OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

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

The Company Law and Regulations

The Company Law, which was amended by the Standing Committee of the National People's Congress of the PRC (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 the 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 of the PRC (the "**NPC**") of the PRC has come into effect and has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors, while the organization form, institutional framework and standard of conduct of foreign-invested enterprises shall be subject to the provisions of the Company Law and other laws. The PRC government implements the management system of pre-entry national treatment and the Negative List for foreign investment. 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 National Development and Reform Commission (the "**NDRC**") and the Ministry of Commerce of the PRC (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 of the PRC (the "**SAMR**"), 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, while the competent commercial department of the local people's government at or above the county level are responsible for reporting information on foreign investment in the region. 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.

Major Regulatory Authorities of the Pharmaceutical Industry

The regulatory authorities of the drug industry in the PRC include: the National Medical Products Administration of the PRC (the "**NMPA**"), the National Health Commission (the "**NHC**", formerly known as the National Health and Family Planning Commission) and the National Healthcare Security Administration (the "**NHSA**").

The NMPA is an authority under the SAMR and 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; organizing and guiding the supervision and inspection of drugs, medical devices and cosmetics; and undertaking management of qualifications for licensed pharmacists.

The NHC 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 the 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 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 catalog 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 DRUG RESEARCH AND REGISTRATION

Administration of Drug Registration

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 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, drugs registration refers to activities that a drug registration applicant files an application and other supplementary applications for clinical trials of drugs, approval for drug marketing, and re-registration, 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.

Non-Clinical Research

The non-clinical safety evaluation study for drugs for the purpose of applying for drug registration and relevant activities shall be conducted in accordance with the Good Laboratory Practice for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》), which was promulgated on August 6, 2003 and revised on July 27, 2017 by the former China Food and Drug Administration (the "**CFDA**"), with the revised version effective as of September 1, 2017. On April 16, 2007, the former CFDA issued the Administrative Measures for the Certification of Good Laboratory Practice 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 were subsequently revised by the NMPA and became effective since July 1, 2023. It provides for the procedures for application and acceptance of Good Laboratory Practice certification by research institutions conducting non-clinical safety evaluation study for drugs, requirements for data review and on-site inspection, audit procedures and supervision and management.

Application for Clinical Trial

After completing the preclinical studies, the applicant must obtain approval for clinical trials of drugs from the NMPA before the conduction of new drug clinical trials. 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 NMPA (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**") promulgated by the Standing Committee of the SCNPC in September 20, 1984 and recently amended in August 26, 2019 and came into effect on December 1, 2019, the dossier on a new drug research and development (R&D), 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 clinical drug 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 the State Council for filing.

Conduct of Clinical Trial

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 1, 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.

A drug clinical trial to be carried out shall be examined and approved by the ethics committee. A sponsor approved to carry out a drug clinical trial shall, before carrying out subsequent drug clinical trial by stages, develop corresponding plan for drug clinical trials, carry out drug clinical trial upon examination and with consent of the ethics committee, and submit a corresponding plan for drug clinical trial and supporting materials on the website of the CDE.

In compliance with the Measures for the Administration of Drug Registration, clinical trials are divided into phase 1, phase 2, phase 3 and phase 4 and bioequivalence trial. 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》), which came into effect on July 24, 2018, 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 phase 3 clinical trial design. According to the Measures for the Administration of Drug Registration and 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 April 1, 2026, effective as of the same date, the applicant can also apply for communication on key technical issues at different stages of clinical R&D.

Good Clinical Practices (GCP)

To improve the quality of clinical trials, the NMPA and NHC promulgated the Good Clinical Practices for Drug Trials (《藥物臨床試驗質量管理規範》) in April 23, 2020 and came into effect on July 1, 2020, which stipulates the criteria for the entire procedure of the clinical trial including preclinical trial preparation and the necessary conditions, protection of subjects' rights and interests, trial protocols, duties of researchers, duties of sponsors, duties of monitors, trial record and report, data management and statistical analysis, administration of drug products for trial, guarantee for quality, polycentric trials, with reference to the internationally recognized principles. Pursuant to the Opinions on Deepening the Reform of the Evaluation and Approval System and Encouraging Innovation of Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) promulgated by the general offices of the

Chinese Communist Party Central Committee and the State Council in October 2017 and further stipulated by the Administrative Regulations for Drug Clinical Trial Institutions, the qualification of clinical trial institutions shall be subject to record management. Clinical trials should follow GCP and protocols approved by the ethics committee of each research center.

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》), promulgated by the CFDA on January 30, 2015 and came into effect from 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 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.

New Drug Application

Pursuant to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), which was issued by SAMR on 22 January 2020 and took effect on 1 July 2020 ("**Circular 27**"), after completing the pharmaceutical research, pharmacological and toxicological research, drug clinical trial, and other research 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.

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.

After an application for drug registration is accepted, the CDE shall conduct preliminary examination 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.

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.

Re-registration and Change of the Registration for Post-Marketing Drugs

According to the Circular 27, the marketing authorization holder (the entity that obtains a drug registration certificate from the relevant drug regulatory authority, who is allowed to market and sell a drug in the approved region and is responsible for the entire lifecycle of the drug, including R&D, manufacturing, marketing, and usage, the "**MAH**") must apply for the re-registration of drugs to the medical products administrative department of the province or the CDE no later than six months prior to the expiry of the drug registration licenses. After the medical products administrative department or the CDE receives such application, it shall conduct post- marketing evaluation and adverse drug reaction monitoring, review the change of information stated in the drug approval certificates and carry out other relevant works as required under the drug certificates and by the NMPA. If all requirements for the re-registration have been satisfied, a drug re-registration approval notification will be issued. The time limit for examination and approval of drug re-registration shall be 120 days, and an administrative approval decision shall be made within 20 days, subject to extension up to an additional half of the original time limit due to variety characteristics and special circumstances.

