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

## REGULATORY AUTHORITIES

In the PRC, the National Medical Products Administration, or the NMPA, which was previously known as the China Food and Drug Administration (together with the NMPA, hereinafter collectively referred to as the NMPA), is the primary regulatory agency for pharmaceutical products and businesses and regulates almost all of the key stages of the life-cycle of pharmaceutical products, including non-clinical studies, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution, and pharmacovigilance. The Center for Drug Evaluation, or the CDE, which is an affiliated institution of the NMPA, conducts the technical evaluation on each drug and biologic application to assess the safety and efficacy of each candidate.

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

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

## LAWS AND REGULATIONS RELATING TO DRUGS

### Introduction

In 2017, the drug regulatory system entered a new and significant period of reform. In October 2017, the General Office of the State Council and the General Office of the Central Committee of the China Communist Party jointly issued the Opinions on Deepening the Reform of the Evaluation and Approval System to Encourage Innovation in Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》), or the "**Innovation Opinion**", to encourage, among others, the reform of clinical trial management and acceleration of the review and approval for drugs and medical devices marketing. To implement the regulatory reform introduced by the Innovation Opinion, the National People's Congress (the "**NPC**") and the NMPA has been revising the fundamental laws, regulations and rules regulating pharmaceutical products and the industry, which include the framework law known as the PRC Drug Administration Law (《中華人民共和國藥品管理法》), (the "**Drug Administration Law**"). The Drug Administration Law was promulgated by the Standing Committee of the NPC, (the "**SCNPC**"), on September 20, 1984 and latest amended on August 26, 2019 and took effect as of December 1, 2019. The State Council issued the Regulations for Implementation of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》), which was promulgated on August 4, 2002 and latest amended on January 16, 2026, to further implement the Drug Administration Law. The NMPA also has its own set of regulations for the Drug Administration Law, and the primary one governing clinical trial applications, marketing approval, and post-approval amendment and renewal is known as the Drug Registration Regulation (《藥品註冊管理辦法》), (the "**Drug Registration Regulation**"), which was latest amended by the NMPA on January 22, 2020 and effective from July 1, 2020.

### Drug Research and Development

#### *Non-Clinical Research*

The NMPA requires preclinical data to support registration applications for imported and domestic drugs. According to the Drug Registration Regulation, non-clinical safety studies shall be carried out in an institution that has passed the certification of the Good Laboratory Practice for Non-clinical Laboratory Studies and comply with the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory (《藥物非臨床研究質量管理規範》), which was issued by NMPA on August 6, 2003 and revised on July 27, 2017. Pursuant to the Measures for Administration of Certification of the Good Laboratory Practice for Nonclinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》) issued by the NMPA on April 16, 2007 and

revised on January 19, 2023, the NMPA and its affiliated institution are responsible for conducting the certification-related document reviews, on-site inspections, comprehensive evaluations, and implementing supervisory inspections of relevant institutions.

***Animal Testing***

Pursuant to the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) promulgated by The State Science and Technology Commission (now known as the Ministry of Science and Technology) in November 1988 and recently amended by the State Council in March 2017, the Administration Measures on Good Practice of Experiment-use Animals (《實驗動物質量管理辦法》) promulgated by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision in December 1997, and the Administrative Measures on the Certificate for Experiment-use Animals (Trial) (《實驗動物許可證管理辦法(試行)》) promulgated by The Ministry of Science and Technology and other regulatory authorities in December 2001, the use of laboratory animals for scientific research and experiments requires a license.

***Clinical Trials Approval***

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

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

***Drug Clinical Trial Registration***

Pursuant to the Drug Registration Regulation, upon obtaining the clinical trial approval and before commencing a clinical trial, the sponsor shall register the scheme on the clinical trial and other information on the Drug Clinical Trial Registration and Information Platform for clinical trials of drugs. During the clinical trial of drugs, the sponsor shall update registration information continuously, and register information on the outcome of the clinical trial of drugs upon completion of the clinical trial of drugs. The registration information shall be published on the platform and the sponsor shall be responsible for the veracity of such information. More details are provided in the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) released by the NMPA on September 6, 2013, providing that for all clinical trials approved by the NMPA and conducted in China shall be published through the Drug Clinical Trial Registration and Information Platform. The applicant shall complete trial pre-registration within one month after obtaining the clinical trial approval to obtain the trial's unique registration number and shall complete certain follow-up information and first submission for publication before the first subject's enrollment in the trial. If the foregoing first time of publication has not been submitted within one year after obtaining the clinical trial approval, the applicant shall submit an explanation, and if the procedure is not completed within three years, the clinical trial approval shall automatically be annulled.

