
REGULATORY OVERVIEW

PRC LAWS AND REGULATIONS

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

Major PRC Regulatory Authorities

NMPA and Center for Drug Evaluation

The National Medical Products Administration (國家藥品監督管理局) (the “**NMPA**”) is the department in charge of the pharmaceutical industry of China. It is responsible for drawing up the laws and regulations related to pharmaceuticals and medical devices, making policies and plans, establishing department manuals and procedures, organizing the development and issuance of pharmaceutical and medical device standards, classification and management regulations, such as national formulary, and supervising the implementation.

The Center for Drug Evaluation (the “**CDE**”) is the technical evaluation unit for drug registration with NMPA. It is mainly responsible for conducting technical evaluation on the drugs applying for registration and verifying the relevant aspects with drug registrations.

NHC

The National Health Commission (國家衛生健康委員會) (the “**NHC**”) is mainly responsible for formulating national health policies, coordinating to deepen the reform of the medical and health system, organizing the formulation of a national essential drugs system, and supervising and managing medical services.

NHSA

The National Healthcare Security Administration (國家醫療保障局) (the “**NHSA**”) is mainly responsible for formulating and organizing the implementation of policies, plans and standards for medical insurance, maternity insurance, medical assistance and other healthcare security systems, organizing the formulation and adjustment of prices and charging standards for drugs and medical services, and formulating and supervising the implementation of the bidding and procurement policies for drugs and medical consumables.

Laws and Regulations in Relation to the Pharmaceutical Industry

Management and Classification of Drugs

According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), for the purpose of drug registration, drugs are classified into traditional Chinese drugs, chemical drugs and biological products. Chemical drugs are further classified into innovative chemical drugs, improved new chemical drugs, generic chemical drugs, etc.

Research and Development of New Drugs

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the “**Drug Administration Law**”) 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》) have laid down the legal framework for the establishment and maintenance of pharmaceutical manufacturing and trading enterprises, as well as for the administration of pharmaceutical products including the development and manufacturing of new drugs. According to the Drug Administration Law and its Implementation Regulations, the PRC

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encourages the research and development of new drugs and protects the legal rights and interests for the research and development of new drugs. The developer and the clinical trial sponsor of any new drug are required to truthfully submit the new drug’s manufacturing method, quality specifications, results of pharmacological and toxicological tests and the related data, documents and samples to the NMPA for approval before any clinical trial is conducted.

Non-Clinical Study

The non-clinical safety evaluation study for drugs for the purpose of applying for drug registration and relevant activities shall be conducted in accordance with the Good Laboratory Practice for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》). 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》) provides for the procedures for application and acceptance of Good Laboratory Practice certification by research institutions conducting non-clinical safety evaluation study for drugs, requirements for data review and on-site inspection, audit procedures and supervision and management.

Application for Clinical Trial

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

Conduct of Clinical Trials

According to the provisions of the Drug Administration Law, drug clinical trials shall be conducted in clinical trial institutions that meet corresponding conditions, and drug clinical trial institutions shall be subject to record-keeping management. The conduct of drug clinical trials shall comply with ethical principles, with a clinical trial protocol developed, and be subject to review and approval by the Ethics Committee. The Ethics Committee shall establish an ethics review system to ensure that the ethics review process is independent, objective, and fair, and supervise the standard conduct of drug clinical trials. Before a clinical trial is conducted, details such as the clinical trial objective and risks shall be truthfully stated and explained to the trial subjects or their guardians, and an informed consent letter signed voluntarily by the trial subject or their guardian shall be obtained, and effective measures shall be taken to protect the lawful rights and interests of the trial subjects. Where safety issues or other risks are discovered during a drug clinical trial, the clinical trial sponsor shall promptly adjust the clinical trial protocol, suspend or terminate the clinical trial, and report to the drug regulatory departments under the State Council. If necessary, the drug regulatory departments under the State Council may order the sponsor to adjust the clinical trial protocol or suspend or end the clinical trial.

The Good Clinical Practice (《藥物臨床試驗質量管理規範》) specifies the quality standards for the whole process of drug clinical trials, including protocol design, organization, implementation, monitoring, auditing, recording, analysis, summarization and reporting. It further clarifies the responsibilities of the Ethics Committee to protect the rights and interests and safety of the trial subjects. The Committee shall review the clinical trial protocol, the qualifications of the

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investigators, the methods and information of recruiting the trial subjects according to the specific requirements, as well as the scientific and ethical nature of clinical trials. It also provides for the qualifications and requirements of the investigators and the clinical trial institutions, and the sponsors shall establish a quality management system for clinical trials which covers the whole process of clinical trial design, implementation, recording, evaluation, results reporting, filing and information acquisition.