Besides, pursuant to the Circular 27 and the Trial Administrative Measures for the Change of the Registration for Post-marketing Drugs (《藥品上市後變更管理辦法(試行)》) which was promulgated by NMPA and became effective on January 12, 2021, within the validity of the drug registration license, if any registration information or management information of the drug changes (including but without limitation the holder of the drug registration certificate, the manufacturing process, the manufacturing site, the manufacturing devices, the API, other ingredients and packing materials of the drug, the content of the drug instruction, and technical specification changes), the MAH must go through certain procedures before they could implement such changes. To be specific, (1) with respect to (i) material changes during the drug manufacturing process; (ii) changes to the contents of the drug instructions concerning the effectiveness and other contents that increase the safety risks; (iii) transfer of market authorisation by the current holder; and (iv) other changes as required to be approved by NMPA, the MAH must submit the supplemental application for approval before implementation of the changes; (2) with respect to (i) medium changes during the drug manufacturing process; (ii) changes to the contents of the drug packaging label; (iii) sub-packaging of drugs; and (iv) other changes as required to be filed with NMPA, the MAH must file such changes for record with before implementation of the changes; and (3) with respect to (i) minor changes during the drug manufacturing process; and (ii) other changes as required to be reported to NMPA, the MAH must record such changes in the annual report of such drugs. The MAH must follow the relevant technical guiding principles to conduct corresponding research, comprehensively evaluate and verify the impact of such changes on the safety, effectiveness, and quality controllability of the drugs, and file supplementary applications and obtain approvals from, make filing with or report to the NMPA accordingly.

For the changes in the manufacturing process, the provincial NMPA shall conduct on-site check and technical review according to Circular 27 and the relevant technical guiding principles before they approve the application of MAH.

In addition, pursuant to the Trial Administrative Measures for the Change of the Registration for Post-marketing Drugs, if the technical guiding principles are unclear about a certain change, and the MAH is unable to determine which process is required, based on sufficient research, assessment, and necessary verification, (i) the domestic MAH may communicate with the provincial drug regulatory authority, which shall reply in writing within 20 days, and the domestic MAH shall (a) submit a supplementary application to the CDE, if the parties disagree on whether such change is subject to approval, or (b) make a filing with the provincial drug regulatory authority, if the parties disagree on whether the change is subject to filing, as applicable;(ii) the overseas MAH should communicate with the CDE.

Marketing Authorization Holder System

Pursuant to the Drug Administration Law and the Measures for the Administration of Drug Registration, the state implements the drug marketing authorization holder system for drug management. After obtaining a drug registration certificate, an applicant shall be the drug marketing authorization

holder. During the validity period, a holder of a drug registration certificate shall continue to ensure the safety, effectiveness and quality controllability of the marketed drug, and apply for re-registration of the drug six months prior to the expiry of the validity period.

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

Transfer of Drug Marketing Authorization

Pursuant to the Drug Administration Law, subject to the approval by the drug administrative department of the State Council, a drug marketing authorization holder may transfer its drug marketing authorization. The transferee shall possess the capability of quality management, risk prevention and control and liability compensation to ensure the safety, efficacy and quality controllability of the drug, and perform the obligations of the drug marketing authorization holder. According to the Measures for the Administration of Drug Registration, transfer of drug marketing authorization by the holder shall be declared by way of supplementary application, and be implemented upon approval.

Pursuant to the Administrative Measures for Drug Post-marketing Changes (for Trial Implementation) (《藥品上市後變更管理辦法(試行)》), drug post-marketing changes shall not have any adverse impact on the safety, effectiveness and quality controllability of drugs. In the case of an application for the change to a drug holder, the production site, prescription, production techniques and quality standards of the drugs shall be consistent with those of the original drugs. In the case of any change, after the change of the holder has been approved, the holder after the change shall conduct full study, evaluation and necessary verification and shall implement or report such changes upon approval or filing as required.

Laws and Regulations in Relation to Drug Manufacturing

Drug Manufacturing Permit

Pursuant to the Drug Administration Law, 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 (GMP)

Pursuant to the Drug Administration Law, and 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, 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 NHC in March 17, 1988, newly amended in January 17, 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.

Contract Manufacturing of Drugs

Pursuant to the Administrative Regulations for the Contract Manufacturing of Drugs (《藥品委託生產監督管理規定》) issued by the CFDA in August 14, 2014, and effective as of October 1, 2014, only when a drug manufacturer temporarily lacks manufacturing conditions due to technology upgrade or is unable to ensure market supply due to insufficient manufacturing capabilities, could such drug manufacturer entrust the manufacturing of the drug to another domestic drug manufacturer. Such contract manufacturing arrangements shall be approved by the provincial branch of the NMPA.

The Administrative Measures on Supervision of Drug Manufacturing (《藥品生產監督管理辦法》) promulgated by SAMR on January 22, 2020 and came effective on July 1, 2020 further stipulates that drug marketing authorization holders entrusting others to manufacture drugs shall enter into outsourcing agreements and quality agreements with qualified drug manufacturing enterprises and submit the relevant agreements together with the actual manufacturing site application materials to the competent drug administrative authority in order to apply for the Drug Manufacturing Certificate.

NMPA further issued the Announcement on Strengthening the Supervision and Administration of Entrusted Production by Drug Listing License Holders (《國家藥監局關於加強藥品上市許可持有人委託生產監督管理工作的公告》) in October 17, 2023, effective as of October 17, 2023 and the Announcement on Strengthening the Supervision and Management of Entrusted Production of Drugs (《國家藥監局關於加強藥品受託生產監督管理工作的公告》) in December 30, 2025, effective as of December 30, 2025, regarding the supervision and administration of contract manufacturing of drugs.

