OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

This section summarizes the principal PRC laws, rules and regulations that are relevant to our business:

Regulatory Authorities

The regulatory authorities of the drug industry in the PRC include: the National Medical Products Administration (國家藥品監督管理局) (the "NMPA"), the National Health Commission (國家衛生健康委員會) (the "NHC") and the National Healthcare Security Administration (國家醫療保障局) (the "NHSA").

The NMPA is an authority under the State Administration for Market Regulation (國家市場監督管理總局) (the "SAMR") and is the primary regulator for medical products. It is primarily responsible for supervising and managing drugs, medical devices and cosmetics, including drafting relevant regulations and policies; undertaking standard management, registration regulation, quality management and post-market risk management for drugs, medical devices and cosmetics; and organizing and guiding the supervision and inspection of drugs, medical devices and cosmetics; undertaking management of qualifications for licensed pharmacists.

The NHC is the primary national regulator for public health. It is primarily responsible for drafting national health policies, supervising and regulating public health, healthcare services, and health emergency systems, coordinating the reform of medical and health system, organizing the formulation of national drug policies and national essential medicine system, launching an early warning mechanism for the monitoring of the use and clinical comprehensive evaluation of medicine as well as the drug shortage, giving suggestions on the pricing policy of national essential medicine, and regulating the operation of medical institutions and practicing of medical personnel.

The NHSA is an authority directly under the State Council of the PRC (中華人民共和國國務院) (the "State Council") responsible for the management of the healthcare security system. It is primarily responsible for drafting and implementing policies and standards on medical insurance, maternity insurance and medical assistance; supervising and administering the healthcare security funds; organizing the formulation of a uniform medical insurance catalogue and payment standards on drugs, medical disposables and healthcare services; and formulating and supervising the implementation of the bidding and tendering policies for drugs and medical disposables.

Laws and Regulations in Relation to New Drugs

Application for New Drug Registration

Drug registration refers to an approval process where the NMPA conducts review of the safety, efficacy and quality controllability of the drugs intended for marketing according to the application for drug registration made by an applicant, and decides whether to approve the application. Pursuant to the provisions of the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), promulgated by the SAMR on January 22, 2020 and came into effect on July 1, 2020, the Measures for the Administration of Drug Registration (2020) shall apply to the development, registration, supervision and management activities carried out in the territory of the PRC for marketing of drugs. In accordance with the Measures for the Administration of Drug Registration (2020), drugs registration refers to activities that a drug registration applicant files an application and other supplementary applications for drug clinical trial, approval for drug marketing, and reregistration, among others, under the legal procedures and according to the relevant requirements, and that the medical products administrative department examines the safety, effectiveness, and quality controllability based on the laws and regulations, and the existing scientific cognitions, to decide whether to agree with the activities applied for. A drug registration certificate shall be valid for five years. During the validity period, a holder of a drug registration certificate shall continue to ensure the safety, effectiveness and quality controllability of the marketed drug, and apply for re-registration of the drug six months prior to the expiry of the validity period.

Non-clinical Research

The non-clinical safety assessment of drugs for marketing approval shall be conducted in accordance with the Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) promulgated by the State Food and Drug Administration (the "SFDA") in

August 2003 and latest amended by the China Food and Drug Administration (the "CFDA") in July 2017 and came into effect on September 1, 2017. The SFDA promulgated the Administrative Measures for the Certification of Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》) in April 2007, which specifies the requirements for institutions applying for Good Laboratory Practices (GLP) certification of non-clinical laboratory studies. On January 19, 2023, the NMPA amended the Administrative Measures for the Certification of Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》), which came into effect on July 1, 2023.

Application for Clinical Trial

After completing the pre-clinical studies, the applicant must obtain approval for clinical trials of drugs from the NMPA before the conduction of new drug clinical trial. According to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA on March 17, 2017 and came into effect on May 1, 2017, the decision on the approval of clinical trials of drugs enacted by the CFDA can be made by the Center for Drug Evaluation of the NMPA (國家藥品審評中心) (the "CDE") from May 1, 2017. Pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the "Drug Administration Law"), the dossier on a new drug research and development, including the manufacturing method, quality specifications, results of pharmacological and toxicological tests and the relevant data, files and samples, shall, in accordance with the regulations of the drug regulatory authority under the State Council be truthfully submitted to the said department for approval before drug clinical trial is conducted.

The drug regulatory authority under the State Council shall decide whether to approve the clinical trial application and notify the decision to the clinical trial applicant within sixty (60) business days from the date of accepting the clinical trial application. If the drug regulatory authority under the State Council fails to do so, the clinical trial application shall be deemed as approval, and if the bioequivalence test is conducted, it is required to report it to the drug regulatory authority under State Council for filing. According to the Announcement of the NMPA on Matters Concerning Optimizing the Review and Approval of Clinical Trials for Innovative Drugs (《國家藥監局關於優化創新藥臨床試驗審評審批有關事項的公告》), which came into effect in September 2025, to further support innovative drug R&D oriented by clinical value and to improve the quality and efficiency of clinical R&D, clinical trial applications for innovative drugs that meet the requirements shall complete review and approval within thirty (30) working days upon acceptance. However, for complex cases, the CDE may notify the applicant to extend the review period to 60 days.

Before conducting the clinical trial, the applicant shall file a series of detailed documents with the NMPA. According to the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), which came into effect in September 2013, and the Standard for the Management of Drug Clinical Trial Registration and Information Disclosure (Trial) (《藥物臨床試驗登記與信息公示管理規範(試行)》), which came into effect in July 2020, all clinical trials approved by the CFDA and conducted in the PRC shall complete the clinical trial registration and information disclosure on the Drug Clinical Trial Information Platform. The applicant must complete the initial registration of the trial within one month after obtaining the approval of the clinical trial to obtain the unique registration number of the trial; and complete the subsequent data registration before the first patient is enrolled and submit it for the first time for disclosure.

After obtaining clinical trial approval, the applicant shall choose institutions qualified for clinical trials of the drug to conduct clinical trials. Pursuant to the Administrative Regulations for Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which came into effect in December 2019, if engaging in drug development activities and conducting clinical trials of drugs (including bioequivalence test conducted after filing) approved by the NMPA within the territory of the PRC, they shall be conducted in the Drug Clinical Trial Institutions. Drug clinical trial institutions shall be subject to filing administration. Institutions that only engage in analysis of biological samples related to drug clinical trials shall not be subject to filing. The national drug regulatory authority is responsible for setting up a filing management information platform for drug clinical trial institutions for registration, filing and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information on supervision and inspection of the drug regulatory authority and competent healthcare authority.

