# REGULATORY OVERVIEW

## OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

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

### Laws and Regulations in Relation to Overseas Listing

#### *Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》)*

According to the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (hereinafter referred to as the "**Trial Measures**") issued by the China Securities Regulatory Commission (the "**CSRC**") on February 17, 2023 and effective from March 31, 2023, where the PRC domestic enterprises directly or indirectly issue securities overseas or list their securities overseas shall file with the CSRC and submit relevant materials. This listing application requires filing with the CSRC within three business days after submitting the overseas listing application, and compliance with the Regulations on Strengthening the Confidentiality and Archives Management for Overseas Offering and Listing of Securities by PRC Domestic Enterprises (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) jointly issued by the CSRC, the Ministry of Finance, the State Secrecy Bureau and the State Archives Bureau on February 24, 2023, and came into effect on March 31, 2023, and shall establish and sound systems for confidentiality and archive management, take necessary measures to implement confidentiality and document management responsibilities, refrain from disclosing state secrets and work secrets of state organs, and jeopardize the interests of the state and the public.

#### *"Full Circulation" of H Shares*

The CSRC promulgated the Guidelines for the "Full Circulation" Program for Domestic Unlisted Shares of H Share Listed Companies (《H股公司境內未上市股份申請"全流通"業務指引》) (the "**Full Circulations Guidelines**") on August 10, 2023, which allows certain qualified H share listed companies and H share companies to be listed for the application of full circulation to the CSRC. Our shareholders intend to apply for the circulation of certain domestic unlisted shares held before the overseas listing on the Stock Exchange after the completion of the overseas listing. In addition to the Full Circulations Guidelines, the relevant application must also comply with regulations such as the "Full Circulation" Program for Domestic Unlisted Shares of H Share Listed Companies (《H股公司境內未上市股份申請"全流通"業務指引》) and the Measures for Implementation of H-Share "Full Circulation" Business (《H股"全流通"業務實施細則》).

#### *Regulatory Organs*

The pharmaceutical industry in China is primarily regulated by the following authorities under the State Council of the People's Republic of China: the National Medical Products Administration of the PRC (the "**NMPA**", formerly known as the China Food and Drug Administration (the "**CFDA**") or State Food and Drug Administration (the "**SFDA**")), the National Healthcare Security Administration of the PRC, the National Health Commission of the PRC (the "**NHC**"), the NDRC, the Ministry of Industry and Information Technology of the PRC, the Ministry of Human Resources and Social Security of the PRC, and the Ministry of Ecology and Environment of the PRC.

## Laws and Regulations in Relation to the Pharmaceutical Industry

### *Regulatory framework of pharmaceutical industry*

Our engagement in the research, production, and operation of drugs must comply with the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the "**Drug Administration Law**"). The Drug Administration Law (promulgated by the Standing Committee of the National People's Congress (the "**SCNPC**") in September 1984 and latest amended in August 2019) and the Implementation Regulations of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》) (promulgated by the State Council in August 2002 and amended in 2024 and latest amended in January 2026 and will take effect since May 15 2026) both establish the legal framework for PRC drug administration, which regulates the management of drug manufacturers, pharmaceutical trading enterprises, and the management of preparations prepared by medical institutions, covering drug development, research, manufacturing, distribution, packaging, pricing and advertising management framework.

### *Laws and Regulations in Relation to Pharmaceutical Research and Registration*

Drug registration involves the process in which the applicant obtains approval for drug clinical trials, drug marketing authorization, re-registration and other supplementary applications in accordance with legal procedures and relevant requirements. The NMPA reviews the safety, effectiveness and quality controllability of drugs based on laws, regulations and existing scientific knowledge, and decides whether to approve the application. Upon obtaining drug registration certificate, the applicant becomes the drug marketing authorization holder ("**drug marketing authorization holder**"). The SAMR promulgated the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), which is applicable to drug development, registration, regulation and management activities carried out for drug marketing in China.