Laws and Regulations on Drug Supply

Drug Supply Permit

According to the Drug Administration Law and 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》) took into effect on January 1, 2024, the operation of drug business, including drug wholesale and drug retail, is prohibited without a Drug Supply Permit. 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.

Good Supply Practice

The Good Supply Practice for Pharmaceutical Products (《藥品經營質量管理規範》) (the "**GSP Rules**") was recently 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.

The Administrative Measures on Internet Drug Information Service (《互聯網藥品信息服務管理辦法》) was promulgated by the SFDA in July 8, 2004 and amended and effective on November 17, 2017, pursuant to which the internet drug information services is to provide drug (including medical device)

information services to online users; services are divided into commercial internet drug information services and non-commercial internet drug information services. The website operator that provides drugs (including medical devices) information services must obtain an Internet Drug Information Service Qualification Certificate from the competent counterpart of the NMPA. The valid term for an Internet Drug Information Service Qualification Certificate is five years and may be renewed at least six months prior to its expiration date upon a re-examination by the relevant governmental authorities. Furthermore, as requested by Internet Drug Measures, the information relating to drugs shall be accurate and scientific in nature, and its provision shall comply with the relevant laws and regulations. No product information of stupefacient, psychotropic drugs, medicinal toxic drugs, radiopharmaceutical, detoxification drugs and pharmaceutics made by medical institutes shall be distributed on the website. In addition, advertisements relating to drugs (including medical devices) shall be approved by the NMPA or its competent counterparts.

Other Laws and Regulations in Relation to Medical Industry

Volume-based Procurement Scheme (VBP) and Bidding Process

On 20 May 2024, the NHSA published the Notice of the National Healthcare Security Administration on Further Promotion of the Experience of Medical Reform in Sanming City and to Continuously Promote the Innovative Development of Medical Insurance (《國家醫療保障局關於進一步推廣三明醫改經驗持續推動醫保工作創新發展的通知》), providing guidance on volume-based procurement practices, aiming to aggressively promote the volume-based procurement of drugs and high-value medical consumables organized by national authorities. It emphasises the need to strengthen coordination among regions, guide and promote local governments to conduct volume-based procurement in a regulated manner, and support the targeted expansion of the range of drugs and medical consumables under the volume-based procurement scheme. This expansion is to be led by willing and responsible provinces, with the participation of all provinces. The notice aims to establish a new pattern of volume-based procurement, where the provinces organize the volume-based procurement of drugs and high-value medical supplies, the national alliance, led by provinces, acts as the main body, and provincial-level centralized procurement serves as a supplement.

On 14 May 2024, the National Healthcare Security Administration published the Notice of the National Healthcare Security Administration on Strengthening Regional Coordination to Improve the Quality and Coverage of Volume-based Procurement of Pharmaceuticals in 2024 (《國家醫療保障局辦公室關於加強區域協同做好2024年醫藥集中採購提質擴面的通知》), aiming to improve the centralized pharmaceutical procurement system, promote the quality and coverage of centralized VBP, and further enhance the capacity and scale of local procurement alliances.

Basic Medical Insurance Policy

Pursuant to the Decision on the Establishment of the Urban Employee Basic Medical Insurance Program (《關於建立城鎮職工基本醫療保險制度的決定》) promulgated by the State Council and effective 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 SFDA 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 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 and effective 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.

National Reimbursement Drug List of China

The National Reimbursement Drug List for Basic Medical Insurance, Work Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》) (the "**NRDL**") sets out the standards for payment of medicines by the basic medical insurance, work injury insurance and maternity insurance funds. The NHSA and other governmental organizations have the authority to determine the drugs to be included in the NRDL. Drugs listed in the NRDL are divided into two parts: Class A and Class B. Class A drugs are widely used for clinical treatment, with favorable efficacy and lower prices than their counterparts, while Class B drugs are used for clinical treatment, with favorable efficacy and slightly higher prices than Class A drugs.

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》) (the "**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. According to the Opinions of the NHSA and the Ministry of Finance on Establishing a List-Based System for Healthcare Security Benefits (《國家醫保局、財政部關於建立醫療保障待遇清單制度的意見》), which came into effect in January 19, 2021, all provinces shall implement the NRDL in a strict manner, and shall not have the discretion to formulate the catalog or increase the drugs in any form, or adjust the scope of limited payment unless explicitly stipulated. On December 5, 2025, the NHSA and the Ministry of Human Resources and Social Security of the PRC released the latest NRDL (effective from 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).

National Basic Drug Catalogue

Pursuant to the Opinions of the General Office of the State Council on Improving the National Basic Drug System (《國務院辦公廳關於完善國家基本藥物制度的意見》) issued and effective on 13 September 2018 and the Circular on the Printing and Issuance of the Measures for the Administration of the National Basic Drug Catalogue (《關於印發國家基本藥物目錄管理辦法的通知》) newly issued, promulgated and effective on 27 January 2026, primary healthcare institutions operated by the government (mainly including county hospitals, county hospitals of traditional Chinese medicine, township health centers and community outpatient clinics) shall be equipped with and use the drugs listed in the National Basic Drug Catalogue. Drugs in the National Basic Drugs Catalogue must be procured through a centralized bidding process and are subject to price control by the NDRC. Therapeutic drugs in the National Basic Drug Catalogue are included in the medical insurance catalogue and the full cost of purchasing such drugs is reimbursed.