Conduct of Clinical Trial

In compliance with the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), clinical trials are divided into Phase 1, Phase 2, Phase 3, Phase 4 and bioequivalence trial:

A drug clinical trial to be carried out shall be examined and approved by the ethics committee. Clinical trials shall be conducted for the application of new drug registration and shall be implemented in accordance with the GCP, promulgated by the NMPA and NHC and came into effect on July 1, 2020. The Good Clinical Practice for Drug Trials stipulates the criteria for the entire procedure of the clinical trial with reference to the internationally recognized principles.

According to the Announcement of the National Medical Products Administration on Adjusting the Review and Approval Procedures for Drug Clinical Trials (《國家藥品監督管理局關於調整藥物臨床試驗審評審批程序的公告》), if a new drug clinical trial has been approved to be carried out, after the completion of Phase 1 and Phase 2 clinical trials and before the implementation of Phase 3 clinical trials, the applicant shall submit an application for a communication meeting to the CDE to discuss with the CDE on key technical issues including the design of the phase 3 clinical trial. The applicant can also apply for communication on key technical issues at different stages of clinical research and development.

According to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), applicants may communicate with CDE on major issues at critical stages such as prior to application for clinical trial of a drug, during the process of clinical trial of a drug, and prior to application for marketing authorization of a drug. According to the Measures for the Administration of Communication and Exchange in Drug Development and Technology Review (《藥物研發與技術審評溝通交流管理辦法》) promulgated by the CDE on December 10, 2020, an applicant may propose to convene a communication meeting with the CDE during the process of drug research and development and registration application.

New Drug Application

Pursuant to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), after completing the pharmaceutical research, pharmacological and toxicological studies, clinical trial, and other studies supporting the marketing registration of a drug, determining the quality standards, completing the verification of commercial large-scale production process, and making sound preparation for the acceptance of drug registration inspection and examination, an applicant shall file an application for drug marketing authorization, and submit relevant research materials in accordance with the requirements of the application materials. After the formal examination of the application materials, an application that satisfies the requirements shall be accepted. Where a generic drug, in vitro diagnostic reagent managed as a drug, or any other eligible circumstance assessed by an applicant to be unnecessary or impossible for conducting drug clinical trial and meeting the conditions for exempting drug clinical trial, the applicant may directly file an application for drug marketing authorization. The technical guiding principles and relevant specific requirements for exempting drug clinical trial shall be developed and announced by the CDE.

The CDE shall organize pharmaceutical, medical and other technical personnel to evaluate the accepted applications for drug marketing authorization as required. Where the comprehensive evaluation conclusion is adopted, the drug shall be approved for marketing, and a drug registration certificate shall be issued. If the comprehensive evaluation conclusion is not adopted, a disapproval decision shall be made. A drug registration certificate shall specify the drug approval number, holder, manufacturer and other information.

Drug registration inspection means the inspection activities carried out for the development sites and production sites for verifying the authenticity and consistency of the application materials and the commercial production conditions for marketing of drugs, and examining the compliance of drug development, and data reliability, among others, and the extended examination activities carried out for manufacturers, suppliers, or other entrusted institutions of chemical active pharmaceutical ingredients (the "APIs"), auxiliary materials, and packaging materials and containers in direct contact with drugs involved in the application for drug registration, if necessary.

The CDE shall decide whether to carry out on-site inspection of drug registration development based on risks, according to the degree of drug innovation and the previous acceptance of inspection by drug research institutions.

The CDE shall decide whether to launch production site inspection for drug registration based on risks according to factors such as variety, process, facility, and previous acceptance of inspection for which an application is filed for registration. For innovative drugs, new modified drugs and biological products, production site inspection for drug registration and pre-marketing examination for management standards for drug production quality shall be conducted. For generic drugs, production site inspection for drug registration and pre-marketing examination for management standards for drug production quality shall be conducted based on the risks, according to whether a drug production license for the corresponding production scope has been obtained and whether a variety of the same dosage form has been marketed.

After an application for drug registration is accepted, the CDE shall conduct preliminary review within forty (40) business days of acceptance, notify the Center for Food and Drug Inspection of NMPA (the "Center for Inspection") of organizing inspection and provide the relevant materials required for inspection, where production site inspection for drug registration is required, and concurrently notify the applicant and the medical products administrative department of the province, autonomous region, or municipality in the place where the applicant or production enterprise is located. In principle, the Center for Inspection shall complete the inspection work forty (40) business days prior to the expiry of the time limit for inspection, and report the inspection information, inspection results and other relevant materials to the CDE.

Drug registration examination shall include standard review and sample examination. The review period for an application for drug marketing authorization shall be 200 business days. Within this two hundred (200) business days period, the review period for the procedures for prioritized review and approval shall be one hundred and thirty (130) business days, and the review period for the procedures for prioritized review and approval for clinically and urgently needed overseas-marketed drug for a rare disease shall be seventy (70) business days.

Reform of Evaluation and Approval System for Drugs

In August 2015, the State Council promulgated the Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment (《關於改革藥品醫療器械審評審批制度的意見》) (the "Reform Opinions"), which provides a framework for reforming the evaluation and approval system for drugs and indicates enhancing the standard of approval for drug registration and accelerating the evaluation and approval process for innovative drugs.

In November 2015, the CFDA promulgated the Announcement on Certain Policies for Drug Registration, Evaluation and Approval (《關於藥品註冊審評審批若干政策的公告》) (the "Certain Policies Announcement"), which further clarifies the measures and policies on simplifying and accelerating the approval process on the basis of the Reform Opinions.

Pursuant to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA in March 2017 and came into effect in May 2017, the following administrative approval decisions on drugs can be directly made by the CDE in the name of the CFDA: the clinical trial approval decisions on drugs (including domestic and imported); decisions on approval of drug supplementary applications (including domestic and imported); decisions on approval of re-registration of imported drugs.

The Evaluation and Approval Procedures for Breakthrough Therapeutic Drugs (Trial) (《突破性治療藥物審評工作程序(試行)》), the Evaluation and Approval Procedures for Conditionally Approved Drugs (Trial) (《藥品附條件批准上市申請審評審批工作程序(試行)》) and The Preferential Evaluation and Approval Procedures for Drug Marketing Authorization (Trial) (《藥品上市許可優先審評審批工作程序(試行)》) promulgated by the NMPA in July 2020 and came into effect in July 2020, replace the Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation (《關於鼓勵藥品創新實行優先審評審批的意見》) promulgated by the CFDA in December 2017 and came into effect in December 2017, which further clarified the Accelerating Registration Procedures for Drugs.

Administrative Protection and Monitoring Periods for New Drugs

According to the Implementing Rules for PRC Drug Administration Law (《中華人民共和國藥品管理法實施條例》) issued on December 6, 2024 and came into effect from January 20, 2025 and the Reform Plan for Registration Category of Chemical Drugs (《化學藥品註冊分類改革工作方案》) issued on March 4, 2016 and came into effect from the same day, the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of five years for new Category 1 drugs approved to be manufactured, commencing from the date of approval, to continually monitor the safety of those new drugs.