According to the Administrative Measures for Drug Registration, drug registration applicants shall complete the relevant research of pharmacy, pharmacology, toxicology and clinical trials before applying to the NMPA for drug marketing registration. Non-clinical safety evaluation studies conducted in institutions certified by quality management standards for drug non-clinical research that meet these standards, in accordance with regulations such as the Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》). Where animal experiments are involved, the provisions of the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) and the Administration Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) and other regulations must be complied with. Clinical trials for drugs shall be approved. Drug clinical trials shall be carried out in institutions that meet relevant regulations and comply with clinical trial quality management practices.

### *Application for Clinical Trial*

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

After obtaining clinical trial approval, we shall choose institutions qualified for clinical trials of the drug to conduct clinical trials. Pursuant to the Administrative Regulations for Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which came into effect in December 2019, if engaging in drug development activities and conducting clinical trials of drugs (including bioequivalence test conducted after filing) approved by the NMPA within the territory of the PRC, they shall be conducted in the Drug Clinical Trial Institutions.

***Clinical Trial***

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

In November 2019, the NMPA and NHC jointly promulgated the Administrative Regulations for Drug Clinical Trial Institutions, which stipulates that each clinical trial institution should have an ethics committee responsible for conducting ethical review of drug clinical trials. The management of drugs used in a clinical drug trial shall satisfy the relevant requirements of the Good Clinical Practice for Drug Trials ("**GCP**") (《藥物臨床試驗質量管理規範》). After being approved to carry out clinical drug trial, we shall, before carrying out subsequent clinical drug trial by stages, develop corresponding plan for clinical drug trial, carry out clinical drug trial upon examination and with consent of the ethics committee, and submit corresponding plan for clinical drug trial and supporting materials on the website of the CDE.

Clinical trials shall be conducted for the application of new drug registration and shall be implemented in accordance with the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》), promulgated and amended by the NMPA and NHC in April 2020 and came into effect on July, 2020. The Good Clinical Practice for Drug Trials refines and specifies responsibility requirements for all parties involved in drug clinical trials. It also emphasizes the importance of basic documents of clinical trials checked by sponsors and drug regulatory agencies, and serves as the basis for confirming the authenticity of clinical trials and the integrity of data collected. The Guidelines for the Maintenance of Essential Documents for Drug Clinical Trials (《藥物臨床試驗必備文件保存指導原則》) was promulgated by the NMPA in June 2020, which became effective in July 2020.

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

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

According to the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial) (《關於發佈國際多中心藥物臨床試驗指南(試行)的通告》), ("**the Multi- Center Clinical Trial Guidelines**"), promulgated by the NMPA on January 30, 2015 and came into effect from March 1, 2015, we may simultaneously perform clinical trials in different centers using the same clinical trial protocol. If we plan to implement the international multi-center clinical trials in the PRC, we shall comply with relevant laws and regulations, such as the PRC Drug Administration Law, the Implementing Regulations of the PRC Drug Administration Law and the Administrative Measures for Drug Registration, execute the Good Clinical Practice, make reference to universal international

principles such as the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), and comply with the laws and regulations of the countries involved in the international multi-center clinical trials.

***Gathering, Collection and Filing of Human Genetic Resources***

After the overseas [REDACTED], as a foreign investment applicant, we must comply with the regulations of the Service Guide for Administrative Licensing of Gathering, Collection, Deal, Export and Exit Approval of Human Genetic Resources 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.

According 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 in May 2019, which came into effect on July 1, 2019 and was newly revised in March 2024, 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 addition, the gathering, preservation, utilization and external provision of Chinese genetic resources shall comply with relevant PRC regulations.

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.

***New Drug Application***

Pursuant to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), after completing clinical trials, determining quality standards, completing commercial-scale production process verification, and completing other relevant preparatory work, we may submit an application for drug marketing license to the NMPA. The NMPA then decides whether to agree to its application based on applicable laws and regulations. New drugs shall only be sold in the PRC market after the applicant has obtained the marketing license.