***Human Genetic Resources Approval and Registration***

The Ministry of Science and Technology promulgated the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) in July 2015, according to which, if the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organization of China shall apply for approval of the China Human Genetic Resources Management Office through the online system.

On May 28, 2019, the State Council of PRC issued the Administrative Regulations on Human Genetic Resources (《人類遺傳資源管理條例》), (the "**Human Genetic Resource Regulation**"), which was revised on March 10, 2024. According to the Human Genetic Resource Regulation, human genetic resource includes human genetic resource materials and information. Human genetic resource materials refer to organs, tissues, cells and other genetic materials containing human genome, genes and other genetic materials. Human genetic resource information refers to information, such as data, generated by human genetic resources materials. The Human Genetic Resource Regulation formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities, under which, no approval is required for international cooperative clinical trials conducted at clinical institutions using Chinese human genetic resources to obtain marketing authorization for relevant drugs and medical devices in China, provided that such trials do not involve the export of human genetic resource materials. However, both Chinese and foreign parties involved in the clinical cooperation shall file with the competent health authority of the State Council the types, quantities, and intended uses of human genetic resources to be utilized prior to commencing the clinical trial. Foreign organizations, individuals and institutions established or actually controlled by foreign organizations and individuals are not allowed to collect or preserve human genetic resources in China or provide human genetic resources abroad.

The Biosafety Law of the PRC (《中華人民共和國生物安全法》) was promulgated by the SCNPC on October 17, 2020, and took effect on April 15, 2021. It was last amended on April 26, 2024. This law explicitly establishes that the state holds sovereignty over China's human genetic resources and biological resources.

***Clinical Trial Process and Good Clinical Practices***

When conducting clinical trials, all parties involved must comply with the Good Clinical Practice for Drug Clinical Trials (《藥物臨床試驗質量管理規範》), which was last revised by the NMPA and the NHC on April 23, 2020, and took effect on July 1, 2020 and stipulates procedural requirements for conducting clinical trials, including preclinical trial preparation, trial protocols, protection of subject rights, responsibilities of investigators, sponsors, and monitors, as well as data management and statistical analysis.

Typically, pursuant to Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) which was issued on October 30, 2002, latest revised on January 22, 2020 and effective on July 1, 2020, drug clinical trials in China shall go through four phases. Based on the characteristics of drugs and research objective, the research contents shall include clinical pharmacology research, exploratory clinical trial, confirmatory clinical trial and post-marketing clinical research. The NMPA requires that the different phases of clinical trials in China shall receive ethics committee approval respectively and comply with the relevant requirements of quality management standards for clinical trial of drugs in PRC. The sponsor shall submit safety update reports on the CDE website regularly during the research and development period. The sponsor shall promptly report to the CDE regarding suspicious and unexpected serious adverse reaction and other potential serious safety risks arising in the course of the clinical trial. Based on the severity of the safety risks, the sponsor may be required to adopt measures to strengthen risk control, and may be required to suspend or terminate the clinical trial of drugs where necessary.

According to the Good Clinical Practice for Drug Clinical Trials, the sponsor shall provide investigators and the clinical trial institution with legal and economic insurance or guarantee relating to the clinical trial, and ensure that such insurance or guarantee is appropriate to the nature and degree of risks of the clinical trial, excluding the damages caused by the negligence of investigators or the clinical trial institution. Pursuant to the Innovation Opinion, the accreditation of the institutions for drug clinical trials shall be subject to record-filing administration. The conduct of clinical trials must adhere to the PRC's Good Clinical Practice for Drug Clinical Trials, and the protocols must be approved by the ethics committees. Pursuant to the newly amended Drug Administration Law and the Regulations on the Administration of Drug Clinical Trial Institution (《藥物臨床試驗機構管理規定》) jointly promulgated by NMPA and NHC on November 29, 2019 and effective from December 1, 2019, drug clinical trial institutions shall be subject to filing administration. Entities that only conduct analysis of biological samples related to clinical trials of drugs are not required to perform filing procedures.

***New Drug Application, Approval and Re-Registration***

According to the Drug Registration Regulation, an applicant shall, upon completion of studies including pharmacy, pharmacology and toxicology and clinical trial of drugs which support the registration of drug marketing, determination of quality standards, verification of commercial scale manufacturing process, and preparation to undergo examination and inspection for drug registration, submit an application for drug marketing authorization, and submit the relevant research materials in accordance with the submission requirements. The CDE shall organize pharmacist, medical and other technical personnel to comprehensively review the application regarding the safety, effectiveness and quality control of the drug. Where the application is cleared by the comprehensive review, the drug shall be approved for marketing and a drug registration certificate shall be issued.

