genetic Resource Regulation formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities, under which, a new filing system (as opposed to the advance approval approach originally in place) is put in place for clinical trials utilizing China's human genetic resources in order to obtain a market license for relevant drugs and medical devices at clinical institutions without involving the export of human genetic resources materials outside of China. Foreign organizations, individuals and institutions established or actually controlled by such foreign organizations or individuals are not allowed to collect or preserve human genetic resources in China or provide human genetic resources abroad.

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 became effective in April 2021 and was latest revised in April 2024. The Biosecurity Law of the PRC reaffirms the regulatory requirements stipulated by the Human Genetic Resource Regulation while potentially increasing the administrative fines significantly in cases where foreign entities are alleged to have collected, preserved, exported Chinese human genetic resources or used such resources in international clinical trial cooperation in violation of applicable laws.

**Scientific Data Management**

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》), or the Scientific Data Measures. According to the Scientific Data Measures, any scientific data involving a state secret, state security, social public interests, commercial secret or personal privacy may not be open and shared, or if indeed needed, the purpose, user's qualification, conditions of confidentiality and other factors shall be reviewed, and the informed scope shall be strictly controlled. Besides, legal entities shall, according to the national administrative provisions governing network security, establish a support system for network security, use secure and reliable products and services, improve data management and control, attribute management, identity recognition, behavior retrospect, blacklist and other management measures, and improve the tamper-proofing, leak-proofing, anti-attacking and anti-virus security protection system.

**Outbound Data Transfer**

On July 7, 2022, the Cyberspace Administration of China, or the CAC, published Outbound Data Transfer Security Assessment Measures (《數據出境安全評估辦法》) that became effective on September 1, 2022 and outline the potential security assessment process for outbound data transfer. Under the Outbound Data Transfer Security Assessment Measures, data processors providing outbound data shall apply for outbound data transfer security assessment with the Cyberspace Administration in any of the following circumstances: (i) where a data processor provides important data abroad; (ii) where a critical information infrastructure operator or a data processor processing the personal information of more than one million individuals provides personal information abroad; (iii) where a data processor has provided personal information of 100,000 individuals or sensitive personal information of 10,000 individuals in total abroad since January 1 of the previous year; and (iv) other circumstances prescribed by the CAC for which declaration for security assessment for outbound data transfers is required.

On March 22, 2024, the CAC promulgated the Regulations on Improving and Regulating the Cross-Border Transfer of Data (《促進和規範數據跨境流動規定》), which provided implementation rules on the security assessment of outbound data transfer, the standard contract for outbound transfer of personal information, the certification of personal information protection and other systems governing the outbound transfer of data. Pursuant to the regulation, except as otherwise provided, (I) a data processor that provides data overseas under any of the following circumstances shall apply to the national cyberspace administration for the security assessment of the outbound data transfer through local provincial cyberspace administration: (A) a critical information infrastructure operator provides personal information or important data abroad, (B) a data processor other than critical information infrastructure operator provides important data abroad, or has provided personal information (excluding sensitive personal information) of over 1,000,000 people or sensitive personal information of over 10,000 people abroad cumulatively since January 1 of the year; and (II) a data processor other than critical information infrastructure operator that has provided personal information (excluding sensitive personal information) of over 100,000 people and less than 1,000,000 people, or sensitive personal information of less than 10,000 people abroad cumulatively since January 1 of the year shall enter into a standard contract for outbound transfer of personal information with the receiver overseas or pass the certification of personal information protection in accordance with laws and regulations.

**New Drug Application, Approval and Renewal**

According to the Drug Registration Regulation, an applicant shall, upon completion of studies including pharmacy, pharmacology and toxicology and clinical trial of drugs which support the registration of drug marketing, determination of quality standards, validation of commercial scale

of manufacturing process, and well preparation to undergo examination and inspection for drug registration, submit an application for drug marketing authorization, and submit the relevant submission dossier in accordance with the submission requirements. The CDE shall organize pharmaceutical, medical and other technical personnel to comprehensively review the application for the safety, effectiveness and quality control of the drug. When the comprehensive review opinion is passed, the drug shall be approved for marketing and a drug registration certificate shall be issued.

