REGULATORY OVERVIEW

OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

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

Regulatory Authorities

The regulatory system for the pharmaceutical industry in the PRC consists of the Standing Committee of the National People's Congress, the State Council and several ministries and agencies under its authority, including, among others, the National Medical Products Administration (the "**NMPA**", formerly known as China Food and Drug Administration (the "**CFDA**")), the National Health Commission (the "**NHC**", formerly known as the National Health and Family Planning Commission), and the National Healthcare Security Administration.

Laws and Regulations in Relation to New Drugs

Application for New Drug Registration

Drug registration refers to an approval process where the NMPA conducts a review of the safety, efficacy and quality controllability of the drugs intended for marketing pursuant to the application for drug registration made by an applicant, and decides whether to approve the application. This process is regulated by the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) promulgated by the SAMR and came into effect on July 1, 2020.

Non-clinical Research and Animal Testing

The non-clinical safety evaluation study for drugs for marketing approval shall be conducted in accordance with the Good Laboratory Practice for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》), which was promulgated by the former CFDA and came into effect on September 1, 2017. The former CFDA issued the Administrative Measures for the Certification of Good Laboratory Practice for Non-Clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》), which became effective since July 1, 2023 after being last revised by the NMPA. It provides for the procedures for application and acceptance of Good Laboratory Practice certification by research institutions conducting non-clinical safety evaluation study for drugs, requirements for data review and on-site inspection, audit procedures and supervision and management.

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, the Administration Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) jointly promulgated by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision, and the Administrative Measures on the Certificate for Experimental 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 and came into effect in January 2002, using experimental animals and related products requires a Certificate for Utilization of Laboratory Animals.

Application and Conduct of Clinical Trials

After completing the preclinical studies, the applicant must obtain approval for clinical trials of drugs from the NMPA before the conduction of new drug clinical trials. Pursuant to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), drug clinical trials are divided into Phase 1 clinical trial, Phase 2 clinical trial, Phase 3 clinical trial, Phase 4 clinical trial and bioequivalence test. Drug clinical trials shall be subject to review and approval by the Ethics Committee.

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

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

Reform of Evaluation and Approval System for Drugs

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

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

The Announcement on Adjusting the Procedures for Review and Approval of Clinical Trials of Drugs issued by the NMPA on July 24, 2018 provides that if no negative or questionable opinion is received from the CDE within 60 days after the acceptance and collection of the application fee for a clinical trial of a drug, the applicant may commence a clinical trial of the drug in accordance with the submitted clinical trial protocol.

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

Administrative Protection and Monitoring Periods for New Drugs

Pursuant to the Implementing Rules for PRC Drug Administration Law (《中華人民共和國藥品管理法實施條例》) issued on March 2, 2019 and the Reform Plan for Registration Category of Chemical Drugs (《化學藥品註冊分類改革工作方案》) issued on March 4, 2016, the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of five years for new Category 1 drugs approved to be manufactured, commencing from the date of approval, to continually monitor the safety of those new drugs. During the monitoring period of a new drug, the NMPA will not approve any other enterprises' applications to manufacture or import the said drug.

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

Pursuant to the Multi-Center Clinical Trial Guidelines, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol.

Applicant may make use of the data derived from the international multi-center clinical trials for application to the NMPA for approval of a NDA/BLA after satisfying certain requirements under the Multi-Regional Clinical Trial Guidelines. International multi-center clinical trials shall follow internationally prevailing GCP principles and ethics requirements. Data derived from

international multi-center clinical trials can be used for the NDAs or BLAs with the NMPA. When using international multi-center clinical trial data to support NDAs or BLAs in China, applicants shall submit the completed global clinical trial report, statistical analysis report and database, along with relevant supporting data in accordance with ICH-CTD (International Conference on Harmonization-Common Technical Document) content and format requirements; subgroup research results summary and comparative analysis shall also be conducted concurrently.

Marketing Authorization Holder System

Pursuant to the Drug Administration Law, the State implements the drug marketing authorization holder system for drug administration. "Drug marketing authorization holder" means an enterprise, a drug development institute, or the like that has obtained the drug registration certificate. The drug marketing authorization holder shall be responsible for the safety, effectiveness, and quality controllability of drugs during the whole process of the development, production, distribution, and use of the drugs, as legally required.

Gathering, Collection and Filing of Human Genetic Resources

Pursuant to the Service Guide for Administrative Licensing of Gathering, Collection, Deal, Export and Exit of Human Genetic Resources (《人類遺傳資源採集、收集、買賣、出口、出境行政許可事項服務指南》) promulgated by the Ministry of Science and Technology in July 2015 and the Notice on the Implementation of the Administrative License for the Gathering, Collection, Deal, Export and Exit of Human Genetic Resources (《關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》) promulgated by the Ministry of Science and Technology in August 2015, if we gather and collect human genetic resources through clinical trials, we should file a record with the China Human Genetic Resources Management Office through an online system.