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

Pursuant to Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), the validity period of a drug registration certificate shall be five years. The drug marketing authorization holder of the drug registration certificate shall ensure the safety, effectiveness and quality control of the marketed drug at all times during the validity period of the certificate and apply for re-registration of the drug six months before the expiry of such validity period.

***Drug Manufacturing***

According to the Drug Administration Law and Administrative Measures on Supervision of Pharmaceutical Manufacturing (《藥品生產監督管理辦法》) which was promulgated by the NMPA on December 11, 2002 and last amended on January 22, 2020 and effective on July 1, 2020, all facilities that manufacture drugs in China must apply for a Pharmaceutical Manufacturing Permit which is issued by the drug supervision and administration department of the province, autonomous region or municipality directly under the central government where it is domiciled. The Pharmaceutical Manufacturing Permit is valid for five years and shall be renewed six months before the expiry date. The drug marketing authorization holder who entrusts another party to produce preparations shall meet the requirements as specified in Administrative Measures on Supervision of Pharmaceutical Manufacturing, sign an entrustment agreement and a quality agreement with a qualified drug producer, and submit the relevant agreements and the application materials of the actual production site to provincial drug administrative departments where the drug marketing authorization holder is located to apply for the drug production license. When an application for marketing authorization is submitted, the applicant and the manufacturer shall have obtained the corresponding Pharmaceutical Manufacturing Permit.

These drug manufacturing facilities shall comply with drug manufacturing quality management norms, establish a sound drug manufacturing quality management system and ensure the whole drug manufacturing process continuously comply with statutory requirements. The drug marketing authorization holder shall establish a quality assurance system for pharmaceuticals, employ designated personnel to be independently in charge of quality control for pharmaceuticals.

The Good Manufacturing Practice for Pharmaceutical Products (《藥品生產質量管理規範》) was last revised on January 17, 2011, and took effect on March 1, 2011. It comprises a detailed set of regulatory standards governing pharmaceutical production, covering areas such as organizational structure and personnel, premises and facilities, equipment, personnel hygiene, production management, quality control, production operations, management of raw materials and excipients, maintenance of sales records, and procedures for handling customer complaints.

***Drug Business Operation***

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

Drug business operators shall comply with the drug operation quality management norms, establish and improve their business operation quality management system, and ensure that the whole drug business process continuously comply with statutory requirements.

***Regulations on Centralized Procurement***

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

***Drug Advertisements***

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 State Administration for Market Regulation on December 24, 2019 and effective from March 1, 2020, advertisements for drugs shall not contain any false or misleading contents. Advertisers shall be responsible for the veracity and legitimacy of the contents of advertisements for drugs, medical devices, health food and formula food for special medical purposes.

***Drug Recalls***

According to the Measures on Drug Recall (《藥品召回管理辦法》) effective from November 1, 2022, the marketing authorization holder shall establish and improve a drug recall system, collect information related to drug quality and safety, investigate and evaluate potential quality issues or other safety hazards, and promptly recall drugs with quality problems or other safety concerns. Drug manufacturers, distributors, and healthcare facilities shall actively assist the holder in investigating and evaluating drugs with potential quality issues or other safety hazards, proactively cooperate with the holder in fulfilling recall obligations, promptly communicate and provide feedback on recall information according to the recall plan, and control and retrieve drugs with quality issues or other safety hazards.

**LAWS AND REGULATIONS RELATING TO VACCINES**

According to the Vaccine Administration Law of the PRC (《中華人民共和國疫苗管理法》), (the "**Vaccine Administration Law**"), which was promulgated by the SCNPC on June 29, 2019 and came into effect on December 1, 2019, the State applies the most stringent management system for vaccines, and adheres to the principles of safety first, risk management, whole-process control, scientific supervision and social co-governance. Also, a National immunization Program system is applied in the PRC, under which the government would provide vaccines under the immunization program to the residents free of charge.

**Vaccine Administration**

On January 15, 2017, the General Office of State Council issued Opinions on Further Enhancing Administration of Circulation and Vaccination of Vaccines (《關於進一步加強疫苗流通和預防接種管理工作的意見》), (the "**Vaccine Opinion**"), among others, to improve the work mechanism for the management of vaccines and promote the independent R&D and quality improvement of vaccines. On June 29, 2019, the SCNPC released the Vaccine Administration Law, which requires the most stringent management system for vaccines, and at the same time, supports the basic research and applied research on vaccines, promotes the development and innovation of vaccines, including the development, production and reserve of vaccines for the prevention and control of serious diseases in the national strategy. Entities and individuals engaged in vaccine development, production, circulation and vaccination shall abide by the laws, regulations, rules, standards and specifications, ensure that the information during the whole process is true, accurate, complete and traceable, assume responsibilities in accordance with the law and accept social supervision.