***Registration of Generic Drugs***

Our certain products are generic drugs. According to the Measures for the Administration of Drug Registration, for generic drugs or other eligible circumstances, if the applicant assesses that it is unnecessary or impossible for conducting clinical drug trial and meeting the conditions for exempting clinical drug trial, the applicant may directly file an application for drug marketing authorization. A generic drug shall be consistent with the quality and efficacy of the reference preparation. An applicant shall apply mutatis mutandis to the relevant technical guiding principles, select reasonable reference preparations. According to the Circular on Implementation of Record-filing Management of Bioequivalence Trials of Chemical Drug (《關於化學藥生物等效性試

驗實行備案管理的公告》), the management of bioequivalence trials of chemical drug has been changed from examination and approval to record-filing. For a generic drug developed based on an already marketed reference preparation, the reference preparation shall be the original research drug, and the generic drug shall complete the filing of bioequivalence trials. In addition, the active ingredients, route of administration, dosage form, drug specifications, etc. of the generic drug shall be consistent with those of the reference preparation. The NMPA shall conduct analysis and technical evaluation of the record-filing materials submitted by an applicant for registration. Where the record-filing materials have obvious defects or high safety risks, the NMPA shall notify the applicant in a timely manner and terminate the bioequivalence trial.

***Marketing Authorization Holder System***

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

With the approval of the drug regulatory department under the State Council, the marketing authorization holder may transfer its marketing authorization. The transferee shall have the capabilities in quality management, risk control, and liability compensation to ensure the drug's safety, efficacy, and quality controllability, and shall perform the obligations of a marketing authorization holder.

**Laws and Regulations in Relation to Drug Manufacturer and Drug Production**

***Drug Manufacturing License***

When conducting drug manufacturing, we shall obtain a Drug Manufacturing License from the relevant provincial authority under the NMPA in accordance with the Drug Administration Law.

Pursuant to the Measures for the Supervision and Administration of Drug Production promulgated by the SFDA on August 5, 2004 and newly amended on January 22, 2020, the validity period of a Drug Manufacturing License is five (5) years. The holder of the Drug Manufacturing License shall apply to the original licensing authority, which is the provincial-level authority under the NMPA at least six (6) months before the expiration of the validity period, and may continue the drug production license only after obtaining approval.

***Good Manufacturing Practice (hereinafter referred to as "GMP")***

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.

***Drug Contractual Manufacturing***

The Drug Administration Law stipulates that, unless otherwise provided by laws and regulations, a drug marketing authorization holder may either manufacture drugs by itself or entrust a drug manufacturer to conduct the manufacturing. If we entrust the production of drugs, we shall comply with the relevant provisions of the Supervision and Administration of Drug

Contractual Manufacturing (《藥品委託生產監督管理規定》) and the Measures for the Supervision and Administration of Drug Production (《藥品生產監督管理辦法》) both promulgated by the NMPA in August 2014. Such contractual manufacturing arrangement shall be subject to the approval of the provincial branch of the NMPA. The Provisions on the Supervision and Administration of Drug Contractual Manufacturing prohibits the contractual manufacturing of certain special drugs, including but not limited to narcotic drugs, psychotropic drugs, biochemical drugs, and APIs.

The Measures for the Supervision and Administration of Drug Production (《藥品生產監督管理辦法》) further stipulates that for a drug marketing authorization holder that entrusts the production of pharmaceutical preparations, it shall sign a commission agreement and a quality agreement with a qualified drug manufacturer, and submit the relevant agreements together with the application materials for the actual production site to the drug regulatory department, so as to apply for a Drug Manufacturing License.

On December 30, 2025, the National Medical Products Administration of the PRC issued the Announcement on Strengthening the Supervision and Administration of Entrusted Drug Manufacturing, which clarifies the specific obligations of contract manufacturers in respect of the quality management system, technology transfer, risk control for shared facility manufacturing, information management, and traceability of quality data. The Announcement requires that the division of responsibilities with the Marketing Authorization Holder through contract manufacturing agreements and quality agreements, and ensure alignment of their respective quality systems.

***Drug Recalls***

Pursuant to the Measures for the Administration of Drug Recalls promulgated on December 10, 2007, newly amended in October 2022, and became effective on November 1, 2022, we shall establish and improve their drug recall systems, collect information related to drug safety, and conduct investigations and evaluations on drugs with potential safety hazards. If a drug sold within the territory of China has any potential safety hazard that endangers human health and life safety, the drug manufacturer of such drug must initiate the drug recall procedure and perform recall obligations.