Pursuant to the Regulations on the Management of Human Genetic Resources of the PRC (《中華人民共和國人類遺傳資源管理條例》) promulgated by the State Council, which came into effect on July 1, 2019, and the Implementation Rules for the Administrative Regulation on Human Genetic Resources (《人類遺傳資源管理條例實施細則》) promulgated by the Ministry of Science and Technology on May 26, 2023, foreign organizations, individuals and institutions established or actually controlled by them shall not gather or preserve Chinese genetic resources within the territory of the PRC, or provide Chinese genetic resources to foreign countries.

In areas such as research, development, and application of biology technology; biosecurity management of pathogenic microorganism laboratories; security management of human genetic resources and biological resources; countermeasures for microbial resistance; and prevention of bioterrorism and defending threats of biological weapons, we must comply with the relevant provisions of the Biosecurity Law of the PRC (《中華人民共和國生物安全法》) if we engage in related businesses.

Laws and Regulations in Relation to Drug Manufacturer

Drug Manufacturing Permit

Pursuant to the Drug Administration Law, drug manufacturing activities are subject to the approval of drug regulatory departments and a drug manufacturing license shall be obtained. The license shall have a validity period of five years. If it is necessary to renew the license after the expiration thereof, the license-holding enterprise shall, within six months before the license expires, apply for a new license in accordance with the provisions of the drug regulatory departments under the State Council.

Good Manufacturing Practices

Our engagement in drug manufacturing activities must comply with the Good Manufacturing Practices (《藥品生產質量管理規範》), and establish a sound GMP management system, to ensure that the entire process of drug manufacturing maintain to meet the statutory requirements, and meet the GMP requirements enacted by the drug regulatory authority under the State Council in accordance with the law.

Laws and Regulations on Drug Supply

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

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

The Good Supply Practice for Pharmaceutical Products (《藥品經營質量管理規範》) (the "**GSP Rules**") was last amended and came into effect on July 13, 2016. The GSP Rules set forth the basic standards in management of operation quality of drugs and apply to enterprises engaged in drug operations in the PRC. 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 the GSP Rules.

Laws and Regulations in Relation to Medical Devices

Pursuant to the Regulations on Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), or the Medical Devices Regulations, promulgated by the State Council and came into effect on January 20, 2025, the NMPA, shall be in charge of national supervision and administration of medical devices. The Medical Device Regulations regulates entities that engage in the research and development, production, operation, use, supervision and administration of medical devices in the PRC.

Production Permit and GMP for Medical Devices

Pursuant to the Measures on the Supervision and Administration of Medical Devices Production (《醫療器械生產監督管理辦法》) came into effect on May 1, 2022, the enterprises engaging in the production of Class I medical devices shall make filings for such Class I medical devices with the local branches at the prefecture city level of the NMPA and submit materials to prove that it is qualified to engage in the production of such medical devices. The enterprises engaging in the production of Class II or Class III medical devices shall apply for a Manufacture License for Medical Devices (醫療器械生產許可證) with provincial branches of the NMPA, and submit materials proving it is qualified to engage in the production of such medical devices and a medical device registration certificate for the production of such medical devices. A Manufacture License for Medical Devices is valid for five years and the registrant shall file for renewal application with the original branch of the NMPA 90 business days to 30 business days prior to its expiration date.

Other Laws and Regulations in Relation to Medical Industry

Basic Medical Insurance Policy

The State Council issued the Opinions of the State Council on the Integration of the Basic Medical Insurance System for Urban and Rural Residents (《國務院關於整合城鄉居民基本醫療保險制度的意見》) on 3 January 2016, which called for the integration of the two systems of basic medical insurance for urban residents and new type rural cooperative medical care, and the establishment of a unified basic medical insurance system for urban and rural residents, i.e., to cover all urban and rural residents other than rural migrant workers and flexibly employed persons participating in basic medical insurance for urban workers in accordance with the law.

Medical Insurance Catalog

Pursuant to the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》), the scope of medical insurance coverage for pharmaceutical products needs to be managed through the formulation of the Medical Insurance Catalog. The currently effective one is the National Insurance Drug List for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (2024) (《國家基本醫療保險、工傷保險和生育保險藥品目錄(2024年)》) came into effect since January 1, 2025.