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 "**MIIT**"), the MOFCOM and the CFDA on May 4, 2015 and came into effect on June 1, 2015, from June 1, 2015, except for narcotic drugs and first-class psychotropic drugs, the price of drugs set by the government will be canceled.

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 21, 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.

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 July 23, 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 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 and effective on December 26, 2016, the Two-Invoice System is a system under which invoices are issued by drug manufacturers to drug distributors on a once-off basis while invoices are issued by drug distributors to medical institutions on a once-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 Notice on Promulgation of the Key Points for the Special Campaign to Rectify the Misconduct in the Medicine Purchase and Sales Field and Medical Services in 2018 (《關於印發<2018年糾正醫藥購銷領域和醫療服務中不正之風專項治理工作要點>的通知》), which was issued and effective on August 15, 2018, the Two-Invoice System shall be fully implemented for drug purchase and sale among public medical institutions. Pharmaceutical companies must comply with the Two-Invoice System in order to engage in procurement processes with public hospitals.

Advertising of Pharmaceutical Products

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》), which was promulgated by the SAMR in December 24, 2019 and came into effect on March 1, 2020, advertisements for drugs, medical devices, health food and formula food for special medical purposes shall be true and legitimate, and shall not contain any false or misleading contents. Holders of registration certificates or filing certificates of drugs, medical devices, health food and formula food for special medical purposes as well as the production enterprises and operating enterprises authorized by such holders of certificates shall be applicants for advertising (the "**Applicants**"). The advertisement review authorities shall review the materials submitted by the Applicants and shall complete the review within ten business days from the date of acceptance. After review, for advertisements that are in line with laws, administrative regulations and these Measures, approval decisions of review shall be made and advertisement approval numbers shall be issued. The validity period of the advertisement approval number for drugs, medical devices, health food and formula food for special medical purposes shall be consistent with the shortest validity period of the product registration certificate, filing certificate or production license. If no valid period is prescribed in the product registration certificate, filing certificate or production license, the valid period of the advertisement approval number shall be two years.

Insert Sheet, Labels and Packaging of Pharmaceutical Products

Pursuant to the Measures for the Administration of the Insert Sheets and Labels of Drugs (《藥品說明書和標籤管理規定》), which was promulgated by the SFDA on March 15, 2006 and came effective on June 1, 2006, the insert sheets and labels of drugs should be reviewed and approved by the SFDA. Pursuant to the Measures for The Administration of Pharmaceutical Packaging (《藥品包裝管理辦法》) which came effective on September 1, 1988, pharmaceutical packaging must comply with the national and professional standards.

Pursuant to the Procedures and Requirements for the Record-filing of Repackaging of Drugs Manufactured Overseas (《國家藥監局藥審中心關於發佈《境外生產藥品分包裝備案程序和要求》的通告》), which was issued by the NMPA on 6 August 2020 and took effect on the same day, repackaging of overseas-manufactured drugs in the PRC is regulated under a record-filing regime. Prior to the implementation of the Circular 27, import drug repackaging that had already obtained an approval for a supplemental drug application and had a valid approval number shall remain valid. After the implementation of the Circular 27, if the packaging specifications of the bulk packaging used for drug repackaging have already obtained the Drug Import Registration Certificate (進口藥品註冊證) and remain valid, the repackaging of drugs manufactured overseas may be directly filed.

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 and effective 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 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》) (the "**Civil Code**") promulgated by the NPC on May 28, 2020 and came 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 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 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. All business operators must pay high attention to protecting customers' privacy and must strictly keep confidential any consumer information they obtain during their business operations.

Laws and Regulations relating to the Construction Industry

The laws, administrative regulations and departmental rules relating to the construction industry that we apply mainly include the Construction Law of the PRC (《中華人民共和國建築法》), the Regulations on the Administration of Construction Engineering Quality (《建設工程質量管理條例》), the Provisions on the Management of Qualifications for Construction Enterprises (《建築業企業資質管理規定》), and the Measures for the Administration of Completion, Final Inspection and Acceptance, and Registration of Building and Municipal Infrastructure Construction Projects (《房屋建築和市政基礎設施工程竣工驗收備案管理辦法》).

Construction Law

The Construction Law of the People's Republic of China (the "**Construction Law**") was adopted on November 1, 1997 by the 28th session of the Standing Committee of the Eighth National People's Congress, and was amended for the first time in accordance with the Decision on the Amendment of the Construction Law of the PRC (《關於修改<中華人民共和國建築法>的決定》) of the 20th session of the Standing Committee of the Eleventh National People's Congress dated April 22, 2011 and amended for the second time in accordance with the Decision on the Amendment of Eight Laws (including the Construction Law of the PRC) (《關於修改<中華人民共和國建築法>等八部法律的決定》) of the 10th session of the Standing Committee of the Thirteenth National People's Congress dated April 23, 2019. Enterprise engaged in construction activities and implementing supervision and management of construction activities within the territory of the PRC shall comply with the Construction Law. Our products relating to steel structure building system are applied in construction activities and construction projects and therefore, we shall comply with the provisions of the Construction Law.

Regulations on the Administration of Construction Engineering Quality

Pursuant to the Construction Law, stipulations pertinent to construction permit, examination of the qualifications for construction enterprises, awarding, contracting and ban on subcontracting of construction projects as well as supervision, safety and quality management of the construction projects shall be applicable to the construction of other special construction projects, with details formulated by the State Council. Accordingly, the State Council has formulated the Regulations on the Administration of Construction Engineering Quality, which were promulgated by the Decree No. 279 of the State Council of the People's Republic of China and effective on January 30, 2000, and amended for the first time in accordance with the Decision of the State Council on the Amendment of Certain Administrative Regulations (《國務院關於修改部分行政法規的決定》) dated October 7, 2017, and amended for the second time in accordance with the Decision of the State Council on the Amendment of Certain Administrative Regulations dated April 23, 2019. All those engaged in the new construction, expansion, reconstruction and other related activities of construction works and the implementation of supervision and management of construction engineering quality within the territory of the PRC shall comply with the Regulations on the Administration of Construction Engineering Quality.

