We are subject to a variety of PRC laws, rules, and regulations across a number of aspects of our business. This section sets forth a summary of the most significant laws and regulations that are applicable to our current business activities within the territory of the PRC.

LAWS AND REGULATIONS IN RELATION TO THE PHARMACEUTICAL INDUSTRY

Regulatory Framework of the Pharmaceutical Industry

The PRC Drug Administration Law (《中華人民共和國藥品管理法》), promulgated by the Standing Committee of the National People's Congress of China (the "**SCNPC**") in September 1984 and last amended in August 2019 (effective as of December 2019), along with the Regulations for the Implementation of the Drug Administration Law (《中華人民共和國藥品管理法實施條例》), promulgated by the State Council in August 2002 and last amended in January 2026 (effective as of May 2026), collectively form the legal framework for the administration of pharmaceutical products in China. This framework governs the research, development, and manufacturing of drugs. The PRC Drug Administration Law regulates pharmaceutical manufacturers, drug trading companies and medicinal institutions' preparations, covering R&D, manufacturing, distribution, packaging, pricing and advertisement of pharmaceuticals. The Regulations for the Implementation of the Drug Administration Law provide detailed rules for the PRC Drug Administration Law.

Major Regulatory Authorities of the Pharmaceutical Industry

The pharmaceutical industry in the PRC is mainly administered by three governmental agencies — namely, the National Medical Products Administration (國家藥品監督管理局) (the "**NMPA**"), a department under the State Administration for Market Regulation (國家市場監督管理總局)(the "**SAMR**"), the National Health Commission (國家衛生健康委員會) (the "**NHC**") and the National Healthcare Security Administration (國家醫療保障局) (the "**NHSA**").

The NMPA serves as China's primary pharmaceutical regulator. It is responsible for overseeing nearly all critical stages of a drug's lifecycle, including non-clinical research and clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution and pharmacovigilance. The NMPA's Center for Drug Evaluation (國家藥品監督管理局藥品審評中心) (the "**CDE**") conducts technical evaluations of drug and biologic applications to assess safety and efficacy.

The NHC functions as China's principal healthcare regulator. It is primarily responsible for drafting national healthcare policies, regulating public health and medical services, managing the health emergency response system, coordinating healthcare reforms, and overseeing medical institutions and practitioners.

Established in May 2018, the NHSA is tasked with drafting and implementing policies, plans, and standards relating to medical insurance, maternity insurance, and medical assistance. It administers healthcare funds, formulates uniform medical insurance catalogs and payment standards on drugs, medical disposables, and healthcare services, and oversees the formulation and administration of bidding and tendering policies for drugs and medical disposables.

REGULATIONS IN RELATION TO CLINICAL TRIALS AND DRUG REGISTRATION

Drug registration refers to the regulatory process through which applicants seek approval for clinical trials, marketing licenses, re-registration, and other supplementary applications in accordance with legal procedures and relevant requirements. The NMPA reviews the safety, effectiveness, and quality controllability of the drug based on laws, regulations, and existing scientific knowledge, and decides whether to approve the application. Once a drug registration certificate is obtained, the applicant becomes a drug marketing authorization holders (the "**DMA Holders**"). The SAMR promulgated the Measures for the Administration of Drug Registration (the "**Registration Measures**") (《藥品註冊管理辦法》), which apply to drug development, registration, supervision, and administration activities within the PRC for the purpose of drug marketing.

Application for Clinical Trial

The CFDA released the Circular Concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》) in November 2015, which clarified the measures and policies regarding, among others, simplifying and accelerating the approval process of clinical trials, including but not limited to the adoption of a one-time umbrella approval procedure allowing the overall approval of all phases of a new drug's clinical trials, replacing the phase-by-phase application and approval procedure.

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 effective on May 1, 2017, the decision on the approval of clinical trials of drugs shall be made by the CDE from May 1, 2017.

After obtaining the clinical trial approval from the NMPA, the applicant must complete the clinical trial registration at the Drug Clinical Trial Information Platform for public disclosure in accordance with the Circular on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), which came into effect in September 2013. The applicant shall complete the initial registration of the trial within one month after obtaining the clinical trial approval to obtain an exclusive trial registration number, and then complete the subsequent information registration before the first patient is enrolled in the trial and submit the registration for public disclosure for the first time.

Conduct of Clinical Trials

After obtaining clinical trial approval, the applicant shall conduct clinical trials at qualified clinical trial institutions. The qualified clinical trial institution refers to institutions that have the conditions to conduct clinical trials in accordance with the requirements and technical guidelines set forth in the Regulations for the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which came into effect on December 1, 2019.

Clinical trials must be conducted in accordance with the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) promulgated by the NMPA and NHC on April 23, 2020 and effective on July 1, 2020, which stipulates the requirements for the procedures of conducting clinical trials, including pre-clinical trial preparation, trial protocols, protection of trial subjects' rights and interests, duties of researchers, sponsors and monitors, as well as data management and statistical analysis.

Acceptance of Foreign Clinical Trial Data

According to the International Multi-Center Clinical Trial Guidelines (Trial) (《國際多中心藥物臨床試驗指南(試行)》), which was issued by the CFDA on January 30, 2015 and became effective on March 1, 2015, the sponsor may conduct clinical trials simultaneously at multiple centers in multiple regions in accordance with the same clinical trial protocol, and may also conduct regional clinical trials simultaneously at multiple centers in different countries within a region in accordance with the same clinical trial protocol. If the applicants plan to use the data derived from international multi-center clinical trials for approval of drug registration in China, such international multi-center clinical trials shall comply with the provisions concerning clinical trials in the Registration Measures. When planning and implementing international multi-center clinical trials in China, the sponsor shall comply with the Drug Administration Law, the Implementation Regulations, the Registration Measures and other related laws and regulations, implement the Good Clinical Practice (《臨床試驗質量管理規範》) provided by the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (人用藥品註冊技術國際協調會議), and meet the legal and regulatory requirements of the corresponding countries.

The NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data (《接受藥品境外臨床試驗數據的技術指導原則》) in July 2018, as one of the implementing rules for the Innovation Opinions, which provides that overseas clinical data can be submitted for drug marketing registration applications in China. Such applications can be in the form of waivers to

China-based clinical trials, bridging trials and direct drug marketing registration. According to the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data, sponsors may use the data of foreign clinical trials to support drug marketing registration in China, provided that sponsors must ensure the authenticity, integrity, accuracy and traceability of foreign clinical trial data and such data must be obtained consistent with the relevant requirements under the Good Clinical Practice. Moreover, sponsors shall ensure the scientific design of overseas clinical trials, the compliance with clinical trial quality management system requirements, and the accuracy and integrity of statistical analysis of data.

New Drug Registration

Pursuant to the Registration Measures, upon completion of clinical trials, determination of quality standards, completion of validation of commercial-scale production processes and completion of other related preparation work, the applicant may apply with the NMPA for the marketing authorization. The NMPA then determines whether to approve the application according to applicable laws and regulations. The applicant must obtain the marketing authorization for a new drug before the drug can be manufactured and sold in the China market. According to the Registration Measures, the holders of any of the following drugs can apply for conditional approval of such drugs: (i) drugs which are used for the treatment of severe life-threatening diseases currently lacking effective treatment and the data of clinical trials can confirm their efficacy and forecast their clinical value; (ii) drugs which are urgently needed for public health and data of clinical trials can demonstrate their efficacy and forecast their clinical value; and (iii) vaccines which are urgently needed to deal with major public health emergencies or other vaccines which the NHC deems to be urgently needed, the benefits of both of which are assessed to be outweigh the risks.