Drug Price

Pursuant to the Drug Administration Law, for drug products with market-regulated prices in accordance with the law, the drug marketing authorization holder, the drug manufacturer, the drug distributor and medical institution shall determine the price pursuant to the principles of fairness, reasonableness, integrity and trustworthiness as well as quality for value in order to supply drug users with reasonably priced drug products; and shall comply with the requirements relating to drug price administration promulgated by the State Council's pricing authorities, determine and clearly mark the retail prices of drug products.

National Centralized Procurement Program and Tendering Procedures

Pursuant to the Implementation Opinions on Expanding the Regional Scope of the Pilot Program Regarding the National Organization of Centralized Procurement and Use of Drugs to Wider Areas (《關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見》) issued and implemented on September 25, 2019, and the Document on National Centralized Drug Procurement (GY-YD2021–1) (《全國藥品集中採購文件 (GY-YD2021–1) 》) issued by the Joint Procurement Office on January 15, 2021, the centralized volume-based drug procurement program will be implemented nationwide. All pharmaceutical manufacturers, exclusive agents of imported drugs, and drug marketing authorization holders are eligible to participate as long as their drugs are within the scope of the centralized procurement program.

The NHSA, the NHC, the NMPA, the MIIT and the Logistics Support Department of the Central Military Commission jointly issued the Notice on Carrying out the Second Batch of National Organization of Centralized Procurement and Use of Drugs (《關於開展第二批國家組織藥品集中採購和使用工作的通知》) (the "Notice"), which came into effect on January 13, 2020. The Notice established several implementation principles for national centralized drug procurement to comprehensively deepen reforms and standardize China's national drug procurement system. On July 29, 2020, the Joint Procurement Office issued the Document on National Centralized Drug Procurement (GY-YD2020–1) (《全國藥品集中採購文件 (GY-YD2020–1)》) to launch a new batch of centralized procurement of drugs that meet the centralized procurement conditions.

On January 22, 2021, the General Office of the State Council issued the Opinions on Promoting the Regular and Institutionalized Implementation of Centralized Volume-Based Drug Procurement (《關於推動藥品集中帶量採購工作常態化制度化開展的意見》), proposing multiple measures to advance the normalization and institutionalization of centralized volume-based drug procurement

nationwide. The document mandates participation from all public medical institutions in centralized drug procurement. Future procurement catalogs will include drugs with high market demand or procurement prices that have been included in the NRDL, while striving to cover domestically produced and marketed drugs that are clinically suitable and reliable in quality.

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 (Yi Bao Han [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), aiming to form a new pattern of centralized procurement with the centralized procurement of drugs and high-value medical consumables organized by provinces, and the centralized procurement of drugs and high-value medical consumables by the national alliance as the main body led by provinces, and centralized procurement of drugs and high-value medical consumables at the provincial level as the supplement.

On May 14, 2024, the NHSA 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》，醫保辦法[2024] 8號) to improve the centralized pharmaceutical procurement system, promote the quality and coverage of centralized procurement, and further enhance the capacity and scale of local procurement alliances, and hence achieving linkage and coordinated progress at the national and local levels.

On January 31, 2026, the Continued Procurement Office for National Centralized Drug Procurement — Products with Expired Agreements (國家組織集採藥續品協定期滿品種接續採購辦公室) commissioned Jiangsu Province, Henan Province and Guangdong Province to take the lead in carrying out the national unified continued procurement work for products with expired agreements under the first to eighth batches of national centralized drug procurement.

Drug Distribution and Two-Invoice System

Pursuant to the Implementing Opinions on Promoting the "Two-Invoice System" for Drug Procurement By Public Medical Institutions (For Trial Implementation) (《關於在公立醫療機構藥品採購中推行「兩票制」的實施意見(試行)》) which was issued on December 26, 2016, the Two-Invoice System is a system under which invoices are issued by drug manufacturers to drug distributors on a once-off basis while invoices are issued by drug distributors to medical institutions on a once-off basis.

Pursuant to the Several Opinions of the General Office of the State Council on Further Reform and Improvement in Policies of Drug Production, Circulation and Use (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》), which was issued on January 24, 2017. Pharmaceutical companies must comply with the Two-Invoice System in order to engage in procurement processes with public hospitals.

Advertising of Pharmaceutical Products

Pursuant to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》), which promulgated by SAMR and came into effect on March 1, 2020, advertisements for drugs, medical devices, health food and formula food for special medical purposes shall be true and legitimate, and shall not contain any false or misleading contents.

Insert Sheet, Labels and Packaging of Pharmaceutical Products

Pursuant to the Measures for the Administration of the Insert Sheets and Labels of Drugs (《藥品說明書和標籤管理規定》), which was promulgated by SFDA and came effective on June 1, 2006, the insert sheets and labels of drugs should be reviewed and approved by the SFDA. The Implementation Regulations of the Drug Administration Law of the PRC, which will take effect on May 15, 2026, stipulate that the content of drug labels and package inserts must be approved by the drug regulatory department.