According to the Regulations on the Administration of Construction Engineering Quality, the owner, survey entity, design entity, construction entity and engineering supervisory entity of a construction project shall be responsible for the quality of such construction project in accordance with the law. If the general contractor subcontracts the construction project to other entities in accordance with the law, the subcontractors shall be accountable to the general contractor for the quality of the subcontracted works under the subcontractor agreement, and the general contractor and the subcontractors shall be jointly and severally liable for the quality of the subcontracted works. The competent administrative department for construction under the State Council implements unified supervision and management of the quality of all construction projects in the country, and the competent administrative departments for construction under the local people's governments at or above the county level implements supervision and management of the quality of construction projects in the corresponding administrative areas.

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》), 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**"), 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 is from the date of application.

Copyright

Copyright in the PRC is primarily protected by the Copyright Law of the PRC (《中華人民共和國著作權法》), which was promulgated by the SCNPC on September 7, 1990, last amended on November 11, 2020 and became effective on June 1, 2021, and Implementation Regulations of the Copyright Law of PRC (《中華人民共和國著作權法實施條例》), which was promulgated by the State Council on August 2, 2002 last amended on January 30,2013, and became effective on March 1, 2013. These law and regulation provide provisions on the classification of works and the obtaining and protection of copyright.

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. When it is necessary to continue using the registered trademark upon expiration of period of validity, a trademark registrant shall make an application for renewal within twelve (12) months before the expiration in accordance with the requirements. If such an application cannot be filed within that period, an extension period of six months may be granted. The period of validity for each renewal of registration shall be ten (10) years as of the next day of the previous period of validity. If the formalities for renewal have not been handled upon expiration of period of validity, the registered trademarks will be deregistered.

Domain Names

Domain names are regulated under the Administrative Measures on the Internet Domain Names (《互聯網域名管理辦法》) issued by the MIIT, on August 24, 2017 and effective from November 1, 2017. The MIIT is the main regulatory authority responsible for the administration of the PRC internet domain names. Domain names registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

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 as of June 27, 2025 and effective on October 15, 2025, 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 by: (i) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion, or any other means; (ii) disclosing, using, or allowing another person to use a trade secret acquired from the right holder by any means as specified in the item (i) above; (iii) disclosing, using, or allowing another person use a trade secret in its possession, in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; (iv) abetting a person, or tempting another person into or in acquiring, disclosing, using, or allowing another person to use the trade secret of the right holder in violation of his or her non-disclosure obligation or the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others' trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and impose fine on the infringing parties.

Laws and Regulations in Relation to Real Properties

Real Estate Leasing

According to the Civil Code, a lease contract is a contract whereby the lessor delivers to the lessee the item for the latter's use or benefit therefrom, and the lessee pays the lease expense. The contents of a lease contract generally include terms such as the name, quantity and purpose of the leased property, lease term, lease expense as well as time limit and method for its payment, and maintenance of the leased property.

According to Administrative Measures on Leasing of Commodity Housing (《商品房屋租賃管理辦法》) promulgated by the Ministry of Housing and Urban-Rural Development of PRC on December 1, 2010 and became effective on February 1, 2011, the lessor and the lessee shall complete property leasing registration and filing formalities within 30 days from execution of the property lease contract with the development (real estate) department of the People's Government of the centrally-administered municipality, municipality or county where the leased property is located. Failure to comply with the above requirements may subject the relevant lessors and lessees to administrative penalties, including orders to make corrections within a certain period of time and fines.

Regulations in Relation to Environment, Health and Safety

Environmental Impact Assessment

According to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), latest amended on April 24, 2014 and came into effect on January 1, 2015, the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》), latest amended and effective on December 29, 2018, and the Administrative Regulations on the Environmental Protection of Construction

Project (《建設項目環境保護管理條例》), latest amended on July 16, 2017 and came into effect on October 1, 2017, enterprises which plan to construct projects shall engage qualified professionals to provide the assessment reports, assessment form, or registration form on the environmental impact of such projects. The assessment reports, assessment form, or registration form shall be filed with or approved by the relevant environmental protection bureau prior to the commencement of any construction work.

Pollutant Discharge

According to the Regulations on the Administration of Pollutant Discharge Permits (《排污許可管理條例》) promulgated by the State Council on January 24, 2021 and came into effect on March 1, 2021, and the Administrative Measures on Pollutant Discharge Permit (《排污許可管理辦法》) issued by the Ministry of Ecology and Environment on April 1, 2024 and came into effect on July 1, 2024, enterprises, public institutions and other producers and operators that are subject to the administration of pollutant discharge permits shall apply for pollutant discharge permit and discharge pollutants in accordance with the requirements of the pollutant discharge permit; and those who have not obtained the pollutant discharge permits shall not discharge pollutants. According to the Classification Management List for Fixed Source Pollution Permits (2019 Edition) (《固定污染源排污許可分類管理名錄(2019年版)》), the manufacturing of biological drugs and products falls into the classification management scope for fixed source pollution permits.

Discharge of Urban Sewage

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 the permit for discharging 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 effect 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》), recently amended on December 1, 2022 and came into effect on February 1, 2023. Where a drainage entity needs to discharge sewage into urban drainage facilities, it shall apply for a drainage license in accordance with the provisions of these Measures.