Vaccine marketing authorization holders shall establish an electronic vaccine traceability system, which is connected with the national electronic vaccine traceability collaboration platform to realize the traceability and verifiability of the smallest packaging units of vaccines in the whole process of production, circulation and vaccination.

**Development and Registration of Vaccines**

On October 14, 2005, the NMPA promulgated the Notice on Issuing Six Technical Guidelines including the Technical Guidelines on Preclinical Study of Preventive Vaccines (《關於印發<預防用疫苗臨床前研究技術指導原則>等6個技術指導原則的通知》), which specified the requirements on preclinical research, change of production process, quality control in clinical stages of vaccine to ensure its safety and efficacy.

According to the Vaccine Administration Law, clinical trials of vaccines shall not be conducted without obtaining the approval of the drug administrative department under the State Council. Clinical trials of vaccines shall be conducted or organized for implementation by Grade III medical institutions that meet the conditions prescribed by the drug administrative department under the State Council and the competent health department under the State Council, or by disease prevention and control institutions at or above the provincial level.

A vaccine to be marketed within the territory of China shall be approved by the drug administrative department under the State Council and obtain a drug registration certificate; when applying for registration of a vaccine, an applicant shall provide true, sufficient and reliable data, information and samples. With respect to the vaccines urgently needed for disease prevention and control as well as the innovative vaccines, the drug administrative department under the State Council shall prioritize their evaluation and approval.

According to the Vaccine Administration Law, for vaccines urgently needed for disease prevention and control as well as the innovative vaccines, the NMPA shall prioritize the evaluation and approval work. With respect to a vaccine urgently needed for responding to a major public health emergency or any other vaccines urgently needed as determined by the health department under the State Council, if the benefits outweigh the risks upon assessment, the drug administrative department under the State Council may conditionally approve the vaccine registration application.

According to the Drug Registration Regulation, before the applicant submits an application for drug marketing authorization, it shall communicate with the CDE and, upon communication and confirmation, submit the application for drug marketing authorization and simultaneously submit an application for prioritized review and approval. Upon included in the procedures for prioritized review and approval, the sponsors could enjoy, among others, a shortened review period for drug marketing authorization within 130 days.

**Post-Approval Studies for Vaccines**

On June 25, 2021, the CDE issued the Technical Guidance Principles for Post-Marketing Pharmaceutical Change Studies of Biological Products (Trial) (《已上市生物製品藥學變更研究技術指導原則(試行)》). Holders shall establish a post-marketing change control system for biological products, assuming responsibility for conducting all post-marketing pharmaceutical change studies, self-assessing study results, and implementing continuous dynamic change management. On June 14, 2024, the CDE issued the Technical Guidance Principles for Post-Marketing Pharmaceutical Change Studies of Vaccines (Trial) (《已上市疫苗藥學變更研究技術指導原則(試行)》). Holders shall strengthen the construction of vaccine quality systems, be responsible for self-assessment of all post-marketing pharmaceutical change studies and their results, and implement continuous dynamic change management. They shall also continuously optimize production processes to maintain the advanced nature of production and control. The NMPA issued the Post-Marketing Change Management Measures for Drugs (Trial) (《藥品上市後變更管理辦法(試行)》) on January 12, 2021. Marketing authorization holders shall proactively conduct post-marketing studies to achieve full lifecycle management of drugs. Post-marketing changes shall not adversely affect the safety, efficacy, or quality control of the drug.

**Production and Batch Release of Vaccines**

According to the Vaccine Administration Law, whoever engages in vaccine production activities shall, in addition to meeting the conditions for engaging in drug production activities as prescribed in the Drug Administration Law, also meet the following conditions: (1) Having moderate scale and sufficient capacity reserves; (2) Having systems, facilities and equipment for ensuring bio-safety; and (3) Meeting the needs of disease prevention and control. A vaccine marketing authorization holder shall have the capacity for production of vaccines. If it is really necessary to entrust the production of vaccines in excess of its capacity, the vaccine marketing authorization holder shall obtain the approval of the drug administrative department under the State Council. Where it accepts the entrustment to produce vaccines, it shall abide by the provisions of this Law and the relevant provisions of the State, so as to guarantee the quality of vaccines.