**Laws and Regulations in Relation to Drug Distribution**

***Drug Distribution***

According to the Drug Administration Law, our distributors shall obtain a Drug Distribution License and comply with the Good Supply Practice (《藥品經營質量管理規範》) ("**GSP**") to implement strict control over their drug distribution activities.

**Other Laws and Regulations in Relation to Medical Industry**

***Coverage of the National Medical Insurance System***

The State Council issued the Opinions of the State Council on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents on January 3, 2016, requiring the integration of the two systems, namely the basic medical insurance for urban residents and the new rural cooperative medical care, to establish a unified basic medical insurance system for urban and rural residents, except that migrant workers and flexible employees shall participate in the basic medical insurance for employees in accordance with the law.

***Medical Insurance Catalogue***

Pursuant to the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》), the scope of medical insurance coverage for pharmaceutical products needs to be managed through the formulation of the Medical Insurance Catalogue. A pharmaceutical product listed in the Medical Insurance Catalogue must be clinically necessary, safe and effective, reasonably priced, convenient to use and the supply of which can be guaranteed by the market, and have the conditions stipulated by laws and regulations. After several adjustments, 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 November 27, 2024. We have certain drugs falling within the scope of the aforementioned catalog.

***Two-invoice System***

On December 26, 2016, eight (8) government departments including the State Food and Drug Administration jointly issued the Notice on Issuing the Implementing Opinions on Launching the "Two-invoice System" in Drug Procurement for Public Medical Institutions (for Trial Implementation) (《關於印發〈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)〉的通知》) (the "**Implementing Notice**"). As defined by the "Implementing Notice", the "Two-invoice System" refers to the fact that a drug manufacturer issues an invoice to the distribution enterprise once, and the distribution enterprise issues an invoice to the healthcare institution once.

According to the Several Opinions Concerning Further Reforms of the Policies Governing Drug Production, Circulation and Usage (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》) issued on January 24, 2017, when participating in public hospital procurement, we must comply with the Two-invoice System.

***National Centralized Procurement Program and Tendering Procedures***

According 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.

***Advertising of Pharmaceutical Products***

The advertising of our pharmaceutical products must comply with the provisions of the Advertising Law of the PRC (《中華人民共和國廣告法》) and 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 in December 2019 and came into effect on March 1, 2020. We may submit their applications for advertisements for drugs at the advertisement review authorities. After review, for that advertisements that are in line with laws, administrative regulations and these Measures, approval decisions of review shall be made and advertisement approval numbers shall be issued.

***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 into effective on June 1, 2006, the insert sheets and labels of the 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. Drug manufacturers shall affix traceability labels on drug packaging in accordance with the regulations. Drugs whose ingredients do not match those stated on the label or package insert may be deemed as counterfeit drugs.

**Laws and Regulations in Relation to Products**

***Product Liability***

Our engagement in the production and sale of pharmaceutical products must comply with the Product Quality Law of the PRC (《中華人民共和國產品質量法》) promulgated by the SCNPC in February 1993, and latest amended in December 2018, and we bear the responsibility for the supervision and management of product quality.

Pursuant to the PRC Civil Code (《中華人民共和國民法典》) promulgated by the NPC in May 2020 and coming into effect in January 2021, the manufacturer shall bear tort liability for harm caused by defects in their products. Where damage is suffered due to defects in products, the infringed party may seek compensation from the manufacturer or the seller of the product.

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

***Production Safety***

Our drug production activities must comply with the Production Safety Law of the PRC (《中華人民共和國安全生產法》) promulgated by the SCNPC in June 2002 and amended in August 2014 and June 2021. Our employees must receive work safety education and be qualified through training before commencing their duties. For new building, rebuilding or expanding project, the safety facilities of the production and operation entity shall be designed, constructed and put into operation simultaneously with the main body of the project.

**Laws and Regulations in Relation to Anti-Bribery**

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by SCNPC, as amended on June 27, 2025, and effective on October 15, 2025, and the Interim Provisions on the Prohibition of Commercial Bribery (《關於禁止商業賄賂行為的暫行規定》) promulgated by the 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.