Regulations on International Multi-Center Clinical Trials and Acceptance of Overseas Clinical Trial Data

According to the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial) (《關於發佈國際多中心藥物臨床試驗指南(試行)的通告》), ("the Multi-Center Clinical Trial Guidelines"), promulgated by the NMPA on January 30, 2015 and came into effect on March 1, 2015, 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 multi-center clinical trials in the PRC, the applicants shall comply with relevant laws and regulations, such as the PRC Drug Administration Law, the Implementing Regulations of the PRC Drug Administration Law and the Administrative Measures for Drug Registration, execute the Good Clinical Practice, make reference to universal international principles such as the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (the "ICH"), and comply with the laws and regulations of the countries involved in the international multi-center clinical trials. 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 and other related laws and regulations.

According to the Opinions on Deepening the Reform of the Evaluation and Approval System and Inspiring Innovation of Drugs and Medical Devices, clinical trial data obtained in an international multi-center that conforms to China's requirements for registration of drugs and medical devices can be used for the application for registration in China.

Marketing Authorization Holder System

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

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

National Reimbursement Drug List of China (the "NRDL")

Participants in the National Health Insurance Scheme and their employers (if any) have to pay a monthly premium. Participants may be reimbursed for all or part of the cost of medicines included in the medical insurance catalogue. The Notice on Provisional Measures for the Administration of

the Scope of Medicines in the Basic Medical Insurance for Urban Workers (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》) (or the Medical Insurance Notice), jointly issued by the Ministry of Labor and Social Security of the PRC and the National Development and Reform Commission (the "NDRC") and other governmental organizations on May 12, 1999, stipulates that the medicines included in the medical insurance catalogue must be clinically necessary, safe and effective, reasonably priced, convenient to use and the supply of which can be guaranteed by the market.

The NRDL for Basic Medical Insurance, Maternity Insurance and Work Injury Insurance (《國家基本醫療保險、生育保險和工傷保險藥品目錄》) sets out the standards for payment of medicines by the basic medical insurance, work injury insurance and maternity insurance funds. The NHSA of the PRC and other governmental organizations have the authority to determine the drugs to be included in the NRDL. On December 5, 2025, the NHSA and the Ministry of Human Resources and Social Security of the PRC released the latest NRDL (implemented on January 1, 2026), which has been expanded to cover a total of 3,253 drugs. Inclusion in the NRDL will generally result in increased sales volume and lower drug prices (which are determined on a case-by-case basis and negotiated based on factors such as the initial drug price).

On July 30, 2020, the NHSA issued the Provisional Measures for the Administration of Medicines for Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) ("Measures for the Administration of the NRDL"), which came into effect on September 1, 2020. The Measures for the Administration of the NRDL provides guidance on the inclusion and adjustment of the NRDL and the payment, management and supervision of basic medical insurance. According to the Measures for the Administration of the NRDL, a dynamic adjustment mechanism shall be established for the NRDL, which shall be adjusted annually in principle.

National Essential Drug List of China (the "NEDL")

On August 18, 2009, the MOH and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the NEDL (《國家基本藥物目錄管理辦法(暫行)》), which was revised on February 13, 2015 by the Notice on Issuing the Measures on the Administration of the NEDL (《關於印發國家基本藥物目錄管理辦法的通知》), and the Guidelines on the Implementation of the NEDL System (《關於建立國家基本藥物制度的實施意見》), which aims to promote essential medicines sold to consumers at fair prices in the PRC and ensure that the general public in the PRC has equal access to the drugs contained in the NEDL. On September 13, 2018, the General Office of the State Council issued the Opinions of the General Office of the State Council on Improving the National Essential Drug System (《國務院辦公廳關於完善國家基本藥物制度的意見》). The NHC and the National Administration of Traditional Chinese Medicine promulgated the NEDL (2018 version) (《國家基本藥物目錄(2018年版)》) on September 30, 2018. According to these regulations, basic healthcare institutions funded by the government, which primarily include county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed in the NEDL. The drugs listed in NEDL shall be purchased by centralized tender process and shall be subject to the price control by the NDRC. Remedial drugs in the NEDL are all listed in the Medical Insurance Catalog and the entire amount of the purchase price of such drugs is entitled to reimbursement.

Gathering, Collection and Filing of Human Genetic Resources

Pursuant to the Regulations on the Management of Human Genetic Resources of the People's Republic of China (《中華人民共和國人類遺傳資源管理條例》) (the "HGR Regulations") promulgated by the State Council in May 2019, newly amended in March 2024 and came into effect on May 1, 2024, the state supports the rational use of human genetic resources for scientific research, development of the biomedical industry, improvement of diagnosis and treatment technology, improvement of China's ability to guarantee biosafety and improvement of the level of people's health. Foreign organizations, individuals and institutions established or actually controlled by them shall not gather or preserve Chinese genetic resources within the territory of the PRC, or provide Chinese genetic resources to foreign countries. In addition, the gathering, preservation, utilization and external provision of Chinese genetic resources shall (i) conform to ethical principles and conduct ethical review in accordance with relevant regulations; (ii) respect the privacy of the human genetic resource providers, obtain their prior consents, and protect their lawful rights and interests; (iii) comply with technical specification promulgated by the healthcare department of the State Council.

On October 17, 2020, SCNPC promulgated Biosecurity Law of the PRC (《中華人民共和國生物安全法》), and latest amended and came into effect on April 26, 2024. As per the Biosecurity Law, the research and development activities of high-risk and medium-risk biotechnology shall be carried out by a legal person organization established within the territory of China, upon obtaining the approval or record-filing. The establishment of a pathogenic microorganism laboratory shall be subject to approval or record-filing requirements in accordance with the law.

The Ministry of Science and Technology promulgated the Implementation Rules for the Administrative Regulation on Human Genetic Resources (《人類遺傳資源管理條例實施細則》) (the "Implementation Rules") on May 26, 2023 and came into effect on July 1, 2023. The Implementation Rules have further provided detailed implementation regulations for the administration of human genetic resources of the PRC, including but not limited to listing the situations where security review may be required, which shall include: (i) human genetic resource information of important genetic families; (ii) human genetic resources information of specific regions, (iii) exome sequencing and genome sequencing information resources with a population greater than 500 cases; and (iv) other situation that may affect the public health, national security and social public interest of the PRC.

Good Clinical Practice Certification and Compliance with the Good Clinical Practice (GCP)

To improve the quality of clinical trials, the NMPA and NHC promulgated the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) (the "GCP") in April 2020 and came into effect on July 1, 2020, which aims to ensure that the clinical trials of drugs are standardized and the results are scientific and reliable, protecting the rights and safety of human subjects.