Laws and Regulations in Relation to Intellectual Property

Patent

The relevant patents are protected by the Patent Law of the PRC (《中華人民共和國專利法》) (the "Patent Law") and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》) (the "Implementation Rules"). Pursuant to the Patent Law, the total effective term of patents for new drugs after market approval shall not exceed fourteen (14) years. Furthermore, the Patent Law stipulates that, for public health purposes, the patent administration department of the State Council may grant compulsory licenses to patented drugs manufactured for export to countries or regions that comply with relevant international conventions to which the People's Republic of China is a party.

Trademarks

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

Domain Name

The Measures for the Administration of Internet Domain Names (《互聯網域名管理辦法》) issued by the Ministry of Industry and Information Technology ("**MIIT**") which took effect on November 1, 2017, and the Rules for the Implementation of the Registration of National Top-Level Domain Names (《國家頂級域名註冊實施細則》) issued by China Internet Network Information Center (CNNIC) on June 18, 2019, provide legal protection for domain names. Domain name registration is handled through domain name registration service organizations established in accordance with relevant regulations. Upon successful registration, the applicant shall become the domain name holder.

Trade Secret

Pursuant to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by SCNPC, as amended and effective as of April 23, 2019, business persons are prohibited from infringing others' trade secrets. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others' trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and impose fine on the infringing parties.

The Company Law and Regulations

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

Regulations in Relation to Foreign Direct Investment

The investment of foreign investors and foreign-invested enterprises in China is subject to the Catalogue of Industries for Guiding Foreign Investment (《外商投資產業指導目錄》). Pursuant to the Special Administrative Measures (Negative List) for the Access of Foreign Investment (2024) (《外商投資准入特別管理措施(負面清單(2024年版))》) and the Catalogue of Industries for Encouraging Foreign Investment (2022 Version) (《鼓勵外商投資產業目錄(2022年版)》) promulgated by the National Development and Reform Commission and the Ministry of Commerce and coming into effect on January 1, 2023, foreign investment projects can be divided into three categories: encouraged, restricted and prohibited. Foreign-invested projects that are not listed in the Negative List are permitted foreign-invested projects.

Regulations in Relation to Product Liability

The Product Quality Law of the PRC (《中華人民共和國產品質量法》), promulgated by the SCNPC and came into effect on December 29, 2018 (the "**Product Quality Law**"), is the principal governing law relating to the supervision and administration of product quality. Pursuant to the Product Quality Law, manufacturers shall be liable for the quality of products produced by them and sellers shall take measures to ensure the quality of the products sold by them. A manufacturer shall be liable to compensate for any bodily injuries or damage to property other than the defective product itself resulting from the defects in the product.

Pursuant to the Civil Code of the People's Republic of China (《中華人民共和國民法典》) promulgated by the National People's Congress and effective on January 1, 2021, also regulate the liability for damages of producers and sellers.

Regulations in Relation to Production Safety

The Production Safety Law of the PRC (《中華人民共和國安全生產法》), promulgated by the SCNPC and came into effect on September 1, 2021, is the basic law for governing production safety. It provides that, any entity whose production safety conditions do not meet the requirements may not engage in production and business operation activities.

Regulations in Relation to Environmental Protection and Fire Safety

Pursuant to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), promulgated by the SCNPC and coming into effect on January 1, 2015 (the "**Environmental Protection Law**"), the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》), promulgated by the SCNPC and came into effect on December 29, 2018, and the Administrative Regulations on the Environmental Protection of Construction Project (《建設項目環境保護管理條例》), promulgated by the State Council and came into effect on October 1, 2017, enterprises which plan to construct projects shall provide the assessment reports, assessment form, or registration form on the environmental impact of such projects. The assessment reports, assessment form, or registration form shall be filed with or approved by the relevant environmental protection bureau prior to the commencement of any construction work.

Pursuant to the Catalogue of Classified Management of Pollutant Discharge Permits for Fixed Pollution Sources (2019) (《固定污染源排污許可分類管理名錄(2019年版)》) promulgated by the Ministry of Ecology and Environment on December 20, 2019 and coming into effect on the same day, key management, simplified management or registration management of pollutant discharge permits shall be implemented pursuant to factors such as the amount of pollutant produced or discharged and the degree of impact on the environment of the enterprises discharging pollutants. Pollutant-discharging units qualified for registration management do not need to apply for pollutant-discharging permits, but should fill in a pollutant-discharging registration form on the national pollutant-discharging permit information management platform.