According to the Compliance Guidelines for Pharmaceutical Enterprises on Prevention of Commercial Bribery Risks (《醫藥企業防範商業賄賂風險合規指引》) issued by the SAMR on January 10, 2025, pharmaceutical enterprises are the principal entities responsible for preventing their own commercial bribery risks. Pharmaceutical enterprises should implement the main responsibility, strengthen internal control and compliance management to prevent commercial bribery risks, and consciously resist commercial bribery behaviors. Pharmaceutical enterprises should establish and improve compliance operation mechanisms based on the objective requirements of preventing commercial bribery risks, effectively preventing and addressing commercial bribery risks through systematic operations.

According to the Guiding Opinions on Establishment of the Trustworthiness Evaluation System for Drug Prices and Procurement by Bidding (《關於建立醫藥價格和招採信用評價制度的指導意見》) promulgated by the NHSA on August 28, 2020 and took effect simultaneously, the NHSA would establish a catalogue of dishonest matters involving drug prices and procurement by bidding, and the kickbacks or other improper benefits in the purchase and sale of drugs, tax-related violations of laws, monopolistic practices, improper pricing practices, disruption of the order of centralized procurement, malicious breach of contracts and other malpractices, will be included in such catalogue. Provincial centralized procurement agencies shall assess and rate the dishonest conduct of pharmaceutical enterprises into four levels: general, medium, serious and particularly serious, based on the nature, circumstances, effectiveness and impact of such dishonest conduct. Further, the provincial centralized procurement agencies shall, according to the trustworthiness ratings of pharmaceutical enterprises, take punitive measures, such as warnings and admonishments, restriction on market entry, and release of dishonest information. On May 20, 2025, the NHSA issued the Notice of the General Office of the National Health Insurance Administration on Further Improving the Credit Evaluation System for Pharmaceutical Pricing and Procurement (《國家醫療保障局辦公室關於進一步完善醫藥價格和招採信用評價制度的通知》), which simplified the credit violation evaluation into three tiers: "Credit Violation", "Serious Credit Violation", and "Especially Serious Credit Violation". For manufacturing enterprises with "Especially Serious Credit Violation", their product market access qualifications will be suspended. For the involved products, measures such as removing inflated pricing components must be taken in accordance with regulations when resuming sales.

**Regulations in Relation to Environmental Protection and Fire Safety**

***Environmental Protection Law***

According to the Environmental Protection Law (《環境保護法》), promulgated by the SCNPC on December 26, 1989 and amended on April 24, 2014 and came into effect on January 1, 2015, any enterprise or institution that discharges or will discharge pollutants during its operation or other activities shall adopt effective environmental protection measures and procedures to control and properly handle the waste gas, waste water, waste residue, dust, malodorous gases, radioactive materials, noise, vibration, electromagnetic radiation and other hazards generated in such activities.

***Environmental Impact Assessment Law***

Pursuant to the Environmental Impact Assessment Law (《中華人民共和國環境影響評價法》) of the PRC promulgated on October 28, 2002 and last amended on December 29, 2018, the State Council implements classified management of environmental impact assessments for construction projects based on the degree of environmental impact of such projects. Entities prepare an environmental impact report, an environmental impact statement or fill out the environmental impact report form in accordance with the rules.

***Regulations in Relation to the Administration of Construction Project Environmental Protection***

Pursuant to the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》), which was promulgated on November 29, 1998 and last amended on July 16, 2017, and became effective on October 1, 2017, construction projects which cause pollution in the construction process shall comply with the national and local standards in respect of the discharge of pollutants; requirements for aggregate control of discharge of major pollutants must be met in areas under aggregate control of discharge of major pollutants.

***Regulations in Relation to Urban Drainage and Sewage Disposal***

Our product production shall, in accordance with the provisions of the Regulations on Urban Drainage and Sewage Disposal (《城鎮排水與污水處理條例》), the Administration of Permits for the Discharge of Urban Sewage into the Drainage Network (《城鎮污水排入排水管網許可管理辦法》) and the Administration of Sewage Discharge Permits (《排污許可管理辦法》), apply for and obtain a drainage license and a pollutant discharge permit.