Laws and Regulations in Relation to Drug Manufacturer

Drug Manufacturing Permit

Pursuant to the Drug Administration Law promulgated by the SCNPC in September 1984 and lastly amended in August 2019 and came into effect in December 2019, the state adopts an industry entry permit system for drug manufacturers. The conduct of drug manufacturing activities shall be approved and granted with a Drug Manufacturing License (《藥品生產許可證》) by the drug regulatory authority of the people's government at provincial, autonomous regional or municipal level. The Drug Manufacturing License shall indicate the validity period and the scope of production, and shall be reviewed for renewing upon expiration.

Good Manufacturing Practices

Pursuant to the Announcement on the Relevant Issues Concerning the Implementation of the Drug Administration Law of the PRC (《關於貫徹實施<中華人民共和國藥品管理法>有關事項的公告》), promulgated by the NMPA on November 29, 2019, and the Drug Administration Law, the GMP and Good Supply Practice (GSP) certifications have been cancelled, applications for GMP and GSP certifications are no longer accepted, and GMP and GSP certificates are no longer issued. When engaging in drug manufacturing activities, a manufacturer shall comply with the GMP and establish a sound GMP management system, to ensure that the entire process of drug manufacturing maintain to meet the statutory requirements, and meet the GMP requirements enacted by the drug regulatory authority under the State Council in accordance with the law. The legal representative of and principal person in charge of a drug manufacturer are fully responsible for the drug manufacturing activities of the enterprise.

The Good Manufacturing Practices (《藥品生產質量管理規範》), promulgated by the Ministry of Health of the PRC (the "MOH", now known as the NHC) in March 1988, newly amended in January 2011 and came into effect on March 1, 2011, provided guidance for the quality management, organization and staffing, production premises and facilities, equipment, material and products, recognition and inspection, documentation maintenance, manufacture management, quality control and quality assurance, contractual manufacture and contractual inspection for the products, product delivery and recalls of a manufacturer in a systematical manner.

Pursuant to the Drug Administration Law, the state implements a supervision system for drug manufacturers to ensure the quality and safety of drugs throughout the production process. The Measures for the Supervision and Administration of Drug Production (《藥品生產監督管理辦法》), promulgated by the SAMR in March 2020 and effective as of July 1, 2020, serve as the key

implementing regulations governing the supervision of drug production activities. These Measures set forth comprehensive requirements regarding the issuance and management of the Drug Manufacturing License, supervision and inspection of production processes, management of quality assurance systems in compliance with GMP, handling of changes in production, and regulatory responsibilities for entrusted production activities. The Measures emphasize a risk-based and full-lifecycle supervision approach, reinforcing the primary responsibility of marketing authorization holders and manufacturers for drug quality.

Laws and Regulations on Drug Supply

According to the Drug Administration Law, the operation of drug business, including drug wholesale and drug retail, is prohibited without a Drug Supply Permit. A Drug Supply Permit shall state the validity period and the scope of business and be subject to review and reissuance upon expiry of the validity period.

According to the Measures for the Supervision and Administration of Drug Supply and Usage (《藥品經營和使用質量監督管理辦法》) came into effect on January 1, 2024, a Drug Supply Permit is valid for five years. Each holder of the Drug Supply Permit must apply for an extension of its permit six months to two months prior to expiration.

The Good Supply Practice for Pharmaceutical Products (《藥品經營質量管理規範》) (the "GSP Rules") was last amended and came into effect on July 13, 2016. The GSP Rules set forth the basic standards in management of drug supply and apply to enterprises engaged in drug supply in the PRC, which require drug suppliers to implement strict controls on its supply of pharmaceutical products, including standards regarding staff qualifications, premises, warehouses, inspection equipment and facilities, management and quality control. Under the Drug Administration Law, the GSP certification is no longer required for drug suppliers, but drug suppliers are still required to comply with the GSP Rules.

Other Laws and Regulations in Relation to Medical Industry

Basic Medical Insurance Policy

Pursuant to the Decision on the Establishment of the Urban Employee Basic Medical Insurance Programme (《關於建立城鎮職工基本醫療保險制度的決定》) promulgated by the State Council on December 14, 1998 and the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》) promulgated by the NDRC, the SDA and other authorities, came into effect on May 12, 1999, all employers in cities and towns, including enterprises (state-owned enterprises, collective enterprises, foreign-invested enterprises, private enterprises, etc.), institutions, public institutions, social organizations, private non-enterprise units and their employees are required to participate in basic medical insurance. Pursuant to the Guiding Opinions on the Pilot of Basic Medical Insurance for Urban Residents (《關於開展城鎮居民基本醫療保險試點的指導意見》) promulgated by the State Council on July 10, 2007, urban residents (not urban employees) in the pilot areas can voluntarily participate in the basic medical insurance for urban residents. Pursuant to the Opinions of the State Council on the Integration of the Basic Medical Insurance System 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 by the State Council on January 3, 2016, a unified basic medical insurance system for urban and rural residents was established, including the existing urban residents' medical insurance and all the insured personnel of New Rural Cooperative Medical System, covering all urban and rural residents except those who should be covered by the employee's basic medical insurance.

Medical Insurance Catalogue

Pursuant to the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》), the scope of medical insurance coverage for pharmaceutical products needs to be managed through the formulation of the Medical Insurance Catalogue. After several adjustments, the currently effective one is the NRDL for Basic Medical Insurance, Maternity Insurance and Work Injury Insurance (2025) (《國家基本醫療保險、生育保險和工傷保險藥品目錄》(2025年)) (implemented on January 1, 2026).

Drug Price

Pursuant to the Drug Administration Law, for drug products with market-regulated prices in accordance with the law, the drug marketing authorization holder, the drug manufacturer, the drug distributor and medical institution shall determine the price pursuant to the principles of fairness, reasonableness, integrity and trustworthiness as well as quality for value in order to supply drug users with reasonably priced drug products; and shall comply with the requirements relating to drug price administration promulgated by the State Council's pricing authorities, determine and clearly mark the retail prices of drug products. Pursuant to the Notice on Issuing Opinions on Promoting Drug Price Reform (《關於印發<推進藥品價格改革意見>的通知》) jointly promulgated by NDRC, NHC, the Ministry of Human Resources and Social Security, Ministry of Industry and Information Technology, the Ministry of Finance, the MOFCOM and the CFDA on May 4, 2015 and came into effect on June 1, 2015.