The State adopts a batch release system for vaccines. Each batch of vaccines shall, before being sold or imported, be examined and inspected according to the relevant technical requirements by the batch release institution designated by the drug administrative department under the State Council. If the requirements are met, a batch release certificate shall be issued; otherwise, a notice on rejecting batch release shall be issued. According to the Measures for Administration of Batch Release of Biological Products (《生物製品批簽發管理辦法》) issued on December 13, 2002 and latest amended on December 11, 2020 and effective on March 1, 2021, the vaccine products with marketing approval shall be subject to document review and sample inspection by the drug batch release institution designated by NMPA and pass the biological product batch release approval before the marketing and sales of each batch of products. Vaccines that are urgently needed for infectious disease prevention and control or for emergencies shall be exempted from the biological product batch release approval upon approval by the NMPA.

**Circulation of Vaccines**

According to the Vaccine Opinion issued by the General Office of State Council on January 15, 2017, vaccines should be procured online on the provincial public resource trading platform in accordance with the principles of transparency, competition, and fair trade.

According to the Vaccine Administration Law, the competent health department under the State Council shall, in concert with the finance department under the State Council and other departments, organize centralized bidding or unified negotiation to form and publish the bid-winning price or transaction price of vaccines under the National Immunization Programs, and all provinces, autonomous regions and municipalities directly under the central government shall implement centralized procurement for such vaccines. The procurement of vaccines under other immunization programs other than those under the National Immunization Program and vaccines not under any immunization program shall be organized by provinces, autonomous regions and municipalities directly under the central government through provincial public resources trading platforms.

According to the Vaccine Administration Law, the price of vaccines shall be set reasonably and independently by the vaccine marketing authorization holder according to law. The price level, price difference rate and profit rate of vaccines shall be kept within a reasonable range. A vaccine marketing authorization holder shall, as agreed upon in the procurement contract, supply vaccines to the disease prevention and control institution. A vaccine marketing authorization holder shall, as agreed upon in the procurement contract, deliver vaccines to the disease prevention and control institution or the inoculation entity designated thereby. The vaccine marketing authorization holder and disease prevention and control institution that distribute vaccines themselves shall have the conditions for cold chain storage and transport of vaccines or may entrust eligible vaccine distribution entities to distribute vaccines. A vaccine marketing authorization holder shall, in accordance with the provisions, set up true, accurate and complete sales records, and preserve them for inspection for at least five years after expiry of the validity of the vaccines.

With regard to storage and transportation of vaccines, the present Notice for Distributing Regulations on Administration of Vaccine Storage and Transportation (2017 Edition) (《疫苗儲存和運輸管理規範(2017年版)》), which promulgated by the NMPA and NHC on December 15, 2017 and effective on the same day, requires that, among others, vaccine production enterprises shall be equipped with full-time staff for vaccine management, establish a management system for vaccine storage and transport, maintain cold chain facilities and equipment for storage and transport of vaccines to ensure the quality of vaccines, and must store and transport vaccines in light of the instructions for use of vaccines, the vaccination work rules and other relevant requirements on temperature for storage and transport of vaccines.

**Anti-Corruption and Anti-Bribery**

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 on September 2, 1993 and last amended on June 27, 2025 prohibits business operators from offering bribes to other entities or individuals by means of property or other means for the purpose of seeking transaction opportunities or competitive advantages. In addition, the Administrative Measures for Pharmaceutical Representatives (《醫藥代表管理辦法》), jointly issued by seven departments including the NMPA and the NHC that will take effect on August 1, 2026 stipulates that medical representatives shall meet certain requirements including education background, knowledge of medicine and training and assessment. Marketing authorization holders shall file information on medical representatives on the medical representative recordation platform and are prohibited from certain activities, including assigning medicinal product sales targets to medical representatives, or requiring medical representatives to engage in sales activities such as payment collection or handling of purchase and sale vouchers.

## LAWS AND REGULATIONS RELATING TO PRODUCT LIABILITY

Pursuant to the PRC Civil Code (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and coming into effect on January 1, 2021, patients may seek compensation from the marketing authorization holder, manufacturer, or blood supply institution for damages caused by defective drugs, disinfection products, or medical devices, or by the transfusion of substandard blood. Patients may also seek compensation from the medical institution. Where compensation is sought from the medical institution, the medical institution shall have the right to seek reimbursement from the liable marketing authorization holder, manufacturer, or blood supply institution after making the compensation payment.