The CFDA released the Circular Concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》) in November 2015, which clarified the measures and policies regarding simplifying and accelerating the approval process of clinical trials, and provided that a fast drug registration pathway can be available for the applications for certain drugs, including the registration of innovative new drugs treating HIV, cancer, serious infectious diseases and orphan diseases, and registration of pediatric drugs, etc.

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

The Registration Measures have incorporated the previous reform in respect of the accelerated approval for clinical trial and drug marketing registration and introduces four procedures for expedited marketing registration of drugs, which are procedures for breakthrough therapeutic drugs, procedures for conditional approval, procedures for prioritized reviews and approval, and procedures for special examination and approval.

According to the Registration Measures, the applicant may submit an application for drug marketing registration to the CDE upon completion of relevant research on pharmacy, pharmacology, toxicology and drug clinical trials, determination of the quality standards of the drug, validation of commercial-scale production processes and preparation for acceptance of verification and inspection conducted by a professional technical institution designated by the competent NMPA. The CDE will organize pharmaceutical, medical and other technicians to conduct comprehensive review of the safety, efficacy and quality controllability, among others, of the drug according to the application materials submitted by the applicant, the results of the verification and inspection conducted by a professional technical institution, etc. If the comprehensive review conclusion is affirmative, the drug shall be approved for marketing and a drug registration certificate will be issued containing the information of the drug approval number, the MAH and the manufacturer.

The MAH System

Pursuant to the Drug Administration Law, China implements the MAH system. Under the Drug Administration Law and the Registration Measures, the holder of a Drug Registration Certificate shall be an MAH. An MAH may manufacture and sell drugs or engage a pharmaceutical manufacturing enterprise to manufacture drugs and/or a pharmaceutical distribution enterprise to sell drugs.

An MAH shall be responsible for non-clinical research, clinical trials, manufacturing and business operation, post-marketing research, adverse reaction monitoring and reporting and handling.

Where an MAH is an overseas enterprise, its designated domestic enterprise shall perform the obligations of an MAH and jointly assume the responsibilities of an MAH.

REGULATION IN RELATION TO MEDICAL DEVICES

Pursuant to the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) last amended by the State Council on December 6, 2024 and came into effect on January 20, 2025, in the PRC, medical devices are classified into three categories based on the degree of risk. Class I medical devices refer to those devices with low risk and whose safety and effectiveness can be ensured through routine administration. Class II medical devices refer to those devices with medium risk and whose safety and effectiveness should be strictly controlled. Class III medical devices refer to those devices with high risk and whose safety and effectiveness must be strictly controlled with special measures. The medical devices of Class I shall be subject to product filing administration, and the medical devices of Class II and Class III shall be subject to product registration administration.

LAWS AND REGULATIONS IN RELATION TO DRUG MANUFACTURING ENTERPRISE AND DRUG MANUFACTURING

Drug Manufacturing License

According to the PRC Drug Administration Law, which was promulgated by the SCNPC in September 1984 and last amended in August 2019, a drug manufacturing enterprise is required to obtain a Drug Manufacturing License from the relevant provincial counterpart of the NMPA. According to the Measures for the Supervision and Administration of Drug Production (《藥品生產監督管理辦法》), which was promulgated by the CFDA on August 5, 2004 and last amended on January 22, 2020, a Drug Manufacturing License is valid for five years. It may be renewed if the holder submits at least six months before its expiration and receives approval from the provincial counterpart of the NMPA that originally issued the license.

Good Manufacturing Practice ("GMP")

Prior to December 1, 2019, in accordance with the provisions of the Administrative Measures for the Certification of Good Manufacturing Practices issued by the CFDA in August 2011, which have since been repealed, the establishment of a new drug manufacturer, construction of new production premises for a drug manufacturer or production of new dosage forms were required to submit an application for Good Manufacturing Practice certification (GMP certification) to the drug regulatory authority in accordance with relevant provisions. If the Good Manufacturing Practices were satisfied, a GMP certificate would be issued. Pursuant to the Announcement on the Relevant Issues Concerning the Implementation of the Drug Administration Law of the PRC (《關於貫徹實施〈中華人民共和國藥品管理法〉有關事項的公告》), promulgated by the NMPA on November 29, 2019, and the Drug Administration Law, the GMP and Good Supply Practice (GSP) certifications have been cancelled, applications for GMP and GSP certifications are no longer accepted, and GMP and GSP certificates are no longer issued. When engaging in drug manufacturing activities, a manufacturer shall comply with the GMP and establish a sound GMP management system, to ensure that the entire process of drug manufacturing consistently meets 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, and principal person in charge of a drug manufacturer are fully responsible for the drug manufacturing activities of the enterprise.

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

Contract Manufacturing of Drugs

Pursuant to the Administrative Regulations for the Contract Manufacturing of Drugs (《藥品委托生產監督管理規定》), which was issued by the NMPA in August 2014, a drug manufacturer in China that holds a drug marketing authorization but temporarily lacks manufacturing conditions due to technology upgrades or insufficient manufacturing capabilities can entrust the production of that drug to another drug manufacturer in China. Such contract manufacturing arrangements require approval by the provincial drug regulatory department of the NMPA.

The PRC Drug Administration Law specifies that the DMA Holders may either produce drugs themselves or entrust their production to other drug manufacturers. DMA Holders and the commissioned manufacturers must enter into an entrustment agreement and a quality agreement, and they are required to strictly fulfill the obligations under these agreements.

The Measures for the Supervision and Administration of Drugs further implement the drug marketing authorization holder system as stipulated in the PRC Drug Administration Law. DMA Holders who entrust others to manufacture preparations must enter into an entrustment agreement and a quality agreement with a qualified drug manufacturing enterprise. They must submit these agreements, along with the actual manufacturing site application materials, to the competent drug administrative authority to apply for a Drug Manufacturing License.

LAWS AND REGULATIONS IN RELATION TO DRUG OPERATION

Drug Operation

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

According to the Measures for the Supervision and Administration of Drug Quality in Operation and Usage (《藥品經營和使用品質監督管理辦法》), promulgated on September 27, 2023 and coming into effect on January 1, 2024, a Drug Operation Permit is valid for five years. Each holder of the Drug Operation Permit must apply for an extension of its permit between six and two months prior to expiration.

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

Drug Price

Pursuant to the PRC Drug Administration Law, for drug products with market-regulated prices, the DMA holder, the drug manufacturer, the drug distributor and medical institution shall set prices based on principles of fairness, reasonableness, integrity and trustworthiness, ensuring quality for value. This is intended to provide drug users with reasonably priced products. These entities must also comply with drug price administration requirements issued by the State Council's pricing authorities, determining and clearly marking the retail prices of drug products.

Pursuant to the Opinions on Promoting Drug Price Reform (《推進藥品價格改革意見》), which were jointly promulgated by the NDRC, the National Health and Family Planning Commission, the Ministry of Human Resources and Social Security of the PRC (the "**MOHRSS**"), the MIIT, the Ministry of Finance of the PRC, the MOFCOM and the CFDA and came into effect in June 2015, the PRC government will no longer set drug prices, except for narcotic drugs and first-class psychotropic drugs.