Drug Purchases by Hospitals

According to the Guiding Opinions concerning the Urban Medical and Health System Reform (《關於城鎮醫藥衛生體制改革的指導意見》) promulgated and came into effect on February 16, 2000, and the Opinions on the Implementation of Classification Management of Urban Medical Institutions (《關於城鎮醫療機構分類管理的實施意見》) promulgated on July 18, 2000 and came into effect on September 1, 2000, a medical institution must be defined as a for-profit or not-for-profit institution at the time of its establishment. A not-for-profit medical institution refers to a medical institution established for the purpose of public interest services, which maintains and develops the institution with its income, while a for-profit medical institution is established by investors for the purpose of investment return. The PRC government has not established any for-profit medical institutions, while non-government entities may establish for-profit medical institutions. Under PRC law, any not-for-profit medical institution must use a centralized tender system to purchase any pharmaceutical products, while any for-profit medical institution is not required to use such system.

According to the Notice on the Trial Implementation of the Centralized Tender with Respect to Drug Purchases by Medical Institutions (《關於印發醫療機構藥品集中招標採購試點工作若干規定的通知》) promulgated and came into effect on July 7, 2000, the Notice on the Further Standardizing of the Centralized Tender with respect to Drug Purchases By Medical Institutions (《關於進一步做好醫療機構藥品集中招標採購工作的通知》) promulgated and came into effect on August 8, 2001 and the Opinions concerning Further Regulating Drug Purchases by Medical Institutions through Centralized Tendering (《關於進一步規範醫療機構藥品集中採購工作的意見》) promulgated and came into effect on January 17, 2009, any not-for-profit medical institutions established and/or controlled by any government at the county level or above must use a centralized tender system for the procurement of drugs which are listed in the Catalog of Drugs for National Basic Medical Insurance (《國家基本醫療保險藥品目錄》) and are generally for clinical use and bulk purchase.

The Good Practice of Medical Institutions with respect to Centralized Procurement of Drugs (《醫療機構藥品集中採購工作規範》) promulgated and came into effect on July 7, 2010, provides detailed provisions on the catalog and procurement methods of centralized procurement of drugs, the procedures of centralized procurement of drugs, the evaluation methods of centralized procurement of drugs, and the construction and management of the expert pools, further regulates the centralized procurement of drugs and clarifies the code of conduct of the parties involved in centralized procurement of drugs. According to the Good Practice of Medical Institutions with respect to Centralized Procurement of Drugs (《醫療機構藥品集中採購工作規範》), not-for-profit medical institutions established by the government at the county level or above or state-owned enterprises (including state-controlled enterprises) must participate in the centralized procurement of drugs for medical institutions. The centralized procurement management authority at provincial (district or municipal) level is responsible for compiling the catalog of drugs for centralized procurement by medical institutions within its own administrative region, and narcotic drugs and Class I psychoactive drugs under special management by the State are not included in such catalog for centralized procurement; Class II psychoactive drugs, radioactive pharmaceuticals, toxicity drugs for medical use, crude drugs, traditional Chinese medicinal materials and traditional Chinese medicine decoction pieces may be excluded from such catalog for centralized procurement.

According to the Guidance Opinion of the General Office of the State Council on the Improvement of the Drug Centralized Procurement Work of Public Hospitals (《國務院辦公廳關於完善公立醫院藥品集中採購工作的指導意見》) promulgated and came into effect on February 9, 2015, the centralized procurement work of public hospitals will be improved through the purchase of drugs by classification. All drugs used by public hospitals (with the exception of traditional Chinese medicine decoction pieces) should be procured through a provincial centralized pharmaceutical procurement platform. The provincial drug procurement agency should work out a summary of the procurement plans and budget submitted by hospitals and compile reasonably a drug procurement catalog of the hospitals within its own administration region, listing by classification the drugs to be procured through bids, negotiations, direct purchases by hospitals or to be manufactured by appointed pharmaceutical manufacturers.

Drug Distribution and 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)》) which was issued on December 26,2016, the Two-Invoice System is a system under which invoices are issued by drug manufacturers to drug distributors on a one-off basis while invoices are issued by drug distributors to medical institutions on a one-off basis. Wholly-owned or holding commerce companies (there shall be only one commerce company throughout the country) and domestic general agents of overseas drugs (there shall be only one domestic general agent throughout the country) that are established by drug manufacturers or group enterprises integrating scientific research, manufacture, and trade to sell the drugs of these enterprises (groups) may be regarded as manufacturers. Within an enterprise that is a drug circulation group, the allocation of drugs between the group and wholly-owned (holding) subsidiaries or between wholly-owned (holding) subsidiaries should not be regarded as invoicing, but invoicing is allowed once at most.

According to 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》), which was issued on January 24, 2017, on a priority basis, the Two-Invoice System would be promoted in pilot provinces (autonomous regions and municipalities directly under the Central Government) and pilot cities for public hospital reform, with the goal of having it implemented nationwide by 2018. Pharmaceutical companies must comply with the Two-Invoice System in order to engage in procurement processes with public hospitals.

Administration of Pathogenic Microorganism Laboratories

According to the Regulations on the Bio-safety Management of Pathogenic Microbe Laboratories (《病原微生物實驗室生物安全管理條例》) promulgated by State Council and latest amended in December 2024, the pathogenic microorganism laboratories are classified into Level 1, Level 2, Level 3 and Level 4 in accordance with its biosafety level for pathogenic microorganisms and the national standards for the bio-safety. Laboratories at Bio-safety Level 1 and Level 2 may only conduct experimental activities relating to any highly pathogenic microbes that are explicitly permitted for such laboratories under the official Catalogue of Pathogenic Microorganisms. Laboratories at Bio-safety Level 3 and Level 4 shall meet certain requirements to conduct experimental activities relating to any highly pathogenic microbes. Newly building, rebuilding or expanding of Bio-safety Level 1 or Level 2 laboratories shall file with the relevant health administrative department or veterinary administrative department in the municipal people's government of the place where it is built. The laboratories of Bio-safety Level 3 and Level 4 shall be subject to the state accreditation for laboratories. Laboratories passing accreditation will be granted with certificates for Bio-safety Laboratories at corresponding level. The certificate will be effective for five years.

Laws and Regulations in Relation to Intellectual Property

Patent

Patents in the PRC are mainly protected by the Patent Law of the PRC (《中華人民共和國專利法》) (the "Patent Law"), which was promulgated by the SCNPC on March 12, 1984 and latest amended on October 17, 2020 and came into effect on June 1, 2021, and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》) (the "Implementation Rules"), promulgated by the State Council on June 15, 2001 and latest amended on December 11, 2023 and came into effect on January 20, 2024. The Patent Law and the Implementation Rules provide for three types of patents, namely "invention," "utility model" and "design." The duration of a patent right for "invention" is twenty (20) years; the duration of a patent right for "utility model" is ten (10) years; and the duration of a patent right for "design" is fifteen (15) years, all of which duration are from the date of application. According to the Patent Law, for the purpose of public health, the patent administrative department of the State Council may grant mandatory licensing for patented drugs manufactured and exported to countries or regions which comply with the provisions of the relevant international treaty participated by the PRC.