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 was amended on August 27, 2009 and October 25, 2013 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. Under the amendments made on October 25, 2013, 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 FOREIGN INVESTMENT

**Foreign Investment**

Investment activities in the PRC by foreign investors are principally governed by The Special Administrative Measures (Negative List) for Access of Foreign Investment (2024 version) (《外商投資准入特別管理措施(負面清單) (2024年版)》), or the Negative List, and Catalogue of Industries for Encouraging Foreign Investment (2025 version) (《鼓勵外商投資產業目錄(2025年版)》), or the Encouraging List. The Negative List, which came into effect on November 1, 2024, sets out special administrative measures in respect of the access of foreign investments in a centralized manner, and the Encouraging List which came into effect on February 1, 2026, sets out the encouraged industries for foreign investment. According to 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 NPC on March 15, 2019 and came into effect as of January 1, 2020, the state shall implement the management systems of pre-establishment national treatment and negative list for foreign investment, and shall give national treatment to foreign investment beyond the negative list.

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

### Environmental Impact Appraisal

According to the Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》), (the "**Construction Environmental Protection Rule**"), which was promulgated by the State Council on November 29, 1998, amended on July 16, 2017 and became effective on October 1, 2017, depending on the impact of the construction project on the environment, an construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form. The Construction Environmental Protection Rule also requires that upon completion of construction for which an environment impact report or environment impact statement is formulated, the constructor shall conduct acceptance inspection of the environmental protection facilities pursuant to the standards and procedures stipulated by the environmental protection administrative authorities of the State Council, formulate the acceptance inspection report, and announce the acceptance inspection report pursuant to the law except for circumstances where there is a need to keep confidentiality pursuant to the provisions of the State. Where the environmental protection facilities have not undergone acceptance inspection or do not pass acceptance inspection, the construction project shall not be put into production or use.

### Pollutant Discharge Licensing

Pursuant to the Administrative Measures for Pollutant Discharge Permits (《排污許可管理辦法》) issued by the Ministry of Ecology and Environment on April 1, 2024, effective July 1, 2024, and the Administrative Regulations on Pollutant Discharge Permits (《排污許可管理條例》) promulgated by the State Council on January 24, 2021, the state implements key management, simplified management, and registration management of pollutant discharge permits for enterprises, institutions, and other production and business operators based on factors such as pollutant generation volume, discharge volume, and environmental impact. Units subject to pollutant discharge permit management under the law shall apply for and obtain a pollutant discharge permit in accordance with the law, and discharge pollutants in compliance with the permit's provisions; those without a pollutant discharge permit shall not discharge pollutants. The pollutant discharge permit is valid for five years. Upon expiration, entities requiring continued discharge must submit an application to the approving authority at least 60 days prior to the permit's expiration date.

According to the Catalog 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.

### Fire Prevention Design and Acceptance

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

## LAWS AND REGULATIONS RELATING TO DATA COMPLIANCE

### Cybersecurity and Data Security

The Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》), promulgated by the SCNPC on November 7, 2016, and most recently amended on October 28, 2025, stipulates that network operators shall adopt technical measures and other necessary safeguards to ensure the security of collected personal information and prevent its leakage, damage, or loss.

On June 10, 2021, the NPCSC 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 defines data as any record of information in electronic or other forms, and data processing as encompassing the collection, storage, use, processing, transmission, provision, and disclosure of data. Data processors shall establish and improve comprehensive data security management systems, organize data security training, and adopt appropriate technical and other necessary measures to protect data security.

On December 28, 2021, the Cyberspace Administration of China and other government departments issued the Cybersecurity Review Measures (《網絡安全審查辦法》), effective February 15, 2022. Under these Measures, operators of online platforms holding personal information of over one million users must submit cybersecurity review applications to the Cybersecurity Review Office when seeking overseas listings.

### Personal Information Protection

Pursuant to the Civil Code (《中華人民共和國民法典》) of the PRC promulgated by the NPC on May 28, 2020, and effective as of January 1, 2021, personal information is protected by law. Any organization or individual seeking to obtain another person's personal information shall acquire it lawfully and ensure information security. No entity may unlawfully collect, use, process, or transmit another person's personal information, nor may it unlawfully buy, sell, provide, or disclose another person's personal information. Natural persons possess the right to privacy, and the provisions governing privacy rights apply to private information contained within personal information.

The Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), promulgated by the SCNPC on August 20, 2021, and effective as of November 1, 2021, defines the scope of personal information and establishes rules for processing personal information both domestically and internationally. This law sets forth specific personal information protection requirements, including but not limited to: requirements for full informed consent in various circumstances; strengthened and categorized obligations for personal information processors; and additional restrictions and rules governing personal information processing.