The NMPA promulgated the China Food and Drug Administration Special Review and Approval Procedure for Drugs (《國家食品藥品監督管理局藥品特別審批程序》) in November 2005, according to which, the NMPA may legally decide to conduct special review and approval procedure on the certain drug needed in responding to a public health emergency.

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, 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.

Pursuant to the newly amended Drug Administration Law, an applicant who has obtained a drug registration certificate shall be recognized as a drug marketing authorization holder, and shall be responsible for non-clinical laboratory studies, clinical trials, production and distribution, post-marketing studies and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of the Drug Administration Law. The drug marketing authorization holder may engage in manufacturing or distribution on their own or to entrust a licensed third party. According to the Drug Registration Regulation, at the time of application for drug marketing authorization, the applicant and the manufacturing enterprise shall have held the corresponding Pharmaceutical Manufacturing Permit.

Pursuant to the Drug Registration Regulation, the validity period of a drug registration certificate shall be five years. The drug marketing authorization holder of the drug registration certificate shall ensure the safety, effectiveness and quality control of the marketed drug at all times during the validity period of the certificate and apply for re-registration of the drug six months before the expiry of such validity period.

**Drug Manufacturing**

According to the Drug Administration Law and Administrative Measures on Supervision of Pharmaceutical Manufacturing (《藥品生產監督管理辦法》) which was promulgated by the NMPA on December 11, 2002 and last amended on January 22, 2020 by the SAMR and effective on July 1, 2020, all facilities that manufacture drugs in China must apply for a Pharmaceutical Manufacturing Permit which is issued by the drug supervision and administration department of the province, autonomous region or municipality directly under the central government where it is domiciled. The Pharmaceutical Manufacturing Permit is valid for five years and shall be apply for renewal six months before the expiry date. The drug marketing authorization holder who entrusts another party to produce preparations shall meet the requirements as specified in Administrative

Measures on Supervision of Pharmaceutical Manufacturing, sign an entrustment agreement and a quality agreement with a qualified drug producer, and submit the relevant agreements and the application materials of the actual production site to provincial drug administrative departments where the drug marketing authorization holder is located to apply for the Pharmaceutical Manufacturing Permit.

**Drug Operation**

Pursuant to Good Manufacturing Practice for Drugs (2010 version) (《藥品生產質量管理規範(2010年版)》), which was promulgated by the Ministry of Health in January 2011 and became effective in March 2011, drug business operators shall comply with the drug operation quality management norms, establish and improve their business operation quality management system, and ensure that the whole drug business process continuously complies with statutory requirements.

In China, governmental pricing controls on drugs (other than narcotic and certain psychiatric drugs) have been lifted since June 2015 when the Opinions on Advancing Drug Price Reform (《推進藥品價格改革意見》) came into effect. Instead of direct governmental controls, the government exercises control over the drugs through establishing a centralized tender process or centralized procurement mechanism, revising the National Reimbursement Drug List (國家醫療保險藥品目錄) or provincial medical insurance drug catalogues and strengthening regulation of medical and pricing practices.

**Regulations on Two-Invoice System**

According to the Implementing Opinions on Promoting the "Two-Invoice System" for 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, or the Two-Invoice System Notice, the Two-Invoice System refers to a system that requires one invoice to be issued from pharmaceutical manufacturers to pharmaceutical distributors and the other invoice to be issued from pharmaceutical distributors to medical institutions. According to the Dual Invoicing System Notice and the Several Opinions of the General Office of the State Council on Further Reform and Improvement in Policies of Drug Production, Circulation 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, the Two-Invoice System would be promoted in pilot provinces (autonomous regions and municipalities directly under the central government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis.

**Monitoring Periods for New Drugs**

According to the Regulations for Implementation of the Drug Administration Law of the PRC, the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of not more than five years for new drugs approved to be manufactured to continually monitor the safety of such new drugs. During the monitoring period of a new drug, no approval shall be granted to any other manufacturer to produce or import the said drug.