The newly amended Patent Law introduces patent extensions to patents of new drugs that launched in the PRC, and stipulates that the Patent Administration Department under the State Council shall, upon request of the patentee, extend the patent term of relevant invention patents of the new drug that is approved to be listed on the market in China, to compensate for the time spent for the review and examination and approval of the listing of a new drug on the market.

The compensated extension shall not exceed five (5) years, and the total valid patent term after the new drug is approved for the market shall not exceed fourteen (14) years.

Trademarks

Registered trademarks in the PRC are mainly protected by the Trademark Law of the PRC (《中華人民共和國商標法》), which was promulgated by the SCNPC on August 23, 1982 and latest amended on April 23, 2019 and came into effect on November 1, 2019, and the Implementation Rules of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》), which were promulgated by the State Council on August 3, 2002 and latest amended on April 29, 2014 and came into effect on May 1, 2014. The Trademark Office is responsible for the registration and administration of trademarks throughout China and grants a term of ten (10) years to registered trademarks.

Trade Secret

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by SCNPC, as amended and effective as of April 23, 2019, the term "trade secrets" refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the Anti-Unfair Competition Law of the PRC, business persons are prohibited from infringing others' trade secrets.

The Company Law and Regulations

The Company Law, which was amended by the SCNPC on December 29, 2023 and became effective on July 1, 2024, provides for the establishment, corporate structure and corporate management of companies, which also applies to foreign-invested enterprises in PRC.

Regulations in Relation to Foreign Direct Investment

Since January 1, 2020, the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the "Foreign Investment Law") promulgated by the National People's Congress (the "NPC") has come into effect. While the organization form, institutional framework and standard of conduct of foreign-invested enterprises shall be subject to the provisions of the Company Law of the PRC and other laws. The PRC government will implement the management system of pre-entry national treatment and the Negative List for foreign investment abolished the original approval and filing administration system for the establishment and change of foreign-invested enterprises. Pre-entry national treatment refers to the treatment accorded to foreign investors and their investments at the stage of investment entry which is no less favorable than the treatment accorded to domestic investors and their investments. Negative List refers to a special administrative measure for the entry of foreign investment in specific sectors as imposed by the PRC. The PRC accords national treatment to foreign investment outside of the Negative List. The current Negative List is the Special Management Measures (Negative List) for the Access of Foreign Investment (2024 Revision) (《外商投資准入特別管理措施(負面清單)(2024年版)》) issued by the NDRC and the MOFCOM on September 6, 2024 and came into effect on November 1, 2024, which lists the special management measures for foreign investment access for industries regulated by the Negative List, such as equity requirements and senior management requirements. While strengthening investment promotion and protection, the Foreign Investment Law further regulates foreign investment management and proposes the establishment of a foreign investment information reporting system that replaces the original foreign investment enterprise approval and filing system of the MOFCOM.

The foreign investment information reporting is subject to the Foreign Investment Information Reporting Method (《外商投資信息報告辦法》) jointly developed by the MOFCOM and the State Administration for Market Regulation, which came into effect on January 1, 2020. According to the Foreign Investment Information Reporting Method, the MOFCOM is responsible for coordinating and guiding the reporting of foreign investment information nationwide. The competent commercial department of the local people's government at or above the county level, as well as the relevant agencies of the Pilot Free Trade Zones and the National Economic and Technological Development Zones, are responsible for reporting information on foreign investment in the region. Foreign investors who directly or indirectly carry out investment activities in China shall submit investment information to the competent commercial department through the enterprise registration system and the National Enterprise Credit Information Publicity System and the reporting methods include initial reports, change reports, cancellation reports, and annual reports. Foreign investors who establish foreign invested enterprises in China or acquire domestic non-foreign-invested enterprises through equity merger and acquisition shall submit initial reports through the enterprise registration system when applying for the registration of the establishment of foreign-invested enterprises or applying for the registration of the change of the acquired enterprises. If the change in the information of initial reports involves registration or filing of the change of enterprises, foreign-invested enterprises shall submit change reports through the enterprise registration system when applying for the registration or filing of change of enterprises. If the change in the information of initial reports does not involve registration or filing of the change of enterprises, foreign-invested enterprises shall submit change reports through the enterprise registration system within twenty (20) business days after the change. Foreign-invested listed companies may report information on changes in investors and their shareholdings only when the cumulative change in the foreign investors' shareholding ratio exceeds 5% or the foreign parties' shareholding or relative holding status has changed.

Regulations on The Security Review of Foreign Investment

On December 19, 2020, the NDRC and the MOFCOM jointly promulgated the Measures on the Security Review of Foreign Investment (《外商投資安全審查辦法》), effective on January 18, 2021, setting forth provisions concerning the security review mechanism on foreign investment, including the types of investments subject to review, the scopes of review and procedures to review, among others.

Regulations in Relation to Product Liability

The Product Quality Law of the PRC (《中華人民共和國產品質量法》), promulgated by the SCNPC on February 22, 1993 and latest amended on December 29, 2018 (the "Product Quality Law"), is the principal governing law relating to the supervision and administration of product quality. According to the Product Quality Law, manufacturers shall be liable for the quality of

products produced by them and sellers shall take measures to ensure the quality of the products sold by them. A manufacturer shall be liable to compensate for any bodily injuries or damage to property other than the defective product itself resulting from the defects in the product. A seller shall be liable to compensate for any bodily injuries or damage to property of others caused by the defects in the product if such defects are attributable to the seller. A seller shall pay compensation if it fails to indicate either the manufacturer or the supplier of the defective product. A person who is injured or whose property is damaged by the defects in the product may claim for compensation from the manufacturer or the seller.

Pursuant to the PRC Civil Code (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and coming into effect on January 1, 2021, where a patient suffers damage due to defects in drugs, he may seek compensation from the drug marketing authorization holder, producer or 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 or producer.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》) was promulgated on October 31, 1993 and latest amended on October 25, 2013 and came into effect on March 15, 2014 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers.

Regulations in Relation to Production Safety

The Production Safety Law of the PRC (《中華人民共和國安全生產法》), promulgated by the SCNPC on June 29, 2002 and latest amended on June 10, 2021 and came into effect on September 1, 2021, is the basic law for governing production safety. It provides that any entity whose production safety conditions do not meet the requirements may not engage in production and business operation activities. Safety facilities of any new building, rebuilding or expanding project (the "construction project") shall be designed, constructed and put into operation simultaneously with the main body of the project. Investment in safety facilities shall be included in the budget of the construction project.