Disposal of Hazardous Wastes

According to the Law of the People's Republic of China on the Prevention and Control of Environmental Pollution Caused by Solid Wastes (《中華人民共和國固體廢物污染環境防治法》), which was recently amended on April 29, 2020 and came into effect on September 1, 2020, entities generating hazardous wastes shall store, utilize and dispose of hazardous wastes pursuant to the relevant provisions of the State and the requirements of environmental protection standards, and shall not arbitrarily dump or pile up such wastes. Entities that undertake the collection, storage, utilization and treatment of hazardous wastes shall apply for and obtain a permit. The hazardous wastes shall be defined by the National Catalogue of Hazardous Wastes (《國家危險廢物名錄》), of which the latest version was issued by the Minister of Ecology and Environment and other authorities on November 11, 2024 and entered into force as of January 1, 2025.

Fire Safety

According to the Fire Safety Law of the PRC (《中華人民共和國消防法》) last amended and effective on April 29, 2021, and the Interim Provisions on Administration of Fire Protection Design Review and Acceptance of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) (the "**Interim Provisions**") last amended on August 21, 2023 and effective on October 30, 2023, the fire protection design or construction of a construction project must conform to the national fire protection technical standards for project construction and construction projects shall undergo the fire protection design review and acceptance system. The special construction projects as defined in the Interim Provisions must apply to the fire control department for fire protection design review, and complete the fire protection acceptance procedures after the completion of the construction project. The construction

unit of other construction projects must complete the fire protection filing of the fire protection design and the completion acceptance within five (5) business days after the completion acceptance of the construction project. If a construction project fails to pass the fire safety inspection before it is put into use, or does not meet the fire safety requirements after the inspection, it will be ordered to suspend the construction and use of such project, or suspend production and business, and be imposed a fine.

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. The production and business operation entities shall educate and train employees regarding production safety so as to ensure that the employees have the necessary knowledge of production safety, are familiar with the relevant regulations and rules for safe production and the rules for safe operation, master the skills of safe operation in their own positions, understand the emergency measures, and know their own rights and duties in terms of production safety. Employees who fail the education and training programs on production safety may not commence working in their positions. Safety facilities of new building, rebuilding or expanding project (as 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.

Hazardous Chemicals

The Regulation on Safety Administration of Hazardous Chemicals (《危險化學品安全管理條例》) (the "**Hazardous Chemicals Regulation**") was promulgated by the State Council on January 26, 2002 and newly revised and effective on December 7, 2013. The Hazardous Chemicals Regulation provides regulatory requirements on the safe production, storage, use, operation and transportation of hazardous chemicals. An enterprise that has obtained a work safety permit of hazardous chemicals, safety use permit of hazardous chemicals or operation permit of hazardous chemicals according to law shall purchase hyper-toxic chemicals or hazardous chemicals that can be used to make explosives upon the strength of relevant permits or certificates. A producer of civil explosives shall purchase hazardous chemicals that can be used to make explosives upon the strength of the permit for production of civil explosives. Any entity other than those as prescribed in the preceding paragraph, when purchasing hyper-toxic chemicals, shall apply to the public security organ of the local people's government at the county level for a permit for purchasing hyper-toxic chemicals; when hazardous chemicals that can be used to make explosives are purchased, the explanations on the legal use of such chemicals issued by such entity shall be presented.

The Regulation on the Administration of Precursor Chemicals (《易製毒化學品管理條例》) promulgated by the State Council on August 26, 2005 and latest revised and effective on September 18, 2018, stipulates and regulates the production, operation, purchase, transportation, import and export of precursor chemicals. The precursor chemicals are classified into three categories. Category I refers to the major materials that may be used to produce drugs. Categories II and III refer to the chemical auxiliary substances that may be used to produce drugs. An enterprise that applies for purchasing the precursor chemicals in Category I shall submit the related certificates and shall obtain the purchase license upon the examination and approval of the supervisory and administrative department of drugs of the people's government of the province, autonomous region or centrally administered municipality where the applicant is located. An entity that purchases any precursor chemicals in Category II or III shall, before the purchase, report the variety and quantity in demand to the public security organ of the local people's government at the county level for archival filing.

According to the Measures for the Public Security Management of Explosives Precursors (《易製爆危險化學品治安管理辦法》) issued by the Ministry of Public Security on July 6, 2019 and effective on August 10, 2019, enterprises which have obtained permits for safe production of hazardous chemicals, permits for the safe use of hazardous chemicals and permits for business operation of hazardous chemicals in accordance with the law shall purchase explosive precursor hazardous chemicals with the corresponding

licenses. A buyer of explosives precursors shall, within five days after purchasing, report the information about the types, quantity and flowing direction of explosives precursors purchased to the local county-level public security organ for filing through the Explosive Precursors Information System.

Prevention and Control of Occupational Diseases

According to the Law of the PRC on the Prevention and Control of Occupational Diseases (《中華人民共和國職業病防治法》) which was lately amended and effective on December 29, 2018, the prevention and control of occupational diseases shall follow the guideline of "focusing on prevention and combining prevention with control." An employer shall: (i) establish and improve the accountability system for prevention and treatment of occupational diseases, enhance management of, and raise the level in this field, and bear responsibility for the occupational disease hazards produced; (ii) contribute to occupational injury insurance; (iii) provide facilities for the effective prevention and protection of occupational diseases, and provide materials to employees for personal use against occupational diseases; (iv) provide alarm equipment, allocate on-spot emergency treatment materials, washing equipment, emergency safety exits and necessary safety zones for work places where acute occupational injuries are likely to take place due to poisonous and harmful elements therein; and (v) inform the employees of, and specify in the labor contracts with the employees the potential harm of, occupational disease as well as the consequences thereof, and the prevention and protection measures and treatment against occupational diseases when signing the labor contracts with employees.