**Regulations on Centralized Procurement**

On January 17, 2009, the Ministry of Health, together with other 5 departments, issued Opinions on Further Regulating Centralized Procurement of Medical Institutions (《進一步規範醫療機構藥品集中採購工作的意見》), which promoted the comprehensive implementation of online drug procurement in a centralized manner directed by government.

In November 22, 2024, the Documents on National Centralized Drug Procurement (GY-YD2024-2) (《全國藥品集中採購文件(GY-YD2024-2)》) was issued and the tenth batch of State organizations for the centralized volume-based drug procurement was officially launched.

### Drug Advertisements

The PRC Advertising Law (《中華人民共和國廣告法》), as recently amended and became effective on April 29, 2021, outlines the regulatory framework for the advertising industry. Advertisers, advertising agents and advertising publishers are required to ensure that the contents of the advertisements they prepare or distribute are true and in full compliance with applicable laws and regulations. For advertisement of drugs, the advertisement contents shall be examined by the relevant authorities prior to the publishing. Pursuant 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》) promulgated by SAMR on December 24, 2019 and became effective from March 1, 2020, advertisements for drugs shall not contain any false or misleading contents. Advertisers shall be responsible for the veracity and legitimacy of the contents of advertisements for drugs, medical devices, health food and formula food for special medical purposes.

### Drug Recalls

According to the Measures on Drug Recall (《藥品召回管理辦法》) effective from November 1, 2022, a marketing authorization holder should establish and improve its recall system by collecting relevant information about drug safety and conducting investigation and evaluation with respect to the drugs with potential safety hazards. If there are any potential safety hazards that endanger human health and life safety in respect of any drugs sold in PRC, such manufacturer must start the drug recall procedures.

## REGULATIONS RELATING TO NATIONAL MEDICAL INSURANCE PROGRAM

According to the Circular on the Printing and Issuance of the Interim Measures for the Administration of the Scope of Medicines Used in Basic Medical Insurance for Urban Workers (《關於印發城鎮職工基本醫療保險用藥範圍管理暫行辦法的通知》), jointly issued by the Ministry of Labor and Social Security and the Ministry of Finance of the People's Republic of China (the "**MOF**") and other departments on May 12, 1999, the scope of medicines used in basic medical insurance is administered through the formulation of a Basic Medical Insurance Drug Catalogue.

Pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program (《國務院關於建立城鎮職工基本醫療保險制度的決定》) issued by the State Council on December 14, 1998, Opinions on the Establishment of the New Rural Cooperative Medical System (《關於建立新型農村合作醫療制度意見的通知》) issued by the three ministries of the State Council including the Ministry of Health on January 10, 2003, the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance (《國務院關於開展城鎮居民基本醫療保險試點的指導意見》) issued by the State Council on July 10, 2007, and the Opinions 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 on January 3, 2016, all employees and residents in rural and urban areas would be involved in the medical insurance program.

According to the Interim Measures for the Administration of the Use of Drugs Covered by Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) issued by the National Healthcare Security Administration on July 30, 2020 and effective from September 1, 2020, the scope of the use of drugs covered by basic medical insurance is administered through the formulation of the Basic Medical Insurance Drug Catalogue. The costs of medicines in line with the Basic Medical Insurance Drug Catalogue are paid by the basic medical insurance fund in accordance with national regulations. Drugs included in the national Basic Medical Insurance Drug Catalogue should be chemical drugs, biological products, proprietary Chinese medicines (ethnomedicines), and Chinese medicine decoction pieces prepared in accordance with national standards, which have been approved by the national drug regulatory authorities and have obtained drug registration certificates, and which meet the basic conditions of being clinically necessary, safe and effective, and reasonably priced. The State Council's administrative department for medical insurance has established a sound dynamic adjustment mechanism, and in principle adjusts the Basic Medical Insurance Drug Catalogue once a year. On the premise of meeting clinical needs, medical insurance designated medical institutions shall give priority to equipping and using drugs in the Basic Medical Insurance Drug Catalogue.