Regulations in Relation to Employment and Social Securities

Pursuant to the Labor Law of the PRC (《中華人民共和國勞動法》), promulgated by the SCNPC on July 5, 1994 and latest amended on December 29, 2018 and the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), promulgated by the SCNPC on June 29, 2007 and latest amended on December 28, 2012 and came into effect on July 1, 2013, employers shall execute written labor contracts with full-time employees. All employers shall comply with local minimum wage standards. Employers shall establish a comprehensive management system to protect the rights of their employees.

According to Social Security Law of the PRC (《中華人民共和國社會保險法》), which was promulgated on 28 October 2010 and amended on 29 December 2018, an employer is required to make contributions to social insurance schemes for its employees, including basic pension insurance, basic medical insurance, unemployment insurance, maternity insurance and work-related injury insurance. If the employer fails to make social insurance contributions in full and on time, the social insurance authorities may demand the employer to make payments or supplementary payments for the unpaid social insurance premium within a prescribed time limit together with a 0.05% per day surcharge of the unpaid social insurance premium from the due date. If the payment is not made within such time limit, the relevant administrative authorities will impose a fine ranging from one to three times the total outstanding amount. Pursuant to the Interpretation (II) of the Supreme People's Court on Issues Concerning the Application of Law in the Trial of Labor Dispute Cases (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)》), promulgated on July 31, 2025 and effective as of September 1, 2025, any agreement between an employer and an employee, or any undertaking by an employee, to waive social insurance contributions shall be deemed invalid by the people's courts. If an employer fails to make social insurance contributions in accordance with the law, the employee is entitled to terminate the labor contract in accordance with Article 38 of the Labor Contract Law and claim economic compensation, which shall be supported by the people's courts.

According to the Reform Plan of the State Tax and Local Tax Collection Administration System (《國稅地稅徵管體制改革方案》), which was promulgated on 20 July 2018, commencing from 1 January 2019, all the social insurance premiums including the premiums of the basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and basic medical insurance shall be collected by the tax authorities.

According to the Administrative Regulations on Housing Provident Funds (《住房公積金管理條例》), which was promulgated on 3 April 1999 and latest amended on 24 March 2019, employers are required to make contribution to housing provident funds for their employees. Where an employer fails to pay up housing provident funds, the housing provident fund administration center may order it to make payment within a prescribed time limit. If the employer still fails to do so, the housing provident fund administration center may apply to the court for compulsory enforcement of the unpaid amount.

Regulations in Relation to Information Security and Data Privacy

Data Security and Export

The NPCSC promulgated the Data Security Law of the People's Republic of China (《中華人民共和國數據安全法》), on June 10, 2021 (effective from September 1, 2021), for the establishment of a data classification and grading protection system to conduct classified and hierarchical protection of data. Entities engaged in data processing activities shall, in accordance with laws and regulations, establish a sound full-process data security management system, organize data security education and training, and take corresponding technical measures and other necessary measures to ensure data security.

According to the Measures for Security Assessment of Data Export (《數據出境安全評估辦法》) issued by the Cyberspace Administration of China on July 7, 2022 and came into effect on September 1, 2022, 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: (i) a data processor provides important data abroad; (ii) the critical information infrastructure operator or the data processor that has processed the personal information of more than 1 million people provides personal information abroad; (iii) the data processor that has provided the personal information of over 100,000 people or the sensitive personal information of over 10,000 people cumulatively since January 1 of the previous year provides personal information abroad.; and (iv) any other circumstance where an application for the security assessment of outbound data transfer is required by the national cyberspace administration.

According to the Measures for Standard Contract for Outbound Transfer of Personal Information (《個人信息出境標準合同辦法》) issued by the Cyberspace Administration of China on February 22, 2023 and effective from June 1, 2023, to provide personal information to an overseas recipient through the conclusion of the standard contract, a personal information processor shall meet all of the following circumstances: (i) it is not a critical information infrastructure operator; (ii) it has processed the personal information of less than one million individuals; (iii) it has cumulatively provided the personal information of less than 100,000 individuals to overseas recipients since January 1 of the previous year; and (iv) it has cumulatively provided the sensitive personal information of less than 10,000 individuals since January 1 of the previous year.

According to the Provisions on Facilitating and Regulating Cross-border Data Flows (《促進和規範數據跨境流動規定》), a data handler that is not a critical information infrastructure operator, will be exempted from declaring for security assessment for outbound data transfer, signing a standard contract with overseas recipient or passing the personal protection certification, if such data handler accumulatively transfers overseas ordinary personal information of less than 100,000 individuals since January 1 of the current year.

Personal Information Protection

According to the Civil Code, personal information of natural persons is protected by law. If any organization or individual needs to obtain other people's personal information, they should obtain it in accordance with the law and ensure the security of the information. They must not illegally collect, use, process, or transmit other people's personal information, and must not illegally buy, sell, provide, or disclose the information. The Personal Information Protection Law

of the People's Republic of China (《中華人民共和國個人信息保護法》) promulgated by the NPCSC on August 20, 2021 and implemented on November 1, 2021, further emphasizes the obligations and responsibilities of processors for the protection of personal information, and requests higher level of protective measures on the processing of sensitive personal information.

According to the Cybersecurity Law of the People's Republic of China (《中華人民共和國網絡安全法》) promulgated by the NPCSC on November 7, 2016 and effective on June 1, 2017, network operators must follow the principles of legality, legitimacy and necessity when collecting and using personal information, and publicly disclose the rules for collection and use, clearly state the purpose, method and scope of collecting and using information, and obtain the consent of the person whose data is being collected. Network operators shall not collect personal information unrelated to the services they provide. Network operators are not allowed to leak, tamper with, or damage the personal information they collect; they are not allowed to provide personal information to others without the consent of the person whose data is being collected. However, this does not apply to cases where a specific individual cannot be identified and the identity cannot be recovered after processing. Network operators should take technical measures and other necessary measures to ensure the security of the personal information they collect and prevent leakage, damage and loss of information.

Laws and Regulations in Relation to Anti-Bribery

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by SCNPC, as amended and effective as of April 23, 2019, and the Interim Provisions on the Prohibition of Commercial Bribery (《關於禁止商業賄賂行為的暫行規定》) promulgated by the SAIC on November 15, 1996, any business operator shall not provide or promise to provide economic benefits (including cash, other property or by other means) to a counter-party in a transaction or a third party that may be able to influence the transaction, in order to entice such party to secure a transactional opportunity or competitive advantages for the business operator. Any business operator breaching the relevant anti-bribery rules above-mentioned may be subject to administrative punishment or criminal liability depending on the seriousness of the cases.

Pursuant to the Provisions on the Establishment of Adverse Records of 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》), which was promulgated by the National Health and Family Planning Commission (currently the NHC) and came into effect on March 1, 2014, any medicine production and operation enterprises or agents that are involved in criminal, investigational or administrative procedures for commercial bribery will be listed in the adverse records of commercial briberies by the relevant government authorities.