According to the Law of the PRC on the Prevention and Control of Occupational Diseases, in the event that any newly built, expanded or renovated construction project, or technology renovation or introduction project (as the construction project) may generate occupational disease hazards, the owner shall conduct the assessment of occupational disease hazards during the feasibility study stage. The occupational disease hazard pre-assessment report shall assess the construction project as to possible occupational disease hazard factors and their impact on the workplace and health of the workers, and determine the type of the hazards and the measures for protection against occupational diseases.

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 and effective 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, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, working location, occupational hazards, and status of safe production as well as remuneration and other conditions.

According to the Social Security Law of the PRC (《中華人民共和國社會保險法》), which was promulgated on October 28, 2010 and amended on December 29, 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% 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.

According to the Administrative Regulations on Housing Provident Funds (《住房公積金管理條例》), which was promulgated on April 3, 1999 and latest amended and effective on March 24, 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 the Import and Export of Drugs

Import and Export of Goods

Pursuant to the Administrative Provisions on the Registration of Customs Declaration Entities of the PRC (《中華人民共和國海關報關單位註冊登記管理規定》) (effective on March 13, 2014, last amended with effect from July 1, 2018 and abrogated on January 1, 2022), the import and export of goods shall be declared by the consignor or consignee itself, or by a customs declaration enterprise entrusted by the consignor or consignee and duly registered with the customs authority. Consignors and consignees of imported and exported goods shall go through customs declaration entity registration formalities with the competent customs departments in accordance with the applicable provisions. After completing the registration formalities with the customs, consignors and consignees of the imported and exported goods may handle their own customs declarations at customs ports or localities where customs supervisory affairs are concentrated within the customs territory of the PRC.

The Provisions on the Filing of Customs Declaration Entities of PRC (《中華人民共和國海關報關單位備案管理規定》), which became effective on January 1, 2022 and replaced the Administrative Provisions on the Registration of Customs Declaration Entities of the PRC, changed the registration of consignors and consignees into record-filing and further simplified the regulatory regime for the import and export of goods.

Import of Drugs

According to the Drug Administration Law, drugs shall be imported through the specific ports for the import of drugs, and the drug importation enterprise shall make a filing with the local NMPA where the port is located. Such local NMPA shall notify the pharmaceutical inspection institution to carry out selective inspections on the imported drugs according to relevant laws and regulations.

Pursuant to the Administrative Measures for the Import of Drugs (《藥品進口管理辦法》), which was promulgated by NMPA and the General Administration of Customs on 18 August 2003, as amended with effect from August 24, 2012, the enterprise must obtain the Drug Import Registration Certificate (進口藥品註冊證) (or Pharmaceutical Products Registration Certificate (醫藥產品註冊證)) or Approval Document for Import of Drugs (進口藥品批件) before it can make the import filings for the imported drugs. However, on July 1, 2020, the NMPA published the Announcement on Launching the Use of the Drug Registration Certificate, the Approval Notice for Drug Re-registration and the Approval Notice for Supplementary Drug Application (2020 Edition) (No. 265) (《關於啟用《藥品註冊證書》《藥品再註冊批准通知書》《藥品補充申請批准通知書》(2020版)的公告(第265號)》), which stipulates that for the purposes of implementing the Administrative Measures for Drug Registration and regulating the format of proof documents for examination and approval results of drug administrative licensing matters, a decision has been made to launch the use of the Drug Registration Certificates (藥品註冊證書), the Approval Notice for Drug Re-registration (藥品再註冊批准通知書) and the Approval Notice for Drug Supplementary Applications for drugs (藥品補充申請批准通知書) manufactured domestically and overseas as at July 1, 2020.

Regulations in Relation to Information Security and Data Privacy

Data Security and Export

The SCNPC 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 Provisions on Facilitating and Regulating Cross-border Data Flows (《促進和規範數據跨境流動規定》) issued by the Cyberspace Administration of China and effective on March 22, 2024, 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 the 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 promulgated by the SCNPC 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 SCNPC on November 7, 2016, which was amended on October 28, 2025 and became effective on January 1, 2026, 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.

Laws and Regulations in Relation to Anti-money Laundering, Anti-corruption and Anti-bribery

Anti-money Laundering

According to the Anti-money Laundering Law of the People's Republic of China (《中華人民共和國反洗錢法》) promulgated by the SCNPC on November 8, 2024 and effective from January 1, 2025, financial institutions shall, according to the provisions of the present law, establish a sound internal control system for anti-money laundering, set up a special body or designate an internal body to take the lead to take charge of the anti-money laundering work. The entities and individuals in business relationship with a financial institution shall cooperate with the financial institution in conducting customer due diligence by providing authentic and valid identity documents or other identity certificates, filling in identity information accurately and completely, and faithfully providing materials relating to transactions and funds. Where an entity or individual refuses to cooperate with the financial institution in taking reasonable measures for customer due diligence according to the present law, the financial institution may take money laundering risk management measures, such as limiting or refusing to handle business and terminating business relationship under the prescribed procedures, and submit a report on doubtful transactions in the light of the situation.

Anti-corruption

According to the Criminal Law of the People's Republic of China (《中華人民共和國刑法》), as last amended by the SCNPC on December 29, 2023 and effective on March 1, 2024, the crime of job appropriation means that an employee of any company, enterprise or any other organization unlawfully takes possession of the money or property of the organization by taking advantage of office, if the amount is relatively large, he shall be sentenced to fixed-term imprisonment of not more than three years or criminal detention and shall be fined concurrently; if the amount is huge, he shall be sentenced to

fixed-term imprisonment of not less than three years but not more than 10 years and shall be fined concurrently; or if the amount is extremely huge, he shall be sentenced to fixed-term imprisonment of not less than 10 years or life imprisonment and shall be fined concurrently.