According to the Interim Measures for the Administration of the Use of Drugs Covered by Basic Medical Insurance, expenses incurred by insured persons for the use of medicines in the Basic Medical Insurance Drug Catalogue can be paid by the basic medical insurance fund if they meet the following conditions: (I) they are for the purpose of the diagnosis or treatment of diseases; (II) the diagnosis and treatment are in line with the condition of the disease, and are in line with the legal indications for the medicines as well as the limited scope of payment by the medical insurance; (III) they are provided by the designated medical institutions in compliance with the regulations, except for emergency and rescue medicines; (IV) the cost of medicines paid for by the pooled fund should be based on a doctor's prescription or hospitalization order; and (V) they are reviewed by pharmacists or licensed pharmacists in accordance with the stipulated procedures. Western medicines and proprietary Chinese medicines in the Basic Medical Insurance Drug Catalogue are divided into "Class A drugs" and "Class B drugs". The use of "Class A drugs" is paid for by the insured according to the payment standards and sharing methods stipulated by the basic medical insurance; the use of "Class B drugs" is paid for according to the payment standards stipulated by the basic medical insurance, with a certain percentage paid out of pocket by the insured first, and then paid for according to the sharing methods stipulated by the basic medical insurance. The proportion of out-of-pocket payments for "Class B drugs" is determined by the medical insurance administrative departments in provinces or regions subject to overall planning.

## REGULATIONS RELATING TO PRODUCT LIABILITY

In addition to the strict drug approval process, certain PRC laws have been promulgated to protect the rights of consumers and to strengthen the control of medical products in the PRC. Under current PRC law, manufacturers and vendors of defective products in the PRC may incur liability jointly for loss and injury caused by such products. According to the Civil Code of the PRC (《中華人民共和國民法典》), which was promulgated in May 2020 and became effective in January 2021, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury. If a patient suffers damage due to defects in drugs, he may seek compensation from the drug marketing authorization holder or also from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution, after it has made the compensation, shall have the right to recover the compensation from the liable drug marketing authorization holder.

## LAWS AND REGULATIONS RELATING TO ANTI-UNFAIR COMPETITION

Since the early 1990s, the legislative authorities at different levels in China have promulgated certain laws and regulations in respect of commercial bribery. According to the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》), or the Anti-Unfair Competition Law, which was most recently amended on June 27, 2025. Operators shall, in production and business activities, abide by the principles of voluntariness, equality, fairness and good faith, observe the laws and business ethics, and participate in market competition fairly. Operators in violation of the Anti-unfair Competition Law shall bear corresponding civil, administrative or criminal liabilities depending on the specific circumstances.

According to the Interim Provisions on the Prohibition of Commercial Bribery (《關於禁止商業賄賂行為的暫行規定》), which was promulgated by the State Administration for Industry and Commerce, which was replaced by the SAMR, on November 15, 1996, commercial bribery refers to an act of offering money or property or using other means by an operator to the other entity or individual for the purposes of selling or buying goods, among which "other means" refer to the means used to provide any types of benefits other than money or property, such as offering overseas or domestic travel.

Pursuant to the Regulations on the Establishment of Adverse Records with Respect to Commercial Briberies in the Medicine Purchase and Sales Industry (2013 revision) (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》) enforced on March 1, 2014 by the National Health and Family Planning Commission, 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 in the above-mentioned regulation.

## LAWS AND REGULATIONS RELATING TO FOREIGN INVESTMENT

### Foreign Investment

Investment activities in the PRC by foreign investors are principally governed by the Special Administrative Measures (Negative List) for Access of Foreign Investment (2024 version) (《外商投資准入特別管理措施(負面清單)(2024年版)》), or the Negative List, and the Catalogue of Industries for Encouraging Foreign Investment (2025 Version) (《鼓勵外商投資產業目錄(2025年版)》), or the Encouraging List. The Negative List, which came into effect on November 1, 2024, sets out special administrative measures in respect of the access of foreign investments in a centralized manner, and the Encouraging List which came into effect on February 1, 2026, sets out the encouraged industries for the 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 agencies promulgated the Rules on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (《關於外國投資者並購境內企業的規定》), 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, domestic enterprise, or a domestic individual, through an offshore 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.