Drug Advertisements

The PRC Advertising Law (《中華人民共和國廣告法》), most recently amended and effective as of April 29, 2021, outlines the regulatory framework for the advertising industry. Advertisers, advertising agents and advertising publishers are required to ensure that the contents of the advertisements they prepare or distribute are true and in full compliance with applicable laws and regulations.

For drug advertisements, the advertisement contents shall be examined by the relevant authorities prior to publication. Pursuant to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) promulgated by SAMR on December 24, 2019 and effective as of March 1, 2020, advertisements for drugs shall not contain any false or misleading contents. Advertisers shall be responsible for the veracity and legitimacy of the contents of advertisements for drugs, medical devices, health food and formula food for special medical purposes.

Pursuant to the Measures Regarding the Administration of Drug Information Service through the Internet (《互聯網藥品信息服務管理辦法》), promulgated by the CFDA and effective as of July 8, 2004, and subsequently amended with effect from November 17, 2017, Internet drug information services, referring to that of providing medical information (including medical devices information) services to Internet users through the Internet, are classified into two categories, for-profit services and non-profit services. Any website intending to provide drug information services through Internet, shall be approved by the provincial-level NMPA before applying for an operation permit or filing a record with the authority in charge of information industry under the State Council or the provincial-level administration of telecommunication.

OTHER LAWS AND REGULATIONS IN RELATION TO MEDICAL INDUSTRY

Coverage of the National Medical Insurance Program

The national medical insurance program was first adopted under the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program (《國務院關於建立城鎮職工基本醫療保險制度的決定》) issued by the State Council on December 14, 1998. This program requires all employers in urban cities to enroll their employees in the basic medical insurance program, with insurance premiums jointly contributed by the employers and employees. On July 10, 2007, the State Council issued the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance (《國務院關於開展城鎮居民基本醫療保險試點的指導意見》), which expanded the program's coverage to include urban residents in the pilot districts, allowing them to voluntarily join urban resident basic medical insurance. In addition, on January 3, 2016, the State Council issued the Opinions of the State Council on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents (《國務院關於整合城鄉居民基本醫療保險制度的意見》), requiring the integration of the

urban resident basic medical insurance and the new rural cooperative medical care system. This integration established a unified basic medical insurance system covering all urban and rural residents, except for rural migrant workers and individuals in flexible employment arrangements who participate in the basic medical insurance for urban employees.

National Essential Drug List

On August 18, 2009, the Ministry of Health of the PRC and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the National Essential Drug List (the "**NEDL**") (《國家基本藥物目錄管理辦法(暫行)》), which was amended on February 13, 2015, along with the Guidelines on the Implementation of the National Essential Drug List System (《關於建立國家基本藥物制度的實施意見》). These measures and guidelines aim to promote the sale of essential medicines at fair prices in the PRC and ensure equal access to the drugs listed in the NEDL for the general public in the PRC. On September 30, 2018, the NHC promulgated the NEDL (2018 edition) (《國家基本藥物目錄(2018年版)》), replacing the NEDL (2012 edition) (《國家基本藥物目錄(2012年版)》) which was promulgated on March 13, 2013. According to these regulations, basic healthcare institutions funded by the PRC government are required to store and use drugs listed in NEDL. The drugs listed in NEDL shall be purchased by centralized tender process and subject to price adjustments by the NDRC. All remedial drugs in the NEDL are listed in the National Drug Catalog for Basic Medical Insurance, Work-related 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》), or the National Reimbursement Drug List (the "**NRDL**") and the entire purchase price of such drugs is entitled to reimbursement.

Medical Insurance Catalog

According to the Interim Measures for the Administration of Use of Drugs Covered by the Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) or the NRDL Administrative Measures, which were promulgated by the NHSA, on July 30, 2020 and took effect on September 1, 2020, the scope of drugs covered by the basic medical insurance shall be administered through a reimbursement drug list.

The NRDL, which was promulgated by the NHSA and the MOHRSS and took effect on January 1, 2025 and last amended on January 6, 2025, sets forth the payment standard for pharmaceutical products under the basic medical insurance, work-related injury insurance and maternity insurance funds. The local government shall strictly implement the NRDL and shall not adjust the contents contained in the NRDL at their own discretion. Medicines listed in the NRDL are divided into two parts, List A and List B. List A drugs are widely used clinical treatments with good efficacy and lower prices compared to similar drugs, while List B drugs are clinical treatments with good efficacy and slightly higher prices compared to List A drugs.

According to the NRDL Administrative Measures, a Provincial Reimbursement Drug List ("**PRDL**") must be made by the provincial healthcare security authorities. Patients purchasing List A drugs can directly obtain reimbursement under the basic medical insurance program. Patients purchasing List B drugs shall pay a certain percentage of the purchase price first and then obtain reimbursement under the basic medical insurance program.

Two-Invoice System

According to the Implementing Opinions on Promoting the "Two-Invoice System" for Drug Procurement By Public Medical Institutions (For Trial Implementation) (《關於在公立醫療機構藥品採購中推行"兩票制"的實施意見(試行)》) issued on December 26, 2016, or the Two-Invoice System Notice, the Two-Invoice System refers to a system that requires one invoice to be issued from pharmaceutical manufacturers to pharmaceutical distributors and the other invoice to be issued from pharmaceutical distributors to medical institutions. According to the Dual Invoicing System Notice and the Several Opinions of the General Office of the State Council on Further Reform and Improvement in Policies of Drug Production, Circulation and Use (《國務院辦公廳關於進一步改革完善藥品生產流通使

用政策的若干意見》) issued on January 24, 2017, the Two-Invoice System would be promoted in pilot provinces (autonomous regions and municipalities directly under the central government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis.

Centralized Procurement and Bidding Process

On May 20, 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 (Yibaohan [2024] No. 25) (《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》(醫保函[2024]25號)), providing guidance on centralized procurement practices, aiming to aggressively promote the centralized procurement of drugs and high-value medical consumables organized by national authorities. It emphasizes the need to strengthen coordination among regions, guide and promote local governments to conduct centralized procurement in a regulated manner, and support the targeted expansion of the range of drugs and medical consumables under centralized procurement. 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 centralized procurement, where the provinces organize the centralized 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 May 14, 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 Centralized Procurement of Pharmaceuticals in 2024 (Yibaobanfa [2024] No. 8) (《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》(醫保辦發[2024]8號)), 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. The goal is to achieve linkage and coordinated progress at the national and local levels.

Rare Disease Scope

On May 11, 2018, the NHC and the NMPA jointly issued the Notice on the Announcement of the First Batch of Rare Diseases List (《關於公佈第一批罕見病目錄的通知》), including 121 rare diseases. On July 10, 2025, the NHC issued the Notice on Printing and Distributing the Therapeutic Guidelines for 86 Rare Diseases such as Cartilage Dysplasia (2025 Edition) (《關於印發軟骨發育不全等86個罕見病病種診療指南(2025年版)的通知》). According to the Notice on Printing and Distributing the Work Program for the Preparation of the Rare Diseases List (《關於印發罕見病目錄製訂工作程序的通知》) issued by the National Health Commission on May 28, 2018. The identification of rare diseases should meet the following four criteria simultaneously: (i) the disease has a low incidence or prevalence rate in the People's Republic of China and abroad; (ii) the disease has a significant impact on the patients and their families; (iii) there is a clear diagnostic method; (iv) the disease can be treated or intervened in an economically feasible manner, or if there are no effective treatment or intervention measures, the disease has been included in the national scientific research projects. In principle, the update time of the list should not be less than 2 years. After certain drugs for rare diseases are listed in the national rare disease list, the company may meet the conditions for the NMPA to prioritize the review and approval of new drugs.