REGULATIONS ON TAXATION

Enterprise Income Tax

According to the CIT Law, which was promulgated by the SCNPC and was latest amended on December 29, 2018, and the Regulation on the Implementation of the CIT Law, which was promulgated by the State Council and was latest amended in April 2019, a uniform 25% enterprise income tax rate is imposed to both foreign invested enterprises and domestic enterprises, except where tax incentives are granted to special industries and projects. The enterprise income tax rate is reduced to 20% for qualifying small low-profit enterprises. The high-tech enterprises that need full support from the PRC's government will enjoy a reduced tax rate of 15% for enterprise income tax.

Value-added Tax

Pursuant to the Value-added Tax Law of the People's Republic of China (《中華人民共和國增值税法》), which was promulgated on December 25, 2024 and came into effect on. January 1, 2026 and the Regulations for the Implementation of the Value-Added Tax Law of the People's Republic of China (《中華人民共和國增值税法實施條例》), which was promulgated and came into effect on the same day, entities and individuals (including individual businesses) engaged in sale of goods, services, intangible assets and immovables and importation of goods within the territory of China are the value-added tax ("VAT") payers. Sale of goods, services, intangible assets and immovables shall mean compensated transfer of ownership of goods and immovables, provision of services for compensation, and compensated transfer of ownership or use right of intangible assets.

According to the Announcement of the Ministry of Finance, the State Taxation Administration and the General Administration of Customs on Relevant Policies for Deepening the Value-Added Tax Reform (《財政部稅務總局海關總署關於深化增值稅改革有關政策的公告》) promulgated on March 20, 2019 and effective from April 1, 2019, the VAT rates of 16% and 10% on sales, imported goods shall be adjusted to 13% and 9%, respectively.

REGULATIONS ON FOREIGN EXCHANGE

Foreign Exchange Regulation

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 on payments of foreign currencies and purchase of foreign currencies, 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.

On November 19, 2012, the SAFE issued the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment (《關於進一步改進和調整直接投資外匯管理政策的通知》), or the SAFE Circular 59, which came into effect on December 17, 2012 and was revised on May 4, 2015, October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 59 aims to simplify the foreign exchange procedure and promote the facilitation of investment and trade. According to the SAFE Circular 59, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, 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, multiple capital accounts for the same entity may be opened in different provinces as well. Later, the SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) in February 2015, which was partially abolished in December 2019, prescribed that the bank instead of SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

According to the Notice of the People's Bank of China and the State Administration of Foreign Exchange on Issues Concerning the Administration of Funds Raised by Domestic Enterprises Listed Overseas (《中國人民銀行國家外匯管理局關於境內企業境外上市資金管理有關問題的通知》), promulgated on December 24, 2025 and effective on April 1, 2026, a domestic enterprise that conducts an overseas listing shall, within 30 working days from the first trading day of the overseas listing or the completion of the [**REDACTED**], apply to a bank within the province or the separately-listed municipality where it is registered (hereinafter referred to as the local bank) for overseas listing registration. In principle, funds raised by domestic enterprises through overseas listings shall be remitted back to the territory in a timely manner. Where such funds are retained overseas for the conduct of overseas direct investment, overseas securities investment, overseas lending and other businesses, the domestic enterprise shall obtain the approval or filing documents from the business competent authorities before the date of completion of the overseas issuance or the [**REDACTED**] and shall comply with relevant cross-border funds administration provisions. The purposes of funds raised through an overseas listing shall be consistent with the relevant contents set out in publicly disclosed documents (hereinafter referred to as publicly disclosed documents), such as the document or resolutions of the board of directors or shareholders' meetings. Any domestic shareholder who reduces their holdings must file a reduction registration with their bank either before or within 30 working days after the transaction.

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 effective on June 1, 2015 and partially

abolished on December 30, 2019 and 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 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 on-lent to a third party; and (d) to purchase real estates not for self-use purposes (save for real estate enterprises).

On June 9, 2016, SAFE issued the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》), or the SAFE Circular 16, which came into effect on the same day and partially amended on December 4, 2023 and effective since then. The SAFE Circular 16 provides that discretionary foreign exchange settlement applies to foreign exchange capital, foreign debt offering proceeds and remitted foreign listing proceeds, and the corresponding RMB capital converted from foreign exchange may be used to extend loans to related parties or repay inter-company loans (including advances by third parties).

On October 23, 2019, SAFE promulgated the Notice on Further Facilitating Cross-Board Trade and Investment (《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》), which became effective on the same date (except for Article 8.2, which became effective on January 1, 2020), and partially amended on December 4, 2023 and effective since then. The notice canceled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. Eligible enterprises in the pilot area are also allowed to use revenues under capital accounts, such as capital funds, foreign debts and overseas listing proceeds for domestic payments without providing materials to the bank in advance for authenticity verification on an item-by-item basis, while the use of funds should be true, in compliance with applicable rules and conforming to the current capital revenue management regulations.

According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《關於優化外匯管理支持涉外業務發展的通知》) issued by the SAFE on April 10, 2020, eligible enterprises are allowed to make domestic payments by using their capital funds, foreign credits and the income under capital accounts of overseas listing, without submitting the evidentiary materials concerning authenticity of such capital for banks in advance, provided that their capital use is authentic and in compliance with administrative regulations on the use of income under capital accounts. The bank in charge shall conduct post spot checking in accordance with the relevant requirements.

REGULATIONS IN RELATION TO OVERSEAS SECURITIES OFFERING AND LISTING BY DOMESTIC COMPANIES

According to the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Enterprises (《境內企業境外發行證券和上市管理試行辦法》) issued by the China Securities Regulatory Commission (the "CSRC") on February 17, 2023 and effective from March 31, 2023 (hereinafter referred to as the "Trial Measures"), where a domestic company seeks overseas securities issuance and listing, the issuer shall file with the CSRC in accordance with the Trial Measures. If an issuer procures an overseas initial public offering or listing, it shall file with the CSRC within three (3) business days after submitting application documents for overseas securities issuance and listing.

According to the Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) jointly issued by the CSRC and other departments on February 24, 2023 and effective on March 31, 2023, in the overseas offering and listing activities of domestic enterprises, domestic enterprises, and securities companies and securities service institutions that provide corresponding services shall strictly comply with the applicable laws and regulations of the People's Republic of China and satisfy the requirements of these Provisions, enhance the legal awareness of safeguarding state secrets and strengthening archives administration, establish and improve the confidentiality and archives work system, and take necessary measures to fulfill the confidentiality and archives administration obligations, and shall not divulge state secrets or work secrets of state organs, or harm the interests of the state or the public.