### Foreign-Invested Enterprises

On December 29, 1993, the SCNPC issued the PRC Company Law (《中華人民共和國公司法》), or the Company Law, which was latest amended on December 29, 2023 and became effective on July 1, 2024. The Company Law regulates the establishment, operation and management of corporate entities in China and classifies companies into limited liability companies and limited companies by shares, including foreign-invested companies.

According to the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》), or the Foreign Investment Law, promulgated by the NPC on March 15, 2019 and came into effect as of January 1, 2020, the state shall implement the management systems of pre-establishment national treatment and negative list for foreign investment, and shall give national treatment to foreign investment beyond the negative list. Simultaneously, Sino-foreign Equity Joint Ventures Law of the PRC (《中華人民共和國中外合資經營企業法》), the Wholly Foreign-owned Enterprises Law of the PRC (《中華人民共和國外資企業法》) and Sino-foreign Cooperative Joint Ventures Law of the PRC (《中華人民共和國中外合作經營企業法》) have been repealed since January 1, 2020, and organization form and structure and operation of foreign-invested companies are all subject to the Company Law and other applicable laws.

According to the Foreign Investment Law, a foreign investment information report system is established in the PRC. On December 30, 2019, the MOFCOM and the SAMR issued the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which came into effect on January 1, 2020, for carrying out investment activities of the foreign investors directly or indirectly in PRC, the foreign investors or foreign-invested enterprises shall submit investment information to the commerce authorities pursuant to these measures.

## REGULATIONS RELATING TO OVERSEAS SECURITIES OFFERING AND LISTING

The CSRC promulgated 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》), or the Overseas Listing Trial Measures, and five relevant guidelines on February 17, 2023, which took effect on March 31, 2023. The Overseas Listing Trial Measures comprehensively reformed the regulatory regime for overseas offering and listing of PRC domestic companies' securities, either directly or indirectly, into a filing-based system.

According to the Overseas Listing Trial Measures, the PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfill the filing procedure with the CSRC and report relevant information. The Overseas Listing Trial Measures provides that an overseas listing or offering is explicitly prohibited, if any of the following applies: (i) such securities offering or listing is explicitly prohibited by provisions in PRC

laws, administrative regulations or relevant state rules; (ii) the proposed securities offering or listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with laws; (iii) the domestic company intending to be listed or offer securities in overseas markets, or its controlling shareholder(s) and the actual controller, have committed crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the latest three years; (iv) the domestic company intending to be listed or offer securities in overseas markets is currently under investigations for suspicion of criminal offenses or major violations of laws and regulations, and no conclusion has yet been made thereof; or (v) there are material ownership disputes over equity held by the domestic company's controlling shareholder(s) or by other shareholder(s) that are controlled by the controlling shareholder(s) and/or actual controller.

Where an issuer submits an application for initial public offering to competent overseas regulators, filing application with the CSRC shall be submitted within three business days thereafter.

On February 24, 2023, the CSRC and other relevant government authorities promulgated the Provisions on Strengthening the Confidentiality and Archives Administration of Overseas Securities Issuance and Listing by Domestic Enterprises (《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》), or the Provision on Confidentiality, which took effect on March 31, 2023. Pursuant to the Provision on Confidentiality, where a domestic enterprise provides or publicly discloses to the relevant securities companies, securities service institutions, overseas regulatory authorities and other entities and individuals, or provides or publicly discloses through its overseas listing subjects, documents and materials involving state secrets and working secrets of state organs, it shall report the same to the competent department with the examination and approval authority for approval in accordance with the law, and submit the same to the secrecy administration department of the same level for filing.

## LAWS AND REGULATIONS RELATING TO ENVIRONMENTAL PROTECTION AND FIRE PREVENTION

### Environmental Impact Appraisal

According to the Environmental Impact Appraisal Law of PRC (《中華人民共和國環境影響評價法》), which was promulgated by the SCNPC on October 28, 2002, amended on July 2, 2016 and December 29, 2018, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the seriousness of effect that may be exerted on the environment.