***Regulations in Relation to Lease***

According to the Civil Code, owners shall have the rights to possess, use, benefit from and dispose of their real estate or movable properties in accordance with the law. The lessee may sublease the leased premises to a third party, subject to the consent of the lessor.

On December 1, 2010, the Ministry of Housing and Urban-Rural Development promulgated the Administrative Measures on Leasing of Commodity Housing (《商品房屋租賃管理辦法》), which became effective on February 1, 2011. According to such measures, the lessor and the lessee are required to complete property leasing registration and filing formalities within 30 days from execution of the property lease contract with the development authorities or real estate authorities of the municipality or county where the leased property is located. If a company fails to do as aforesaid, it may be ordered to rectify within a stipulated period, and if such company fails to rectify, a fine ranging from RMB1,000 to RMB10,000 may be imposed on each lease agreement.

**Regulations in Relation to Intellectual Property**

***Patent***

We hold several patents. 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**"). According 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***

We have certain trademarks. Trademarks are protected by the Trademark Law of the PRC (《中華人民共和國商標法》) and the Implementation Regulations of the PRC Trademark Law (《中華人民共和國商標法實施條例》). The Trademark Office under the State Administration for Market Regulation handles trademark registrations. The Trademark Office grants a ten-year term to registered trademarks and the term may be renewed for another ten-year period upon request by the trademark owner.

***Trade Secret***

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》), 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 illegal activities according to law and impose fine on the infringing parties.

**Regulations in Relation to Cybersecurity and Data Protection**

***Data Security and Export***

The Data Security Law of the PRC (《中華人民共和國數據安全法》) came into effect on September 1, 2021 stipulates that China's central government shall establish a central data security work coordination mechanism to coordinate the formulation of catalogues of important data by relevant departments across various industries and implement special measures to protect the security of important data.

Pursuant to the Civil Code of the PRC (《中華人民共和國民法典》), personal information of natural persons is protected by law. According to the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》), which came into effect on June 1, 2017, we must not collect or use personal information in violation of legal provisions or agreements with users. The Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) further emphasizes the obligations and responsibilities of data processors for the protection of personal information, and provides stricter protection measures on the processing of sensitive personal information.

According to the Measures on Security Assessment of Outbound Data Transfer (《數據出境安全評估辦法》) issued by the Cyberspace Administration of China on July 7, 2022 and came into effect on September 1, 2022, a data processor that provides data overseas under specific circumstances shall apply to the Cyberspace Administration of China for the security assessment of the outbound data transfer through local provincial cyberspace administration.

According to the Measures for Standard Contract for Outbound Transfer of Personal Information (《個人信息出境標準合同辦法》) effective from June 1, 2023, to provide personal information to an overseas recipient through the conclusion of the standard contract, a personal information processor shall meet all of the following circumstances: (I) it is not a critical information infrastructure operator; (II) it has processed the personal information of less than one million individuals; (III) it has cumulatively provided the personal information of less than 100,000 individuals to overseas recipients since January 1 of the previous year; and (IV) it has cumulatively provided the sensitive personal information of less than 10,000 individuals since January 1 of the previous year. The Cyberspace Administration of China promulgated the Provisions on Facilitating and Regulating Cross-border Data Flows (《促進和規範數據跨境流動規定》) on March 22, 2024, which came into effect on March 22, 2024, have updated the regulatory mechanism for outbound data transfer.

The Management Measures of Standards, Safety and Service of Health and Medical Big Data (《健康醫療大數據標準、安全和服務管理辦法》) which became effective on July 12, 2018 provide guidance and principles for the administration of standards, security and services of health and medical big data. Healthcare institutions and related enterprises (including enterprises entrusted by healthcare institutions with the storage and operation of health and medical big data) shall adopt such measures as data classification, backup of important data and encryption authentication to ensure the security of health and medical big data, and provide secure channels for information inquiry and duplication.

The Regulation on Network Data Security Management (《網絡數據安全管理條例》), which promulgated on January 1, 2025, reaffirms the general provisions on data processing activities and rules for the protection of personal information, protection of important data security, cross-border management of network data, and obligations of network platform service providers.