### Scientific Data Management

According to the Measures for Scientific Data Management (《科學數據管理辦法》) issued and implemented by the General Office of the State Council on March 17, 2018, scientific data primarily encompasses data generated through basic research, applied research, experimental development, and other activities in fields such as natural sciences and engineering technology sciences. It also includes raw data and its derivative data obtained through observation, monitoring, investigation, inspection, testing, and other means for use in scientific research activities. Scientific data involving state secrets, national security, public interests, commercial secrets, or personal privacy shall not be made available for external sharing. Where external sharing is absolutely necessary, the purpose of use, user qualifications, and confidentiality conditions must undergo review, and access shall be strictly controlled. When providing scientific data involving state secrets in international exchanges and cooperation, the legal entity shall clearly specify the category, scope, and purpose of data utilization, and report to the competent authority for approval in accordance with confidentiality management procedures. Following approval by the competent authority, the legal entity shall complete relevant procedures as required and sign a confidentiality agreement with the user.

## LAWS AND REGULATIONS RELATING TO SOCIAL SECURITIES

### Social Securities

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which issued by the SCNPC on October 28, 2010 and came into effect on July 1, 2011 and was newly revised on December 29, 2018, enterprises and institutions in the PRC shall provide their employees with welfare schemes covering basic pension insurance, unemployment insurance, maternity insurance, work-related injury insurance and basic medical insurance. The employer shall apply to the local social insurance agency for social insurance registration within 30 days from the date of its formation. And it shall, within 30 days from the date of employment, apply to the social insurance agency for social insurance registration for the employee. Any employer who violates the regulations above shall be ordered to make correction within a prescribed time limit; if the employer fails to rectify within the time limit, the employer and its directly liable person will be fined. If the employer fails to pay social insurance contributions on time and in full, the social insurance agency shall place an order with the employer demanding full payment within a prescribed period, and an overdue payment fine at the rate of 0.5‰ shall be levied as of the date of indebtedness. When the payment is not made at the expiry of the prescribed period, a fine of no less than one time and no more than three times the overdue amount shall be imposed by the authoritative administrative department. Meanwhile, the Interim Regulation on the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) (issued by the State Council on January 22, 1999 and came into effect on the same day and was recently revised on March 24, 2019) prescribes the details concerning the social securities. Apart from the general provisions about social insurance, specific provisions on various types of insurance are set out in the Regulation on Work-Related Injury Insurance (《工傷保險條例》) (issued by the State Council on April 27, 2003, came into effect on January 1, 2004 and revised on December 20, 2010), the Regulations on Unemployment Insurance (《失業保險條例》) (issued by the State Council on January 22, 1999 and came into effect on the same day), the Trial Measures on Employee Maternity Insurance of Enterprises (《企業職工生育保險試行辦法》) (issued by the Ministry of Labor on December 14, 1994 and came into effect on January 1, 1995). Enterprises subject to these regulations shall provide their employees with the corresponding insurance.

### Housing Provident Fund

According to the Regulation Concerning the Administration of Housing Provident Fund (《住房公積金管理條例》), implemented since April 3, 1999 and amended on March 24, 2002 and March 24, 2019, any newly established entity shall make deposit registration at the housing accumulation fund management center within 30 days as of its establishment. After that, the entity shall open a housing accumulation fund account for its employees in an entrusted bank. Within 30 days as of the date an employee is recruited, the entity shall make deposit registration at the housing accumulation fund management center and seal up the employee's housing accumulation fund account in the bank mentioned above within 30 days from termination of the employment relationship. Any entity that fails to make deposit registration of the housing accumulation fund or fails to open a housing accumulation fund account for its employees shall be ordered to complete the relevant procedures within a prescribed time limit. Any entity failing to complete the relevant procedure within the time limit will be fined RMB10,000 to RMB50,000. Any entity fails to make payment of housing provident fund within the time limit or has shortfall in payment of housing provident fund will be ordered to make the payment or make up the shortfall within the prescribed time limit, otherwise, the housing provident management center is entitled to apply for compulsory enforcement with the People's Court.

## LAWS AND REGULATIONS RELATING TO INTELLECTUAL PROPERTIES

### Patents

Pursuant to the Patent Law of the PRC (《中華人民共和國專利法》) (the "**Patent Law**"), which was issued by the SCNPC on March 12, 1984, and latest revised on October 17, 2020 which came into effect on June 1, 2021, the term of a patent for invention is twenty years, and the term of a utility model patent is ten years, both calculated from the filing date. After an invention or utility model patent is granted, unless otherwise provided by this Law, no entity or individual may implement the patent without the specific authorization of the patent holder. This means they may not manufacture, use, offer for sale, sell, or import the patented product for production or business purposes, nor may they use the patented method or use, offer for sale, sell, or import products

directly obtained by the patented method. Any organization or individual proposing to implement the patent of others shall enter into a licensing contract with the patentee for implementation and pay royalties to the patentee. A licensee shall have no right to allow any other organization or individual that is not stipulated in the contract to implement such patent. Without the patent holder's authorization, the implementation of their patent constitutes an infringement of their patent rights. Where disputes arise, the parties shall resolve them through negotiation. Where the parties are unwilling to negotiate or fail to reach an agreement, the patent holder or an interested party may file a lawsuit with the People's Court or request the department responsible for patent administration to handle the matter.