The Construction Environmental Protection Rule also requires that upon completion of construction for which an environment impact report or environment impact statement is formulated, the constructor shall conduct acceptance inspection of the environmental protection facilities pursuant to the standards and procedures stipulated by the environmental protection administrative authorities of the State Council, formulate the acceptance inspection report, and announce the acceptance inspection report pursuant to the law except for circumstances where there is a need to keep confidentiality pursuant to the provisions of the State.

### Urban Drainage and Sewage Treatment

Enterprises that engage in the activities of industry, construction, catering, and medical treatment, etc. that discharges sewage into urban drainage facilities shall apply to the relevant competent urban drainage department for collecting the permit for discharging urban sewage into drainage pipelines under relevant laws and regulations, including the Regulations on Urban Drainage and Sewage Disposal (《城鎮排水與污水處理條例》), which was promulgated on October 2, 2013 and came into force on January 1, 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 on January 22, 2015 and was amended on December 1, 2022 and became effective on February 1, 2023.

### Fire Prevention Design and Acceptance

The Fire Prevention Law of the PRC (《中華人民共和國消防法》), or the Fire Prevention Law, was adopted on April 29, 1998 and latest amended on April 29, 2021. According to the Fire Prevention Law, for special construction projects stipulated by the housing and urban-rural development authority of the State Council, the developer shall submit the fire safety design documents to the housing and urban-rural development authority for examination, while for construction projects other than those stipulated as special development projects, the developer shall, at the time of applying for the construction permit or approval for work commencement report, provide the fire safety design drawings and technical materials which satisfy the construction needs. According to Interim Regulations on Administration of Examination and Acceptance of Fire Control Design of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) issued by the Ministry of Housing and Urban-Rural Development of the PRC on April 1, 2020 and amended on August 21, 2023, an examination system for fire prevention design and acceptance only applies to special construction projects, and for other projects, a record-filing and spot check system would be applied.

## LAWS AND REGULATIONS RELATING TO EMPLOYMENT AND SOCIAL SECURITY

### Employment

The major PRC laws and regulations that govern employment relationships are the Labor Law of the PRC (《中華人民共和國勞動法》), or the Labor Law, issued by the SCNPC on July 5, 1994, effective on January 1, 1995 and revised on August 27, 2009 and December 29, 2018, the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), or the Labor Contract Law, which was promulgated by the SCNPC on June 29, 2007 and became effective on January 1, 2008, and then amended on December 28, 2012, and the Implementation Rules of the Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》), which was issued by the State Council on September 18, 2008 and came into effect on the same day. According to the aforementioned laws and regulations, labor relationships between employers and employees must be executed in written form.

### Social Security

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which issued by the SCNPC on October 28, 2010 and came into effect on July 1, 2011 and was newly revised on December 29, 2018, enterprises and institutions in the PRC shall provide their employees with welfare schemes covering basic pension insurance, unemployment insurance, maternity insurance, work-related injury insurance and basic medical insurance. The employer shall apply to the local social insurance agency for social insurance registration within 30 days from the date of its formation. And it shall, within 30 days from the date of employment, apply to the social insurance agency for social insurance registration for the employee.

### Housing Provident Fund

According to the Regulations Concerning the Administration of Housing Provident Fund (《住房公積金管理條例》), implemented since April 3, 1999 and amended on March 24, 2002 and March 24, 2019, any newly established entity shall make deposit registration at the housing accumulation fund management center within 30 days as of its establishment. After that, the entity shall open a housing accumulation fund account for its employees in an entrusted bank. Within 30 days as of the date an employee is recruited, the entity shall make deposit registration at the housing accumulation fund management center.

## LAWS AND REGULATIONS RELATING TO INTELLECTUAL PROPERTY

### Patents

According to the Patent Law of the PRC (《中華人民共和國專利法》), or the PRC Patent Law, promulgated by the SCNPC on March 12, 1984 and effected on April 1, 1985 and newly amended on October 17, 2020 and came into effect on June 1, 2021 and the Implementing Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), promulgated by the China

Patent Bureau on January 19, 1985 and last amended on December 11, 2023 by the State Council and came into effect on January 20, 2024, the term "invention-creations" refers to inventions, utility models and designs. 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. In addition, pursuant to the PRC Patent Law, 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 the duration of patent rights for the invention of a new drug approved to be put on the 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 marketing shall not exceed 14 years.