Pursuant to the Fire Safety Law of the PRC (《中華人民共和國消防法》) promulgated by the SCNPC and came into effect on April 29, 2021, and the Interim Provisions on Administration of Fire Protection Design Review and Acceptance of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) (the "**Interim Provisions**") promulgated by the Ministry of Housing and Urban-Rural Development and came into effect on October 30, 2023, the fire protection design or construction of a construction project must conform to the national fire protection technical standards for project construction and construction projects shall undergo the fire protection design review and acceptance system. The special construction projects as defined in the Interim Provisions must apply to the fire control department for fire protection design review, and complete the fire protection acceptance procedures after the completion of the construction project. The construction unit of other construction projects must complete the fire protection filing of the fire protection design and the completion acceptance within five (5) business days after the.

Regulations in Relation to Prevention and Control of Occupational Diseases

The Prevention and Control of Occupational Diseases Law of the PRC (《中華人民共和國職業病防治法》), which was promulgated by the SCNPC and came into effect on December 29, 2018 (the "**Prevention and Control of Occupational Diseases Law**"), is the basic law for the prevention and control of occupational diseases. Pursuant to the Prevention and Control of Occupational Diseases Law, budget for facilities for the prevention and control of occupational diseases of a construction project shall be included in the budget of the project and those facilities shall be designed, constructed and put into operation simultaneously with the main body of the project. The entity that takes charge of the project should carry out the assessment of the effectiveness of measures for the prevention and control of occupational diseases before the final acceptance of the construction project. In addition, employers shall take required administrative measures to prevent and control occupational diseases in work.

Regulations in Relation to Employment and Social Securities

Pursuant to the Labor Law of the People's Republic of China (《中華人民共和國勞動法》), which was revised by the NPC Standing Committee and came into effect on December 29, 2018, the Labor Contract Law of the People's Republic of China (《中華人民共和國勞動合同法》), which was revised by the NPC Standing Committee on December 28, 2012 and came into effect on July 1, 2013, and the Regulations on the Implementation of the Labor Contract Law of the People's Republic of China, which was issued by the State Council and came into effect on September 18, 2008, the employer shall strictly abide by national standards, provide relevant training for laborers, and guarantee that laborers enjoy labor right and fulfill labor obligations. The employer and the laborers shall sign a written labor contract. Labor contracts consist of fixed-term labor contract, open-ended labor contracts and labor contracts that expire upon completion of given jobs. The wages paid by the employers to the laborers shall not be lower than the local minimum wage standard.

Pursuant to the Social Insurance Law of the People's Republic of China (《中華人民共和國社會保險法》), which was revised by the NPC Standing Committee and took effect on December 29, 2018, the Regulations on Management of Housing Provident Funds (《住房公積金管理條例》), which was revised by the State Council and took effect on March 24, 2019 and the Interim Regulation on the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) revised by the State Council and taking effect on March 24, 2019, the employers shall pay basic pension insurance, unemployment insurance, maternity insurance, work-related injury insurance, basic medical insurance and housing provident funds for their employees pursuant to the statutory payment base and proportion. If any employer fails to pay the relevant monies to the relevant local administrative authority on time and in full, it may be ordered to make up the shortage or be fined.

Regulations in Relation to Information Security and Data Privacy

Data Security and Export

The NPCSC promulgated the Data Security Law of the People's Republic of China (《中華人民共和國數據安全法》), (effective from September 1, 2021), for the establishment of a data classification and grading protection system.

Pursuant to the Measures for Security Assessment of Data Export (《數據出境安全評估辦法》) issued by the Cyberspace Administration of China and came into effect on September 1, 2022, a data processor must apply for a CAC security assessment through the provincial cyberspace administration before transferring data overseas in specified circumstances, including transfers of important data, transfers by critical information infrastructure operators, or transfers involving personal information or sensitive personal information exceeding prescribed thresholds.

Pursuant to the Measures for Standard Contract for Outbound Transfer of Personal Information (《個人信息出境標準合同辦法》) issued by the Cyberspace Administration of China on February 22, 2023 and effective from June 1, 2023, a personal information processor may transfer personal information overseas by entering into the standard contract only if it is not a critical information infrastructure operator and remains below the prescribed thresholds for processing and outbound provision of personal information and sensitive personal information.

On March 22, 2024, the CAC promulgated the Regulations on Improving and Regulating the Cross-Border Transfer of Data (《促進和規範數據跨境流動規定》) (the "**Regulations on Cross-Border Transfer of Data**"), data processors other than operators of critical information infrastructure are exempt from declaring a security assessment for cross-border data transfer, concluding a standard contract for the cross-border transfer of personal information, and obtaining personal information protection certification, provided that they have cumulatively provided non-sensitive personal information of less than 100,000 individuals overseas since January 1 of the current year.