Anti-bribery

According to the Anti-Unfair Competition Law of the PRC 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 SAMR (formerly known as the State Administration for Industry and Commerce of the PRC) and effective 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 NHC on December 25, 2013 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, as a result of which, for two years from the date the list of adverse records of commercial briberies is published, (i) their products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies within the relevant provinces, and (ii) the scores of their products in the centralized tender processes of public medical institutions or medical and health institutions receiving financial subsidies in other provinces will be reduced. As for those enterprises or agents listed in adverse records twice within five years, their products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies throughout China for two years from the date the list of adverse records of commercial briberies is published.

Regulations on Taxation

Enterprise Income Tax

According to the Enterprise Income Tax Law of the People's Republic of China (《中華人民共和國企業所得稅法》), which was promulgated by the SCNPC and was latest amended and effective on December 29, 2018, and the Regulation on the Implementation of the Enterprise Income Tax Law (《中華人民共和國企業所得稅法實施條例》), which was promulgated by the State Council and was latest amended on December 6, 2024 and effective on January 20, 2025, a uniform 25% enterprise income tax rate is imposed on 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. Key high-tech enterprises that are supported by the PRC's government may enjoy a reduced tax rate of 15% for enterprise income tax.

Value-added Tax (VAT)

According to the Value-added Tax Law of the PRC (《中華人民共和國增值稅法》), which was promulgated by the NPC on December 25, 2024 and effective on January 1, 2026, the Regulation on the Implementation of the Value-Added Tax Law of the PRC (《中華人民共和國增值稅法實施條例》), which was promulgated by the State Council on December 25, 2024 and effective on January 1, 2026, and the Implementation Rules for the Provisional Regulations the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例實施細則》), which was promulgated by the Ministry of Finance and was latest amended on October 28, 2011 and effective from November 1, 2011, entities and individuals engaging in selling goods, providing processing, repairing or replacement services or importing goods within the territory of the PRC are taxpayers of the VAT.

According to the Notice of the Ministry of Finance and the State Taxation Administration on the Adjusting Value-added Tax Rates (《財政部稅務總局關於調整增值稅稅率的通知》) effective in May 1, 2018, the VAT rates of 17% and 11% on sales, imported goods shall be adjusted to 16% and 10%, respectively.

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.

According to the Value-added Tax Law of the PRC (《中華人民共和國增值稅法》), which was promulgated by the NPC on December 25, 2024 and effective on January 1, 2026, the tax rate for taxpayers engaging in sale of services and intangible assets shall be 6%, except for the Article 10, Subparagraphs one, two and five of the Value-added Tax Law of the PRC.

According to the Notice on the Application of Low Value Added Tax Rates and Simplified Methods for Collecting Value Added Tax on Some Goods (《關於部分貨物適用增值稅低稅率和簡易辦法徵收增值稅政策的通知》) which was lately revised by the Notice of the Ministry of Finance and the State Taxation Administration on the Policy of Streamlining and Adjusting the Value Added Tax Collection Rates (《財政部、稅務總局關於簡併增值稅徵收率政策的通知》) on 13 June 2014, VAT general taxpayers who sell self-produced biological products made from microorganisms, microbial metabolites, animal toxins, human or animal blood or tissues may choose to compute and pay VAT at a rate of 3% under the simplified method.

Regulation on Foreign Exchange

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.

Later, the State Administration of Foreign Exchange of the PRC (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 13, 2015 and effective on June 1, 2015, 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.

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》), which was latest amended by the Notice of the SAFE on Announcing the Abolishment and Invalidation of Certain Foreign Exchange Regulatory Documents and Relevant Provisions (《國家外匯管理局關於公佈廢止和失效部分外匯管理規範性文件及相關條款的通知》) on October 10, 2018, 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 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 國家外匯管理局發佈《關於境內企業境外上市資金管理有關問題的通知》》) issued by the People's Bank of China and the SAFE on December 24, 2025 and effective on April 1, 2026, the domestic companies that conduct 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.

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 by the Notice of the SAFE on Further Deepening Reform to Facilitate Cross-Border Trade and Investment (《國家外匯管理局關於進一步深化改革促進跨境貿易投資便利化的通知》) 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. In addition, restrictions on the use of funds for foreign exchange settlement of domestic accounts for the realization of assets have been removed and restrictions on the use and foreign exchange settlement of foreign investors' security deposits have been relaxed. Eligible enterprises in the pilot area are also allowed to use revenues under capital accounts, such as capital funds, foreign debts and overseas listing revenues 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 and effective on June 1, 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 Overseas Listing Trial Measures issued by the China Securities Regulatory Commission (the "**CSRC**") on February 17, 2023 and effective from March 31, 2023, where a domestic company seeks overseas securities issuance and listing, the issuer shall file with the CSRC in accordance with the Overseas Listing 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. A domestic enterprise that, either directly or through its overseas listed entity, publicly discloses or provides to relevant securities companies, securities service institutions, overseas regulators, and other entities and individuals, any documents and materials that involve state secrets or work secrets of state organs, shall obtain approval from the competent department

with the power of examination and approval according to the law, and report to the administrative department of confidentiality at the same level for filing. A domestic enterprise that, either directly or through its overseas listed entity, publicly discloses or provides to relevant securities companies, securities service institutions, overseas regulators, and other entities and individuals, other documents and materials whose divulgence will have adverse impact on national security or public interest, shall strictly undergo the relevant procedures in accordance with the relevant regulations of the state.