**Trademarks**

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) which was promulgated on August 23, 1982 and last amended on April 23, 2019 and came into effect on November 1, 2019, the Implementation Regulations of the Trademark Law of PRC (《中華人民共和國商標法實施條例》) which was issued on August 3, 2002 and amended on April 29, 2014, the Trademark Office under the State Administration for Industry and Commerce of the PRC, or the Trademark Office, shall handle trademark registrations and grant a term of ten years to registered trademarks, which may be renewed for an additional ten-year period upon request from the trademark owner. The Trademark Law of the PRC has adopted a "first-to-file" principle with respect to trademark registration. Where an application for a trademark for which application for registration has been made is identical or similar to another trademark that has already been registered or is under preliminary examination and approval for use on the same kind of or similar commodities or services, the application for registration of such trademark may be rejected.

**Domain Names**

In accordance with the Measures for the Administration of Internet Domain Names (《互聯網域名管理辦法》) which was issued by the Ministry of Industry and Information Technology on August 24, 2017 and came into effect on November 1, 2017, the Ministry of Industry and Information Technology is responsible for supervision and administration of domain name services in the PRC. Communication administrative bureaus at provincial levels shall conduct supervision and administration of the domain name services within their respective administrative jurisdictions. Domain name registration services shall, in principle, be subject to the principle of "first apply, first register".

**Copyright**

The SCNPC adopted PRC Copyright Law (《中華人民共和國著作權法》) in 1990 and most recently amended in 2020, with its implementing rules adopted in 1991 and most recently amended in 2013 by PRC State Council. In addition, there is a voluntary registration system administered by the China Copyright Protection Center. According to the aforementioned law and regulation, the term of protection for the right of publication of a work is fifty years. In order to further implement the Regulations for the Protection of Computer Software (《計算機軟件保護條例》) promulgated by the State Council on December 20, 2001 and last amended on January 30, 2013, the National Copyright Administration issued the Registration of Computer Software Copyright Procedures (《計算機軟件著作權登記辦法》) on February 20, 2002, and was revised on June 18, 2004, which applies to software copyright registration, license contract registration and transfer contract registration with respect to software copyright.

## LAWS AND REGULATIONS RELATING TO FOREIGN EXCHANGE AND OVERSEAS INVESTMENT AND DIVIDEND DISTRIBUTION

**Foreign Exchange and Overseas Investment**

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. 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.

On May 11, 2013, the SAFE issued the Administrative Provisions on Foreign Exchange in Domestic Direct Investment by Foreign Investors (《外國投資者境內直接投資外匯管理規定》), or the SAFE Circular 21, which became effective on May 13, 2013, amended on October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 21 specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC must be conducted by way of registration and banks must process foreign exchange business relating to the direct investment in the PRC based on the registration information provided by SAFE and its branches.

According to the Notice of 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》), or the SAFE Circular 19 promulgated on March 30, 2015, coming into effect on June 1, 2015, partially abolished on December 30, 2019 and amended on March 23, 2023, foreign-invested enterprises could settle their foreign exchange capital on a discretionary basis according to the actual needs of their business operations. Whilst, foreign-invested enterprises are prohibited to use the foreign exchange capital settled in RMB (a) for any expenditures beyond the business scope of the foreign- invested enterprises or forbidden by laws and regulations; (b) for direct or indirect securities investment; (c) to directly or indirectly provide entrusted loans (unless permitted in the business scope), repay loans between enterprises (including advances by third parties) or repay RMB bank loans that have been relent to a third party; and (d) to purchase real estates not for self-use purposes (save for real estate enterprises).