Personal Information Protection

Pursuant to the Civil Code (《民法典》), personal information of natural persons is protected by law. If any organization or individual needs to obtain other people's personal information, they should obtain it in accordance with the law and ensure the security of the information. They must not illegally collect, use, process, or transmit other people's personal information, and must not illegally buy, sell, provide, or disclose the information. The Personal Information Protection Law of the People's Republic of China promulgated by the NPCSC and implemented on November 1, 2021, further emphasizes the obligations and responsibilities of processors for the protection of personal information, and requests higher level of protective measures on the processing of sensitive personal information.

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

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

Laws and Regulations in Relation to Anti-money Laundering

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

Laws and Regulations in Relation to Anti-corruption

Pursuant to the Criminal Law of the People's Republic of China (《中華人民共和國刑法》), as last amended by the Standing Committee of the National People's Congress on December 29, 2023, the crime of job appropriation means that an employee of any company, enterprise or any other organization unlawfully takes possession of the money or property of the organization by taking advantage of office, if the amount is relatively large, he shall be sentenced to fixed-term imprisonment of not more than three years or criminal detention and shall be fined concurrently; if the amount is huge, he shall be sentenced to fixed-term imprisonment of not less than three years but not more than 10 years and shall be fined concurrently; or if the amount is extremely huge, he shall be sentenced to fixed-term imprisonment of not less than 10 years or life imprisonment and shall be fined concurrently.

Laws and Regulations in Relation to Anti-bribery

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

Pursuant to the 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》) came into effect on March 1, 2014, 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. First-time listing results in a two-year ban on purchases by public and subsidized medical institutions within the local province, and lower bidding/purchasing ratings in other provinces. Two or more listings within five years lead to a nationwide two-year purchase ban.

In May 2023, 14 government authorities, including the NHC, jointly issued the Key Points for the Correction of Malpractice in the Purchases and Sales of Medical Products and Medical Services in 2023 (《2023年糾正醫藥購銷領域和醫療服務中不正之風工作要點》), focusing on rectifying corruption in the pharmaceutical industry, such as disguised fees under donations or academic events, illegal donations/financial support, and kickbacks in pharmaceutical sales by manufacturers, distributors, and representatives.

OVERVIEW OF LAWS AND REGULATIONS IN THE UNITED STATES

This section summarizes the principal laws and regulations in the United States that are relevant to our business.

Laws and Regulations in Relation to New Drug

U.S. Government Regulation of Drug and Biological Products

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations, and biologics under the FDCA and the Public Health Service Act and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition.

Once a product candidate is identified for development, it enters preclinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Preclinical testing is conducted in accordance with FDA's Good Laboratory Practice regulations.

An Institutional Review Board (the "**IRB**"), must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval.

An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to subjects.

Clinical trials generally are conducted in three sequential phases, known as phase 1, phase 2 and phase 3, and may overlap.

Concurrent with clinical trials, companies usually complete additional animal studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA or a BLA.

Within 60 days of its receipt, the FDA reviews the NDA/BLA to ensure that it is sufficiently complete for substantive review before it accepts the NDA/BLA for filing. After accepting the NDA/BLA filing, the FDA begins an in-depth substantive review to determine, among other things, whether a product is safe and effective for its intended use. The FDA also evaluates whether the product's manufacturing is cGMP-compliant to assure the product's identity, strength, quality and

purity. Before approving the NDA/BLA, the FDA typically will inspect whether the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA/BLA to an advisory committee, a panel of experts, for review whether the application should be approved and under what conditions and considers such recommendations when making decisions.

The FDA may refuse to approve the NDA/BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. The FDA will issue a complete response ("**CR**") letter describing all of the specific deficiencies that the FDA identified in the NDA/BLA that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the CR letter may include recommended actions that the applicant might take to place the application in a condition for approval. The applicant may either resubmit the NDA/BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

OVERVIEW OF EU LAWS AND REGULATIONS

The European Medicines Agency ("**EMA**") is the scientific agency of the European Union (EU) that coordinates the evaluation and monitoring of new and approved medicinal products such as small molecules and biologics. It is responsible for the scientific evaluation of applications for EU marketing authorizations, as well as the development of technical guidance and the provision of scientific advice to sponsors. The approval process for medicinal products within the EU is broadly analogous to that of the United States. It typically necessitates the successful completion of the following stages: (i) preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable EU Good Laboratory Practice regulations; (ii) submission of a clinical trial application ("**CTA**") must be done in the Clinical Trials Information System ("**CTIS**") for each clinical trial, which must be approved before human clinical trials may begin; (iii) performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication; (iv) satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with cGMP; (v) potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and (vi) review and approval by the relevant national authority of the MAA before any commercial marketing, sale or shipment of the product.