In recent years, the PRC's pharmaceutical industry has undergone multiple policy reforms and implementations, such as adjustments to the NRDL and PRDL, national volume-based procurement ("**National VBP**"), the two-invoice system, and centralized procurement and bidding process reforms. See "— Other Laws and Regulations in Relation to Medical Industry" for more details. While these reforms have aimed to promote the long-term healthy development of the industry, they have exerted significant short-term pressure on pharmaceutical companies, including us. As of the date of the document, among our major products, five of our acquired products and 13 of our CSO products are included in the NRDL.

We primarily sell our products to independent distributors through a buy-sell model. Apart from contractual safeguards required by law and market practices, we do not retain ownership or day-to-day control over downstream inventory or resale activities and typically enter into standard buy-sell agreements with our distributors. In light of the "Two-Invoice System" implementation, for distributors selling our products to public medical institutions, the law generally prohibits them from appointing sub-distributors. However, for sales to private medical institutions and pharmacies, distributors may collaborate with sub-distributors. We do not have contractual relationships with sub-distributors, nor does it directly manage them or verify their precise numbers. Instead, our distributors are responsible for supervising their respective sub-distributors.

Consequently, the substantive impact of the Two-Invoice System on our business operations is primarily reflected in two aspects. First, in the public medical institution channel, product coverage and distribution fulfillment must rely on distribution arrangements that comply with the Two-Invoice System requirements, thereby imposing stricter compliance demands on distributor selection, regional coverage strategies, and distribution management. Second, in the private medical institution and retail terminal channels, distributors may adopt sub-distribution collaboration models to expand coverage. However, we still need to ensure indirectly the channels' compliance and service quality through contractual constraints on distributors and ongoing assessments.

Furthermore, regarding financial performance, the Two-Invoice System itself does not directly determine whether products are included in the national medical insurance system or centralized procurement programs. However, it may indirectly affect the sales expense structure, coverage efficiency, and payment collection pace through channel structure adjustments, distribution management and compliance investments, and changes in fulfillment arrangements in the public channel. The extent of such impacts will depend on the terminal sales structure of our products, the compliance execution level of the distribution network, and differences in policy implementation across provinces.

To ensure ongoing compliance with relevant rules, regulations, and policies, we have implemented internal control measures to monitor the implementation of the Two-Invoice System in each province. These measures include providing training to management and commercial teams, requiring commercial teams to adjust distribution strategies promptly based on the latest developments in Two-Invoice System implementation, and suspending or terminating distribution agreements with distributors if violations are identified, along with potentially taking other legal actions.

Products included in centralized procurement are typically those already covered by the NRDL, high-volume products, or mature products facing intense homogeneous competition. Homogeneous competition refers to situations where mature products have been on the market for a long time, and many local manufacturers have developed numerous generic versions with the same chemical name. In contrast, innovative or exclusive products do not face such homogeneous competition. Most of our major products are innovative drugs, which are generally not affected by such procurement policies. See "Business — Overview — Our Diversified and Differentiated Product Portfolio — Our Major Products and Pipeline of Innovative Products" for more details. For some of our mature non-innovative products, we can effectively manage potential procurement risks and stabilize sales performance by leveraging the products' strong brand recognition, reliable quality, and our innovative multi-channel marketing models. As of the Latest Practicable Date, none of our major products have been included in centralized procurement in China.

As advised by our PRC Legal Advisors, during the Track Record Period and up to the Latest Practicable Date, we had not been subject to any legal proceedings or penalties by any competent authorities in relation to the compliance of the NRDL and PRDL, the "Two-Invoice System" and centralized procurement and bidding process.

LAWS AND REGULATIONS IN RELATION TO ANTI-BRIBERY

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by the SCNPC, as amended and effective as of October 15, 2025, 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 State Administration for Industry and Commerce 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 mentioned above may be subject to administrative punishment or criminal liability depending on the seriousness of the case.

According to the Regulations on the Establishment of Adverse Records with Respect to Commercial Briberies in the Medicine Purchase and Sales Industry (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》) promulgated in January 2007 and amended in December 2013, where a manufacturer of drugs, medical devices and medical disposables, an enterprise, an agency or an individual offers staff of a medical institution any items of value or other benefits, the enterprise should be listed in the adverse records with respect to commercial bribery in the event of the following circumstances: (1) where the act has constituted a crime of bribery as determined by the ruling of a people's court, or where the circumstance of crime is not serious enough for the imposition of criminal punishment and criminal punishment is exempted as decided by the people's court in accordance with the Criminal Law; (2) where the circumstance of the crime of bribery is minor and the relevant people's procuratorate has decided not to lodge a prosecution; (3) where a discipline inspection and supervision authority has initiated a case of bribery and conducted investigation, and punishment has been imposed in accordance with the law; (4) where administrative penalties against the act of bribery have been imposed by, *inter alia*, the finance administration, the SAMR, the NMPA; (5) any other circumstances specified by laws, regulations and rules.

If medical production and operation enterprises are listed into the Adverse Records of Commercial Briberies for the first time, their products shall not be purchased by public medical institutions, and medical and health institutions receiving financial subsidies in the local province for two years since publication of the record, and public medical institution, and medical and health institutions receiving financial subsidies in other provinces shall lower their rating in bidding or purchasing process. If medical production and operation enterprises are listed into the Adverse Records of Commercial Bribery for twice or more in five years, their products shall not be purchased by public medical institutions, and medical and health institutions receiving financial subsidies nationwide for two years since publication of the record.

According to the Guiding Opinions on Establishment of the Trustworthiness Evaluation System for Drug Prices and Procurement by Bidding (《關於建立醫藥價格和招採信用評價制度的指導意見》) promulgated by the NHSA in August 2020 and taking effect simultaneously, the NHSA would establish a catalog of dishonest matters involving drug prices and procurement by bidding, and the kickbacks or other improper benefits in the purchase and sale of drugs, tax-related violations of laws, monopolistic practices, improper pricing practices, disruption of the order of centralized procurement, malicious breach of contracts and other malpractices, will be included in such catalog. Provincial centralized procurement agencies shall assess and rate the dishonest conduct of pharmaceutical enterprises into four levels: general, medium, serious and particularly serious, based on the nature, circumstances, effectiveness and impact of such dishonest conduct. Further, the provincial centralized procurement agencies shall, according to the trustworthiness ratings of pharmaceutical enterprises, take punitive measures, such as warnings and admonishments, restriction on market entry, and release of dishonest information.