Pursuant to the Circular of 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》), or the Circular 37, which was promulgated by the SAFE and became effective on July 4, 2014, a PRC resident shall register with the local SAFE branch before he or she contributes assets or equity interests in an overseas special purpose vehicle, or 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. Pursuant to the Circular of the SAFE on Further Simplifying and Improving the Direct Investment Related Foreign Exchange Administration Policies (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》), or the Circular 13, which was promulgated on February 13, 2015, became effective on June 1, 2015 and was partially abolished on December 30, 2019, the above-mentioned registration will be handled directly by the bank that has obtained the financial institution identification codes issued by the foreign exchange regulatory authorities and has opened the capital account information system at the foreign exchange regulatory authorities in the place where it is located and the foreign exchange regulatory authorities shall perform indirect regulation over the direct investment-related foreign exchange registration via banks.

**Dividend Distribution**

The SAFE promulgated the Notice on Improving the Check of Authenticity and Compliance to Further Promote Foreign Exchange Control (《國家外匯管理局關於進一步推進外匯管理改革完善真實合規性審核的通知》) in January 2017, which stipulates several capital control measures with respect to outbound remittance of profits exceeding USD50,000 from domestic entities to offshore entities, including the following: (1) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (2) domestic entities shall hold income to account for previous years' losses before remitting the profits.

## LAWS AND REGULATIONS RELATING TO TAXATION

### Enterprise Income Tax

The Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得税法》), or the EIT Law, promulgated by the NPC on March 16, 2007, came into effect on January 1, 2008 and amended on February 24, 2017 and December 29, 2018, as well as the Implementation Rules of the EIT Law (《中華人民共和國企業所得税法實施條例》), or the EIT Implementation Rules, promulgated by the State Council on December 6, 2007, came into force on January 1, 2008 and last amended on December 6, 2024, are the principal law and regulation governing enterprise income tax in the PRC. According to the EIT Law and the EIT Implementation Rules, enterprises are classified into resident enterprises and non-resident enterprises. Resident enterprises refer to enterprises that are legally established in the PRC, or are established under foreign laws but whose actual management bodies are located in the PRC. And non-resident enterprises refer to enterprises that are legally established under foreign laws and have set up institutions or sites in the PRC but with no actual management body in the PRC, or enterprises that have not set up institutions or sites in the PRC but have derived incomes from the PRC. A uniform income tax rate of 25% applies to all resident enterprises and non-resident enterprises that have set up institutions or sites in the PRC to the extent that such incomes are derived from their set-up institutions or sites in the PRC, or such income are obtained outside the PRC but have an actual connection with the set-up institutions or sites. And non-resident enterprises that have not set up institutions or sites in the PRC or have set up institutions or sites but the incomes obtained by the said enterprises have no actual connection with the set-up institutions or sites, shall pay enterprise income tax at the rate of 10% in relation to their income sources from the PRC.

### Withholding Tax

Pursuant to the EIT Law and the EIT Implementation Rules, if a non-resident enterprise has not set up an organization or establishment in the PRC, or has set up an organization or establishment but the income derived has no actual connection with such organization or establishment, it will be subject to a withholding tax on its PRC-sourced income at a rate of 10%. According to the Arrangement between Chinese Mainland and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Tax Evasion on Income (《內地和香港特別行政區關於對所得避免雙重徵税和防止偷漏税的安排》) effective from December 8, 2006, dividends repatriated from a PRC entity to its Hong Kong shareholder owning more than 25% of capital would be entitled to a reduced withholding tax rate of 5% subject to certain conditions.

The State Taxation Administration, or the SAT, issued the Administrative Measures on Entitlement of Non-residents to Treatment under Treaties (《非居民納税人享受協定待遇管理辦法》) on October 14, 2019 and effective on January 1, 2020, which applies to non-resident taxpayers who have tax liability in China and need to claim treaty benefits. Non-resident taxpayers enjoying their tax treaty benefits shall adopt the method of "self-assessment, claims by declaration and retention of the relevant materials for future inspection".

### Value-Added Tax (VAT)

According to Article 10 of the Value-Added Tax Law of the PRC (《中華人民共和國增值税法》), promulgated on December 25, 2024 and effective from January 1, 2026, the VAT rates applicable to taxable sales or imports of goods are 13% and 9%.