In specific circumstances, EU legislation (Article 14(7) Regulation (EC) No. 726/2004and Regulation (EC) No. 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for products (including medicines designated as orphan medicinal products), if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs, and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data.

Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

REGULATIONS ON TAXATION

Enterprise Income Tax

Pursuant to the CIT Law, which was promulgated by the SCNPC and was latest amended on December 29, 2018, and the Regulation on the Implementation of the CIT Law, which was promulgated by the State Council and was latest amended in December 2024, a uniform 25% enterprise income tax rate is imposed to both foreign invested enterprises and domestic enterprises, except where tax incentives are granted to special industries and projects. The enterprise income tax rate is reduced to 20% for qualifying small low-profit enterprises. The high-tech enterprises that need full support from the PRC's government will enjoy a reduced tax rate of 15% for enterprise income tax.

Value-added Tax

Pursuant to the Provisional Regulations of the PRC on Value-added Tax (《中華人民共和國增值税暫行條例》), which was promulgated by the State Council and was latest amended on November 19, 2017, and the Implementation Rules for the Provisional Regulations the PRC on Value-added Tax (《中華人民共和國增值税暫行條例實施細則》), which was promulgated by the Ministry of Finance and effective from November 1, 2011, entities and individuals engaging in selling goods, providing processing, repairing or replacement services or importing goods within the territory of the PRC are taxpayers of the value-added tax ("**VAT**").

Pursuant to the Notice of the Ministry of Finance and the State Administration of Taxation on Adjusting Value-added Tax Rates (《財政部、税務總局關於調整增值税税率的通知》) which was promulgated by the Ministry of Finance and the State Taxation Administration and coming into effect on May 1, 2018, the tax rates of 17% and 11% applicable to any taxpayer's VAT taxable sale or import of goods are adjusted to 16% and 10%, respectively. Pursuant to the Announcement on Relevant Policies for Deepening the Value-added Tax Reform (《關於深化增值税改革有關政策的公告》) promulgated by the Ministry of Finance, the State Taxation Administration and the General Administration of Customs and becoming effective on April 1, 2019, the value added tax rates were adjusted to 13% and 9%, respectively.

REGULATIONS ON FOREIGN EXCHANGE

Foreign Exchange Regulation

On January 29, 1996, the State Council promulgated the Administrative Regulations on Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) which became effective on April 1, 1996. Foreign exchange payments under current account items shall, pursuant to the administrative provisions of the foreign exchange control department of the State Council on payments of foreign currencies and purchase of foreign currencies, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in conversion and sale of foreign currencies by presenting the valid document. Domestic entities and domestic individuals making overseas direct investments or engaging in issuance and trading of overseas securities and derivatives shall process registration formalities pursuant to the provisions of the foreign exchange control department of the State Council.

Pursuant to the Notice on Relevant Issues Concerning the Administration of Foreign Exchange for Overseas Listing (《關於境外上市外匯管理有關問題的通知》) issued by the SAFE on December 26, 2014, the domestic companies shall register the overseas listed with the foreign exchange control bureau located at its registered address in 15 working days after completion of the overseas listing and issuance. The funds raised by the domestic companies through overseas listing may be repatriated to China or deposited overseas, provided that the intended use of the fund shall be consistent with the contents of the document and other public disclosure documents.

According to the Notice of the State Administration of Foreign Exchange on Further Deepening Reforms to Promote the Facilitation of Cross-border Trade and Investment (《國家外匯管理局關於進一步深化改革促進跨境貿易投資便利化的通知》), which was promulgated by the SAFE on December 4, 2023 and effective from the same date, foreign exchange funds raised by domestic enterprises from overseas listings may be directly remitted into a capital account settlement account, and funds in the capital account settlement account may be freely settled and used.

Regulations in Relation to Overseas Securities Offering and Listing by Domestic Companies

Pursuant to the Overseas Listing Trial Measures issued by the CSRC and effective from March 31, 2023, where a domestic company seeks overseas securities issuance and listing, the issuer shall file with the CSRC in accordance with the Overseas Listing Trial Measures. If an issuer procures an overseas initial public offering or listing, it shall file with the CSRC within three (3) business days after submitting application documents for overseas securities issuance and listing.