LAWS AND REGULATIONS IN RELATION TO ENVIRONMENT PROTECTION

Environmental Protection Law

Pursuant to the Environmental Protection Law of the People's Republic of China (《中華人民共和國環境保護法》) promulgated by the SCNPC on December 26, 1989, and amended on April 24, 2014, with effect from January 1, 2015, any entity which discharges or will discharge pollutants during the course of operations or other activities must implement effective environmental protection safeguards

and procedures to control and properly treat waste gas, wastewater, waste residue, dust, malodorous gases, radioactive substances, noise, vibrations, electromagnetic radiation, and other hazards produced during such activities.

Environment Impact Assessment Law

According to the Environmental Impact Assessment Law of PRC (《中華人民共和國環境影響評價法》) (the "**Environmental Impact Assessment Law**"), which was promulgated by the SCNPC on October 28, 2002, amended on July 2, 2016 and December 29, 2018, construction entities shall implement the following procedures for their construction projects in accordance with the Category-based Administration Directory for the Environmental Impact Assessment of Construction Projects (《建設項目環境影響評價分類管理名錄》): (i) for projects with potentially significant environmental impacts, an environment impact report shall be prepared to provide a comprehensive assessment of their environmental impacts; (ii) for projects with potentially minor environmental impacts, an environmental impact statement shall be prepared to provide an analysis or specialized assessment of their environmental impacts; and (iii) for projects with very small environmental impacts so that an environmental impact assessment is not required, an environmental impact registration form shall be filled out. The construction project at issue may not proceed if its environmental impact assessment documents fail to pass the review of the competent authority in accordance with the laws and regulations or are disapproved after the review.

According to the Category-based Administration Directory for the Environmental Impact Assessment of Construction Projects (Edition 2021) (《建設項目環境影響評價分類管理名錄(2021年版)》) promulgated by the Ministry of Ecology and Environment (the "**MEE**"), construction entities shall, in accordance with the provisions of this Directory, respectively prepare environmental impact reports or environmental impact statements on construction projects, or complete environmental impact registration forms on construction projects. The construction projects not covered by this Directory will not be included in the administration of environmental impact assessment of construction projects.

Pollutant Discharge Licensing

Pursuant to the Administrative Measures for Pollutant Discharge Licensing (《排污許可管理辦法》) promulgated on January 10, 2018 and latest revised on July 1, 2024 by the MEE, enterprises and public institutions as well as other producers and operators included in the Catalogue of Classified Administration of Pollutant Discharge License for Stationary Pollution Sources shall apply for and obtain a pollutant discharge license within a prescribed time limit. Any enterprise that fails to obtain a pollutant discharge license as required shall not discharge pollutants.

According to the Catalogue of Classified Administration of Pollutant Discharge License for Stationary Pollution Sources (2019 Version) (《固定污染源排污許可分類管理名錄(2019年版)》) issued by the MEE on December 20, 2019 and effective on the same day, key management, simplified management and registration management of pollutant discharge permits are implemented according to factors such as the amount of pollutants generated, the amount of emissions, the degree of impact on the environment, etc., and only pollutant discharge entities that implement registration management do not need to apply for a pollutant discharge permit.

In addition, the Regulation on Pollutant Discharge Permit Administration (《排污許可管理條例》), issued by the State Council on January 24, 2021 and effective on March 1, 2021, stipulates that the review, decision and information disclosure of pollutant discharge licenses shall be handled through the national pollutant discharge license management information platform. A pollutant discharge license is valid for 5 years, and renewal must be applied for 60 days before expiration.

LAWS AND REGULATIONS IN RELATION TO FIRE PREVENTION

Pursuant to the Administrative Measures on the Construction Permits for Construction Projects (《建築工程施工許可管理辦法》) promulgated by the Ministry of Housing and Urban-Rural Development on June 25, 2014 and most recently amended on March 30, 2021, the construction entity

shall apply for the Construction Permit before commencing the construction and decoration of all types of buildings and their ancillary facilities, the installation of supporting lines, pipelines and equipment, and the construction of municipal infrastructure projects in cities and towns within the territory of China, except where the investment amount of the construction project is below RMB300,000 or the construction area of the construction project is below 300 m^2. With respect to each construction project that commences without a Construction Permit, the construction entity may be ordered to suspend construction, take remedial measures within a prescribed period, and may be fined 1% to 2% of the contract price of the construction project, while the contractor may be subject to a fine of up to RMB30,000.

According to the Fire Prevention Law of the People's Republic of China (《中華人民共和國消防法》) promulgated by the SCNPC on April 29, 1998, and most recently amended on April 29, 2021, and the Interim Provisions on the Administration of Examination and Acceptance of Fire Prevention Design of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) promulgated by the Ministry of Housing and Urban-Rural Development on April 1, 2020 and last amended effective on October 30, 2023, fire acceptance should be done for special construction projects which meet certain conditions, while fire filing should be conducted for other types of construction projects. The construction project that fails to complete the required as-built acceptance check on fire prevention shall be ordered by the relevant governmental authorities to close down and shall be subject to a fine of RMB30,000 up to RMB300,000.

On August 12, 2015, the Ministry of Public Security promulgated Eight Measures to Deepen Reform and Serve Economic and Social Development (《公安消防部門深化改革服務經濟社會發展八項措施》), or the Eight Measures. According to the Eight Measures, construction projects with an investment of less than RMB300,000 or a construction area of less than 300 m^2 are not required to obtain the as-built acceptance check on fire prevention or complete fire safety filing, and competent authorities of housing and urban-rural development at the provincial level may formulate detailed implementation rules pursuant to these measures.

LAWS AND REGULATIONS IN RELATION TO INTELLECTUAL PROPERTY

Patent Law

According to the Patent Law of the PRC (《中華人民共和國專利法》) promulgated by the SCNPC on March 12, 1984 and currently effective from June 1, 2021, the China National Intellectual Property Administration (CNIPA) is responsible for administering patent law in the PRC. The patent administration departments of provincial, autonomous regions or municipal governments are responsible for administering patent law within their respective jurisdictions. The Chinese patent system adopts a first-to-file principle, which means that when more than one person files different patent applications for the same invention, only the person who files the application first is entitled to obtain a patent of the invention. The protection period is twenty years for an invention patent and ten years for a utility model patent and fifteen years for a design patent, commencing from their respective application dates.

Trademark Law

Trademarks are protected by the PRC Trademark Law (《中華人民共和國商標法》) which was promulgated by the SCNPC on August 23, 1982 and last amended in 2019, as well as by the Implementation Regulations of the PRC Trademark Law (《中華人民共和國商標法實施條例》) promulgated by the State Council in 2002 which was last amended on April 29, 2014. The Trademark Office under the SAMR handles trademark registrations. The Trademark Office grants a ten-year term to registered trademarks and the term may be renewed for another ten-year period upon request by the trademark owner. A trademark registrant may license its registered trademarks to another party by entering into trademark license agreements, which must be filed with the Trademark Office for its record. As with patents, the Trademark Law has adopted a first-to-file principle with respect to trademark registration.

Copyright law

Pursuant to the Copyright Law of the PRC (《中華人民共和國著作權法》), effective in June 1, 1991 and latest amended on November 11, 2020 and became effective on June 1, 2021, copyrights include personal rights such as the right of publication and that of attribution as well as property rights such as the rights of reproduction and distribution. Reproducing, distributing, performing, projecting, broadcasting or compiling a work or communicating the same to the public via an information network without permission from the owner of the copyright therein, unless otherwise provided in the Copyright Law of the PRC, constitutes infringements of copyrights.