**Laws and Regulations in Relation to Labor Protection**

***Labour Law and Labour Contract Law***

The Labor Law of the PRC (《中華人民共和國勞動法》) and the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》) stipulate the rights and obligations of employers and employees, including the establishment, performance, and termination of labor contracts. Employers and employees who are about to establish or have already established an employment relationship shall enter into a written labor contract.

Employers must not force employees to work overtime and shall pay overtime wages to employees in accordance with national regulations. Additionally, employees' wages must not fall below the local minimum wage standard and must be paid on time.

***Social Insurance and Housing Provident Fund***

According to the Social Insurance Law (《社會保險法》), the Interim Measures concerning Maternity Insurance for Enterprise Employees (《企業職工生育保險試行辦法》) implemented on January 1, 1995, the Decisions on the Establishment of a Unified Program for Basic Old-Aged Pension Insurance for Employees of Corporations of the State Council (《國務院關於建立統一的企業職工基本養老保險制度的決定》) issued on July 16, 1997, the Decisions on the Establishment of the Medical Insurance Program for Urban Workers of the State Council (《國務院關於建立城鎮職工基本醫療保險制度的決定》) promulgated on December 14, 1998, the Regulations on Unemployment Insurance (《失業保險條例》) promulgated on January 22, 1999, and the Regulations on Work-Related Injury Insurance (《工傷保險條例》) implemented on January 1, 2004 and amended in 2010, within China, employers shall provide their employees with benefits such as pension insurance, unemployment insurance, maternity insurance, work-related injury insurance, and medical insurance. Such funds shall be paid to the local human resources and social security departments. Any employer that fails to pay social insurance premiums may be ordered to make corrections, make up the required fees within the specified time, and be imposed with late payment fines. If the employer still fails to make corrections within the time limit, it may be fined between one to three times the amount of arrears.

According to the Regulations on the Administration Housing Provident Funds (《住房公積金管理條例》) promulgated by the State Council in 1999 and latest amended in March 2019, employers must register with the designated housing provident fund management center and open a bank account for depositing employees' housing provident fund. In accordance with the regulations of the Ministry of Housing and Urban-Rural Development and its local housing provident fund management centers, employers and employees must also pay the housing provident fund on time and in full, and the amount shall not be less than 5% of each employee's average monthly wage of the previous year.

**Laws and Regulations in Relation to Tax**

***Enterprise Income Tax***

According to the Enterprise Income Tax Law (《企業所得税法》) and the Implementation Regulations of the Enterprise Income Tax, both resident enterprises and non-resident enterprises are required to pay taxes in China and are subject to the supervision of the SAT and its local competent authorities. A resident enterprise refers to an enterprise established within China in accordance with Chinese laws, or an enterprise established in accordance with foreign laws but actually controlled by a management institution within China. A non-resident enterprise refers to an enterprise established in accordance with foreign laws with its actual management located outside China, but which has set up institutions or places within China, or which has not set up such institutions or places but has income derived from sources within China. Pursuant to the Enterprise Income Tax Law and the Implementation Regulations of the Enterprise Income Tax, the income tax rate applicable to all enterprises is 25%. However, for non-resident enterprises that have not set up permanent institutions or places within China, or have set up such permanent institutions or places but the relevant income obtained within China has no actual connection with the institutions or places they have set up, they shall pay enterprise income tax at a rate of 10% on their income derived from sources within China.

***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》), promulgated on December 13, 1993 and last amended on November 19, 2017, as well as The Decisions of the State Council on Abolishing the Provisional Regulations of the PRC on Business Tax and Amending the Provisional Regulations of the PRC on Value-added Tax (《國務院關於廢止〈中華人民共和國營業税暫行條例〉和修改〈中華人民共和增值税暫行條例〉的決定》) promulgated on November 19, 2017, all enterprises and individuals engaged in the sale of goods, provision of processing, repair and replacement services, sale of services, intangible assets, real estate, and import of goods within China shall pay value-added tax. In accordance with Announcement No. 39 issued by the SAT and its local competent authorities, the generally applicable VAT rates were simplified to 13%, 9%, 6% and 0%, which took effect on April 1, 2019. The VAT rate applicable to small-scale taxpayers is 3%.