Pursuant to the Management Trial Measures, overseas securities issuance and listing is not allowed if one of the following circumstances exists: (I) financing through listing is explicitly prohibited by laws, administrative regulations or relevant national regulations; (II) the overseas offering and listing may endanger national security as determined by the relevant competent department under the State Council after examination pursuant to the law; (III) a domestic enterprise or its controlling shareholder or actual controller has committed a criminal crime of corruption, bribery, embezzlement, misappropriation of property or disrupting the order of the socialist market economy in the last three years; (IV) a domestic enterprise is under formal investigation pursuant to the law for being suspected of any crime or major violation of laws and regulations, but no clear conclusions have been made; or (V) there is a major dispute over ownership of the equity held by the controlling shareholder or a shareholder controlled by the controlling shareholder or the actual controller.

LAWS AND REGULATIONS ON SANCTIONS AND EXPORT CONTROL

United States

The Office of Foreign Assets Control ("**OFAC**") is the primary agency responsible for administering U.S. sanctions programmes against targeted countries, entities, and individuals. "Primary" U.S. sanctions apply to "U.S. persons" or activities involving a U.S. nexus (e.g., funds transfers in U.S. currency even if performed by non-U.S. persons), and "secondary" U.S. sanctions apply extraterritorially to the activities of non-U.S. persons even when the transaction has no U.S. nexus.

Depending on the sanctions program and/or parties involved, U.S. law also may require a U.S. company or a U.S. person to "block" (freeze) any assets/property interests owned, controlled or held for the benefit of a sanctioned country, entity, or individual when such assets/property interests are in the United States or within the possession or control of a U.S. person. Upon such blocking, no transaction may be undertaken or effected with respect to the asset/property interest — no payments, benefits, provision of services or other dealings or other type of performance (in case of contracts/agreements) — except pursuant to an authorization or license from OFAC.

OFAC's comprehensive sanctions programmes currently apply to Cuba, Iran, North Korea, the Crimea region of Russia/Ukraine, and the self-proclaimed Luhansk People's Republic ("**LPR**") and Donetsk People's Republic ("**DPR**") regions (the comprehensive OFAC sanctions programme against Sudan was terminated on October 12, 2017). OFAC also prohibits virtually all business dealings with persons and entities identified in the SDN List. Entities that a party on the SDN List owns (defined as a direct or indirect ownership interest of 50% or more, individually or in the aggregate) are also blocked, regardless of whether that entity is expressly named on the SDN List.

REGULATORY OVERVIEW

United Nations

The United Nations Security Council (the "**UNSC**") can take action to maintain or restore international peace and security under Chapter VII of the United Nations Charter.

The UNSC measures have ranged from comprehensive economic and trade sanctions to more targeted measures such as arms embargoes, travel bans, and financial or commodity restrictions.

European Union

Under European Union sanction measures, there is no "blanket" ban on doing business in or with a jurisdiction targeted by sanctions measures. It is not generally prohibited or otherwise restricted for a person or entity to do business (involving non-controlled or unrestricted items) with a counterparty in a country subject to European Union sanctions where that counterparty is not a Sanctioned Person and not engaged in prohibited activities, such as exporting, selling, transferring or making certain controlled or restricted products available (either directly or indirectly) to, or for use in a jurisdiction subject to sanctions measures, provided that no funds and economic resources are made available to the Sanctioned Persons.

United Kingdom and United Kingdom overseas territories

The United Kingdom applies its own sanctions programs and has extended its autonomous sanctions regimes to apply to and in the United Kingdom overseas territories.

Australia

The Australian restrictions and prohibitions arising from the sanctions laws apply broadly to any person in Australia, any Australian anywhere in the world, companies incorporated overseas that are owned or controlled by Australians or persons in Australia, and/or any person using an Australian flag vessel or aircraft to transport goods or transact services subject to United Nations sanctions.

U.S. Export Controls

The United States has implemented and has proposed additional restrictions, some of which may impact Chinese companies, including us. The United States has increased export controls.

Restrictions on China through the Export Administration Regulations (the "**EAR**"), administered by the Bureau of Industry and Security of the U.S. Department of Commerce (the "**BIS**"), which includes a list of foreign persons on which certain trade restrictions are imposed (the "**Entity List**"). Where a foreign person is included on the Entity List, the export, re-export and/or transfer (in-country) of items which are subject to the EAR generally is prohibited unless the specified license requirements are met.

In addition, EAR also maintains a list of items, software, and technology that are subject to export controls (the "**Commerce Control List**"). BIS can also implement unilateral licensing requirements and other controls on items subject to U.S. export controls jurisdiction that can restrict exports and reexports to certain countries, as well as transfers within a country to a different end-user or end-use. The Commerce Control List is divided into ten categories, represented by the first digit of the Export Control Classification Number ("**ECCN**"). Each ECCN is subject to the respective control(s) and licensing requirement applicable for sales to controlled countries and/or entities.