Pursuant to the Computer Software Copyright Protection Regulations (《計算機軟件保護條例》) promulgated on June 4, 1991 and latest amended on January 30, 2013, a software copyright owner may complete registration formalities with a software registration authority recognized by the State Council's copyright administrative department. A software copyright owner may authorize others to exercise that copyright, and is entitled to receive remuneration.

Regulations on Domain Names

The Ministry of Industry and Information Technology (the "**MIIT**") promulgated the Administrative Measures on Internet Domain Names (《互聯網域名管理辦法》) (the "**Domain Name Measures**") on August 24, 2017, which took effect on November 1, 2017. Pursuant to the Domain Name Measures, the MIIT oversees the administration of PRC internet domain names. The domain name registration follows a first-to-file principle.

LAWS AND REGULATIONS IN RELATION TO FOREIGN EXCHANGE

Under the PRC Foreign Currency Administration Rules (《中華人民共和國外匯管理條例》) promulgated by the State Council on January 29, 1996 and last amended on August 5, 2008 and various regulations issued by the State Administration of Foreign Exchange (the "**SAFE**") and other relevant PRC government authorities, RMB is generally freely convertible for payments of current account items, such as trade and service-related foreign exchange transactions and dividend payments, but not freely convertible for capital account items, such as direct investment, loan, or investment in securities outside Chinese mainland, unless the prior approval by the SAFE or its local counterparts is obtained.

On March 30, 2015, the SAFE promulgated Notice on Reforming the Mode of Management of Settlement of Foreign Exchange Capital of Foreign-Funded Enterprises (《關於改革外商投資企業外匯資本金結匯管理方式的通知》) (the "**Circular 19**"), which came into effect on June 1, 2015. According to Circular 19, the foreign exchange capital of FIEs shall be subject to the discretional foreign exchange settlement (the "**Discretional Foreign Exchange Settlement**") and its proportion is temporarily determined as 100%. Furthermore, Circular 19 stipulates that the use of capital by FIEs shall follow the principles of authenticity and self-use within the business scope of enterprises. The capital of an FIE and capital in RMB obtained by the FIE from foreign exchange settlement shall not be used for certain purposes as prescribed in the Circular 19. On June 9, 2016, the SAFE promulgated the Circular on Reforming and Regulating Policies on the Management of the Settlement of Foreign Exchange of Capital Accounts (《關於改革和規範資本項目結匯管理政策的通知》) (the "**SAFE Circular 16**"). The SAFE Circular 16 unifies policies on discretionary settlement of foreign exchange receipts under capital accounts of domestic institutions.

In accordance with the Circular on Further Promoting Cross-border Trade and Investment Facilitation (Hui Fa [2019] No. 28) (《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》) (匯發[2019]28號), which was issued and came into effect on October 23, 2019 by the SAFE and was amended on December 4, 2023, foreign-invested enterprise engaged in non-investment business are permitted to settle foreign exchange capital in RMB and make domestic equity investments with such RMB funds according to laws and regulations under the condition that the current Special Administrative Measures (Negative List) for Foreign Investment Access are not violated and the relevant domestic investment projects are true and compliant.

LAWS AND REGULATIONS IN RELATION TO FOREIGN INVESTMENT

Company Law

Companies established and businesses operating in the PRC are subject to the PRC Company Law, which was promulgated by the SCNPC on December 29, 1993, was last amended on December 29, 2023 and which became effective on July 1, 2024. The PRC Company Law, regulated by SAMR, MOFCOM, and their local counterparts, provides general regulations for companies' set up and operation in the PRC including the FIEs. Unless otherwise provided in the PRC Foreign Investment Law (《中華人民共和國外商投資法》), the provisions in the PRC Company Law shall prevail.

Foreign Investment Law

The term "foreign investments", according to the Foreign Investment Law, refers to investment activities within the PRC directly or indirectly conducted by foreign natural persons, enterprises, or other organizations (the "**foreign investors**"), including the following circumstances: (i) a foreign investor, alone or jointly with any other investors, forms a foreign-invested company within the PRC; (ii) a foreign investor acquires any shares, equities, portion of property, or other similar interests in a PRC domestic enterprise; (iii) a foreign investor, alone or jointly with any other investors, invests in any new PRC domestic project; and (iv) the investments in any other manner as specified by laws, administrative regulations or provisions regulated by the State Council. The Foreign Investment Law stipulates that the PRC implements system of pre-establishment national treatment and negative list foreign investment. The Special Administrative Measures (Negative List) for the Access of Foreign Investment (2024 Version) (《外商投資准入特別管理措施(負面清單)(2024年版)》, the "**Negative List**"), which would be issued by or upon approval by the State Council, refers to special administrative measures for access of foreign investment in specific fields in China. A foreign investor shall not invest in any field prohibited from foreign investment under the negative list. A foreign investor shall meet the investment conditions stipulated under the negative list for any restricted fields under the negative list. For fields not mentioned in such negative list, there shall be equal treatment of domestic and foreign investments. Foreign-invested enterprises can raise funds through public issuance of stocks, corporate bonds, and other securities in accordance with the law.

LAWS AND REGULATIONS IN RELATION TO CYBER SECURITY AND DATA PROTECTION

On November 7, 2016, the SCNPC promulgated the Cybersecurity Law (《網絡安全法》), which was newly revised on October 28, 2025, and is scheduled to take effect on January 1, 2026. The Cybersecurity Law requires the adoption of necessary technical and other measures to ensure cybersecurity and maintain stable network operations. It also mandates effective responses to cybersecurity incidents and the safeguarding of network data's integrity, confidentiality, and availability. The Cybersecurity Law regulates network operation security and network information security. It includes provisions for tiered network security protection, state security review, personal information protection, data security and safeguards, cybersecurity and data security emergency response plans, and reporting obligations.

On June 10, 2021, the SCNPC promulgated the Data Security Law of the PRC (《中華人民共和國數據安全法》), which took effect on September 1, 2021. The Data Security Law of the PRC sets forth a comprehensive regulatory framework for data security, detailing various foundational data protection management systems. It mandates the establishment of a data categorization and classification system, enforces stricter management measures for important data and national core data. The Data Security Law also stipulates several key obligations for data security protection. These include establishing a robust data security management system throughout the entire data lifecycle, requiring enhanced risk monitoring and the implementation of remedial measures upon the discovery of data security defects, bugs, or other risks, and establishing a data security emergency response mechanism.

On December 28, 2021, the Cyberspace Administration of China (the "**CAC**") and other twelve PRC regulatory authorities jointly revised and promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the "**Cyber Review Measures**"), which came into effect on February 15, 2022.

The Cyber Review Measures stipulate that, among others, (i) when the purchase of network products and services by a critical information infrastructures operator (the "**CIIO**") or the data processing activities conducted by a network platform operator affect or may affect national security, a cybersecurity review shall be conducted pursuant to the Cyber Review Measures; (ii) an application for cybersecurity review shall be made by an issuer who is a network platform operator holding personal information of more than one million users before such issuer applies to list its securities abroad; and (iii) the relevant PRC Governmental Authorities may initiate cybersecurity review if such Governmental Authorities determine that the issuer's network products or services, or data processing activities affect or may affect national security. As of the Latest Practicable Date, we had not received any notification from the relevant competent or regulatory authorities that we had been determined to be a critical information infrastructure operator or network platform operators engaging in data processing activities that affect or may affect national security.