**Trademarks**

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) which was promulgated on August 23, 1982 and last amended on April 23, 2019 and came into effect on November 1, 2019, the Implementation Regulations of the Trademark Law of PRC (《中華人民共和國商標法實施條例》) which was issued on August 3, 2002 and amended on April 29, 2014, the Trademark Office under the State Administration for Industry and Commerce of the PRC, (the "**Trademark Office**"), shall handle trademark registrations and grant a term of ten years to registered trademarks, which may be renewed for additional ten year period upon request from the trademark owner. The Trademark Law of the PRC has adopted a "first-to-file" principle with respect to trademark registration. Where an application for trademark for which application for registration has been made is identical or similar to another trademark which has already been registered or is under preliminary examination and approval for use on the same kind of or similar commodities or services, the application for registration of such trademark may be rejected. Any person applying for the registration of a trademark may not prejudice the existing right of others, nor may any person register in advance a trademark that has already been used by another party and has already gained a "sufficient degree of reputation" through such party's use. A trademark registrant may, by entering into a trademark licensing contract, license another party to use its registered trademark. Where another party is licensed to use a registered trademark, the licenser shall report the license to the Trademark Office for recordation, and the Trademark Office shall publish it. An unrecorded license may not be used as a defense against a third party in good faith. Where the exclusive right to use a registered trademark is infringed, the trademark registrant or an interested party may file a lawsuit with the people's court or request the administrative department for industry and commerce to handle the matter.

**Domain Names**

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

**LAWS AND REGULATIONS RELATING TO TAXATION**

**Enterprise Income Tax**

According to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》), promulgated on March 16, 2007, and last amended on December 29, 2018, and the Implementing Regulations of the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》), promulgated on December 6, 2007, and last amended on December 6, 2024, enterprises are classified as either resident enterprises or non-resident enterprises. A resident enterprise refers to an enterprise established within the territory of China in accordance with the law, or an enterprise established under the laws of a foreign country (region) but with its place of effective management within the territory of China. An enterprise established under the laws of a foreign country (region) that does not have its place of effective management within the territory of China, but has an establishment or place of business within the territory of China, or an enterprise that does not have

an establishment or place of business within the territory of China but has income sourced from within the territory of China, shall be deemed a non-resident enterprise. Resident enterprises shall pay corporate income tax at a rate of 25% on their domestic and foreign income. Non-resident enterprises that establish an institution or place of business within China shall pay corporate income tax at a rate of 25% on income derived from within China by such institution or place of business, as well as on income arising outside China but having an effective connection with such institution or place of business. Non-resident enterprises that have not established an institution or place of business within China, or that have established such an institution or place of business but whose income is not effectively connected with it, shall pay corporate income tax at a reduced rate of 10% on passive income sourced from within China.

**Value-Added Tax**

According to the Value-Added Tax Law of the PRC (《中華人民共和國增值税法》), promulgated by the SCNPC on December 25, 2024, and effective as of January 1, 2026, entities and individuals (including individual industrial and commercial households) that sell goods, services, intangible assets, or real estate (hereinafter referred to as taxable transactions) within the territory of the PRC, as well as those importing goods, are taxpayers of value-added tax (the "**VAT**") and shall pay the VAT in accordance with the provisions of this Law.

## LAWS AND REGULATIONS RELATING TO OVERSEAS SECURITIES ISSUANCE AND LISTING

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

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

On February 24, 2023, the CSRC jointly with other authorities, promulgated the Provisions on Strengthening Confidentiality and File Management Related to Overseas Issuance and Listing of Securities by Domestic Enterprises or the Confidentiality Provisions (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》), which came into effect on March 31, 2023. Pursuant to the Confidentiality Provisions, domestic joint stock companies that directly issue shares to be listed overseas and domestic operating organizations of enterprises listed overseas through indirect share issuance shall submit for approval and comply with other regulations, before filing prior to publicly disclosing or providing to securities companies, securities service providers, overseas regulatory bodies and other entities and individuals any documents or information that involves state secrets, the working secrets of state organs, or documents and information that, if divulged, would jeopardize national security or public interests.