On September 24, 2024, the Administration Regulations on Cyber Data Security (《網絡數據安全管理條例》) (the "**Data Security Regulations**") was promulgated by the State Council, which came into effect on January 1, 2025. The Data Security Regulations reiterate and refine the general regulations for cyber data processing activities, rules of personal information protection, important data security protection, cyber data cross-border transfer management, and the responsibilities of online platform service providers. In particular, the Data Security Regulations provide that cyber data processors whose cyber data processing activities affect or may affect national security shall be subject to national security review in accordance with the relevant regulations. However, the Data Security Regulations provide no further explanation or interpretation for the criteria on determining the risks that "affect or may affect national security". Additionally, since the Data Security Regulations are still relatively new, the interpretation and implementation of these regulations may further evolve and develop.

On August 20, 2021, the SCNPC promulgated the Personal Information Protection Law (《個人信息保護法》), which took effect on November 1, 2021. The Personal Information Protection Law regulates personal information protection and defines the principles for its processing. It emphasizes the lawful, fair, and necessary processing of personal information, ensuring transparency and accountability. The law establishes specific rules for obtaining consent, handling sensitive personal information, providing special protection for the personal information of minors under the age of fourteen, conducting personal information protection impact assessments, and fulfilling cross-border data transfer requirements. It also sets forth obligations for personal information processors, including security measures, notification of personal information breaches, and penalties for violations.

LAWS AND REGULATIONS IN RELATION TO LABOR PROTECTION

Labor Law and Labor Contract Law

According to the Labor Law of the PRC (《中華人民共和國勞動法》) or the Labor Law, which was promulgated on July 5, 1994 and last amended on December 29, 2018, employer shall establish and improve its system of workplace safety and sanitation, strictly abide by state rules and standards on workplace safety, and conduct employee training on labor safety and sanitation in the PRC.

The PRC Labor Contract Law (《中華人民共和國勞動合同法》), which was promulgated on June 29, 2007 and amended on December 28, 2012, is primarily aimed at regulating rights and obligations of employer and employee relationships, including the establishment, performance, and termination of labor contracts. Pursuant to the PRC Labor Contract Law, regulated by the MOHRSS and its local counterparts, labor contracts shall be concluded in writing if labor relationships are to be or have been established between employers and employees.

Employers are prohibited from forcing employees to work above certain time limits and employers shall pay employees for overtime work in accordance with national regulations. In addition, employee wages shall be no lower than local standards on minimum wages and must be paid to employees in a timely manner.

Social Insurance and Housing Fund

As required under the Social Insurance Law, the Provisional Measures for Maternity Insurance of Employees of Corporations (《企業職工生育保險試行辦法》) implemented on January 1, 1995, the Decisions on the Establishment of a Unified Program for Old-Aged Pension Insurance of the State Council (《國務院關於建立統一的企業職工基本養老保險制度的決定》) issued on July 16, 1997, the Decisions on the Establishment of the Medical Insurance Program for Urban Workers of the State Council (《國務院關於建立城鎮職工基本醫療保險制度的決定》) promulgated on December 14, 1998, the Unemployment Insurance Measures (《失業保險條例》) promulgated on January 22, 1999 and the Regulation of Insurance for Labor Injury (《工傷保險條例》) implemented on January 1, 2004 and amended in 2010, employers are required to provide their employees in the PRC with welfare benefits covering pension insurance, unemployment insurance, maternity insurance, work-related injury insurance and medical insurance. These payments are made to local human resources and social security departments. Any employer that fails to make social insurance contributions may be ordered to rectify the non-compliance and pay the required contributions within a prescribed time limit and be subject to a late fee. If the employer still fails to rectify the failure to make the relevant contributions within the prescribed time, it may be subject to a fine ranging from one to three times the amount overdue.

In accordance with the Regulations on the Administration of Housing Funds which were promulgated by the State Council in 1999 and last amended in March 2019, employers must register at the designated administrative centers and open bank accounts for depositing employees' housing funds. Regulated by the MOHURD and its local housing fund administration centers, employer and employee are also required to pay and deposit housing funds, with an amount no less than 5% of the monthly average salary of each employee in the preceding year in full and on time.

According to the Supreme People's Court's Interpretation (II) on Several Issues Concerning the Application of Law in Labour Dispute Cases (which took effect in September 2025) (最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)), where an employer and a worker agree or a worker undertakes to an employer that there is no need to pay social insurance premiums, the people's court shall determine that such an agreement or undertaking is void. If the employer fails to pay social insurance premiums in accordance with the law, and the worker files a claim for rescission of the labor contract and payment of economic compensation by the employer in accordance with Article 38(3) of the Labor Contract Law, the people's court shall support such a claim in accordance with the law.

LAWS AND REGULATIONS ON EMPLOYEE STOCK INCENTIVE PLAN

Pursuant to the Notice of Issues Related to the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Listed Company (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計畫外匯管理有關問題的通知》), which was issued by the SAFE on February 15, 2012, employees, directors, supervisors, and other senior management who participate in any stock incentive plan of a publicly-listed overseas company and who are PRC individuals or non-PRC individuals residing in China for a continuous period of no less than one (1) year, subject to a few exceptions, are required to register with the SAFE through a qualified domestic agent, which may be a PRC subsidiary of such overseas listed company, and complete certain other procedures.

In addition, the State Taxation Administration (the "**STA**"), has issued certain circulars concerning employee stock options and restricted shares. Under these circulars, employees working in the PRC who exercise stock options or are granted restricted shares will be subject to PRC individual income tax. The PRC subsidiaries of an overseas listed company are required to file documents related to employee stock options and restricted shares with relevant tax authorities and to withhold individual income taxes of employees who exercise their stock options or purchase restricted shares. If the employees fail to pay or the PRC subsidiaries fail to withhold income tax in accordance with relevant laws and regulations, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC governmental authorities.

LAWS AND REGULATIONS IN RELATION TO TAX

Enterprise Income Tax

Pursuant to the EIT Law, which was promulgated by the National People's Congress of the People's Republic of China, or the NPC of the PRC on March 16, 2007, effective on January 1, 2008 and amended by the Standing Committee of the NPC on February 24, 2017 and December 29, 2018, and its implementing rules, last amended by the State Council on April 23, 2019, enterprises are classified into resident enterprises and non-resident enterprises. PRC resident enterprises typically pay an enterprise income tax at the rate of 25%. According to the EIT Law, the enterprise income tax rate of a High and New Technology Enterprise is 15%. Pursuant to the Administrative Measures for the Recognition of High and New Technology Enterprises (《高新技術企業認定管理辦法》) which were promulgated by Ministry of Science and Technology of the PRC and relevant authorities on April 14, 2008 and last amended on January 29, 2016 and came into effect on January 1, 2016, the Certificate of a High and New Technology Enterprise is valid for three years.

Value-added Tax

Pursuant to the Provisional Regulations of the People's Republic of China on Value-added Tax (《中華人民共和國增值税暫行條例》), promulgated on December 13, 1993 and latest amended on November 19, 2017, and the Decision of State Council on Abolition of the Provisional Regulations of the People's Republic of China on Business Tax and Revision of the Provisional Regulations of the People's Republic of China on Value-added Tax (《國務院關於廢止《中華人民共和國營業税暫行條例》同修改《中華人民共和國增值税暫行條例》的決定》), promulgated on November 19, 2017, all enterprises and individuals engaged in the sale of goods, the provision of processing, repair and replacement services, sales of services, intangible assets, real property, and the importation of goods within the territory of the PRC shall be liable to pay VAT. According to Announcement 39, regulated by the STA and its local counterparts, the VAT tax rates generally applicable are simplified as 13%, 9%, 6%, and 0%, which become effective on April 1, 2019, and the VAT tax rate applicable to the small-scale taxpayers is 3%.

Dividend Withholding Tax

The EIT Law provides that since January 1, 2008, an income tax rate of 10% will normally be applicable to dividends declared to non-PRC resident investors that do not have an establishment or place of business in the PRC, or that have such establishment or place of business but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends are derived from sources within the PRC.

Pursuant to the Double Taxation Avoidance Arrangement, and other applicable PRC laws, if a Hong Kong resident enterprise is determined by the competent PRC tax authority to have satisfied the relevant conditions and requirements under such Double Taxation Avoidance Arrangement and other applicable laws, the 10% withholding tax on the dividends the Hong Kong resident enterprise receives from a PRC resident enterprise may be reduced to 5%. However, based on the Circular on Certain Issues with Respect to the Enforcement of Dividend Provisions in Tax Treaties (《關於執行税收協定股息條款有關問題的通知》), issued on February 20, 2009 by the STA, if the relevant PRC tax authorities determine, in their discretion, that a company benefits from such reduced income tax rate due to a structure or arrangement that is primarily tax-driven, such PRC tax authorities may adjust the preferential tax treatment. According to the Circular on Several Questions regarding the "Beneficial Owner" in Tax Treaties (《關於税收協定中"受益所有人"有關問題的公告》), which was issued on February 3, 2018 by the STA and became effect on April 1, 2018, when determining the applicant's status as the "beneficial owner" regarding tax treatments in connection with dividends, interests or royalties in the tax treaties, several factors, including, without limitation, whether the applicant is obligated to pay more than 50% of his or her income in twelve months to residents in third country or region, whether the business operated by the applicant constitutes the actual business activities, and

whether the counterparty country or region to the tax treaties does not levy any tax or grant any tax exemption on relevant incomes or levy tax at an extremely low rate, will be taken into account, and such factors will be analyzed according to the actual circumstances of the specific cases.

LAWS AND REGULATIONS IN RELATION TO IMPORT AND EXPORT OF GOODS

Under the Foreign Trade Law, which was promulgated by the SCNPC on May 12, 1994, came into effect on July 1, 1994 and last amended with effect from December 30, 2022, foreign trade operators engaged in the import and export of goods or technologies are no longer required to make a record-filing with the administrative authority of the foreign trade of the State Council or its authorized agency from December 30, 2022.

Pursuant to the Administrative Provisions of the Customs of the PRC on Record-filing of Customs Declaration Entities (《中華人民共和國海關報關單位備案管理規定》), which was promulgated by the General Administration of Customs on November 19, 2021 and became effective on January 1, 2022, unless otherwise required by laws, where the consignee or consignor of imported or exported goods or a customs declaration enterprise applies for fillings, it shall obtain the qualification of market entities; particularly where the consignee or consignor of imported or exported goods applies for fillings, it shall be filed as a foreign trade business.

LAWS AND REGULATIONS IN RELATION TO DIVIDEND DISTRIBUTION

The principal regulations governing distribution of dividends of foreign-invested enterprises include Foreign Investment Law and the PRC Company Law regulated by SAMR, MOFCOM, and their local counterparts, wholly foreign-owned enterprises and Sino-foreign equity joint ventures in the PRC may pay dividends only out of their accumulated profits, if any, as determined in accordance with PRC accounting standards and regulations. Additionally, these foreign-invested enterprises may not pay dividends unless they set aside at least 10% of their respective accumulated profits after tax each year, if any, to fund certain reserve funds, until such time as the accumulative amount of such fund reaches 50% of the enterprise's registered capital.

LAWS AND REGULATIONS RELATING TO M&A RULES AND OVERSEAS LISTING

On February 17, 2023, the CSRC issued the PRC Overseas Listing Regulations (《境內企業境外發行證券和上市管理試行辦法》), which became effective on March 31, 2023, and five supporting guidelines. Pursuant to the PRC Overseas Listing Regulations, companies in the PRC that directly or indirectly offer or list their securities in an overseas market, including a company in the PRC limited by shares and an offshore company whose main business operations are in the PRC and intends to offer shares or be listed in an overseas market based on its equities, assets or similar interests in the PRC are required to file with the CSRC within three business days after submitting their listing application documents to the regulator in the place of intended listing. Failure to complete the filing under the PRC Overseas Listing Regulations or conceals any material fact or falsifies any major content in its filing documents may subject the company to administrative penalties, such as order to rectify, warnings, fines, and its controlling shareholders, actual controllers, direct officers-in-charge and other direct personnel-in-charge may also be subject to administrative penalties, such as warnings and fines. The PRC Overseas Listing Regulations also provide that a company in the PRC must file with the CSRC within three business days for its follow on offering of securities after it is listed in an overseas market.

In addition, pursuant to the PRC Overseas Listing Regulations, enterprises in the PRC are prohibited from overseas offering and listing under any of the following circumstances, if (i) the overseas offering and listing is explicitly prohibited by PRC laws; (ii) the overseas offering and listing may constitute a threat to or endanger national security as determined by relevant PRC authorities; (iii) the domestic enterprises and their controlling shareholders and actual controllers have committed certain criminal offenses (such as corruption, bribery, embezzlement, misappropriation of property or other criminal offenses undermining the order of the socialist market economy) in the past three years; (iv) the domestic enterprises are currently under investigations in connection with suspicion of having committed criminal offenses or material violations of applicable laws and regulations and there is still

no explicit conclusion; or (v) there are material ownership disputes over the shareholdings held by the controlling shareholder or the shareholder under the control of the controlling shareholder or the actual controllers.

On February 24, 2023, the CSRC, jointly with other relevant governmental authorities, issued the Provisions on Strengthening the Confidentiality and Archive Management Work Relating to the 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》), which took effect on March 31, 2023, pursuant to these provisions companies based in the PRC that offer and list securities in overseas markets shall establish confidentiality and archives system. The phrase "companies based in the PRC" refers to companies in the PRC limited by shares which are directly listed in the overseas capital market and the domestic operating entities of an offshore company being indirectly listed in a foreign stock exchange. Additionally, companies based in the PRC shall complete corresponding procedures when (i) providing or publicly disclosing documents and materials which may adversely affect national security and public interest to the relevant securities companies, securities service agencies or the offshore regulatory authorities, (ii) providing or publicly disclosing such documents and materials through its offshore listing entity; or (iii) providing accounting files or copies to relevant securities companies, security service institutions, overseas regulators and individuals. Companies based in the PRC are also required to provide written statements on the implementation of the aforementioned rules to the relevant securities companies and securities service agencies. If a company based in the PRC finds that the documents and materials related to state secrets or secrets of the government authorities or other materials which may adversely affect national security and public interest have been leaked or are going to be leaked, it should take remedial measures immediately and report to the relevant authorities.