Administration of Drug Registration

The Administrative Measures for Drug Registration shall apply to the activities of drug research, registration, supervision and management in China for the purpose of drug marketing. Drug registration refers to the procedure that a drug registration applicant (hereinafter referred to as the “applicant”) submits an application for drug clinical trial, drug marketing authorization, re-registration and other supplementary applications in accordance with legal procedures and relevant requirements, and the drug regulatory departments, based on laws and regulations and existing scientific knowledge, reviews the safety, effectiveness and quality controllability of relevant drugs, and decides whether to approve of the application. The applicant shall be a drug marketing authorization holder (hereinafter referred to as the “authorization holder”) after obtaining the drug registration certificate.

According to the Administrative Measures for Drug Registration, the NMPA shall be in charge of the administration of drug registration throughout the country; the CDE of the NMPA shall be responsible for the evaluation of clinical trial application, marketing authorization application, supplementary application and re-registration application of overseas produced drugs; the National Institutes for Food and Drug Control, Center for Food and Drug Inspection of NMPA and other specialized drug technical institutions shall be responsible for examination, verification, monitoring and evaluation of drug registration, preparation and service of certificate and corresponding information construction and management.

According to the Administrative Measures for Drug Registration, an applicant shall upon completion of studies in areas such as pharmacy, pharmacology and toxicology and clinical trial to support registration of drug marketing, determination of quality standards, verification of commercial scale manufacturing process, and preparation to undergo examination and inspection for drug registration, submit a new drug application (the “NDA”), which shall be evaluated by the NMPA in accordance with applicable laws and regulations. The applicant must obtain approval of an NDA before the drugs can be manufactured and sold in China. During the drug clinical trials, for drugs which fall under the following circumstances, an application for conditional approval may be submitted: (i) for drugs used for the treatment of severe and life-threatening diseases that cannot be treated in an effective manner and those the clinical trial data of which already show their efficacy and their clinical value is predictable; (ii) for drugs urgently needed for public health and those the clinical trial data of which already show their efficacy and their clinical value is predictable; and (iii) for vaccines that are urgently needed for major public health emergencies or other vaccines deemed by the NHC to be urgently needed, whose benefits outweigh their risks according to the evaluation.

Marketing Authorization Holder System

The Drug Administration Law formalizes the drug marketing authorization holder system and stipulates that the drug marketing authorization holder shall be responsible for the non-clinical research, clinical trial, production and management, post-marketing research, adverse reaction monitoring, reporting and handling of drugs. It also requires the drug marketing authorization holder to establish a drug quality assurance system, and assign ad hoc personnel to be independently responsible for the supervision and management of drug quality.

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Pharmacovigilance

According to the Good Pharmacovigilance Practices (《藥物警戒質量管理規範》), the drug marketing authorization holder and the drug registration applicant who has been approved to conduct drug clinical trials shall establish a pharmacovigilance system, through the effective operation and maintenance of which, they can monitor, identify, evaluate and control the adverse drug reactions and other drug-related harmful reactions. The drug marketing authorization holder shall formulate pharmacovigilance quality objectives, establish a quality assurance system, and conduct quality management of the pharmacovigilance system and activities, so as to continuously improve the operation efficiency of the pharmacovigilance system and ensure that pharmacovigilance activities continue to comply with the requirements of relevant laws and regulations. The legal representative or the key person-in-charge of the drug marketing authorization holder is fully responsible for the pharmacovigilance activities. The drug marketing authorization holder shall complete information registration in the National Adverse Drug Reaction Monitoring System within 30 days after obtaining the first drug approval document.

Drug Manufacturing License

According to the Administrative Measures on Supervision of Pharmaceutical Manufacturing (《藥品生產監督管理辦法》), all facilities that manufacture drugs in China must apply for a pharmaceutical manufacturing permit which is issued by the drug supervision and administration department of the province, autonomous region or municipality directly under the central government where they are domiciled. The pharmaceutical manufacturing permit is valid for five years and shall be renewed six months before the expiry date. The drug marketing authorization holder who entrusts another party to produce preparations shall meet the requirements as specified in the Administrative Measures on Supervision of Pharmaceutical Manufacturing, sign an entrustment agreement and a quality agreement with a qualified drug producer, and submit the relevant agreements and the application materials of the actual production site to the provincial drug supervision and administration department where the drug marketing authorization holder is located to apply for the pharmaceutical manufacturing permit. According to the Administrative Measures for Drug Registration, when an application for marketing authorization is submitted, the applicant and the drug manufacturer shall have obtained the corresponding pharmaceutical manufacturing permit.

Pursuant to the Administrative Regulations for the Contract Manufacturing of Drugs (《藥品委託生產監督管理規定》) (the “**Contract Manufacturing Regulations**”), in the event a drug manufacturer in China that has obtained a drug marketing authorization temporarily lacks manufacturing conditions as a result of technology upgrade or is unable to ensure market supply due to insufficient manufacturing capabilities, it can entrust the manufacturing of that drug to another domestic drug manufacturer. Such contract manufacturing arrangements need to be approved by the provincial branch of the NMPA. The Contract Manufacturing Regulations prohibit the contract manufacturing arrangement of certain special drugs, including but not limited to narcotic drugs, psychoactive drugs, biochemical drugs, multi-component biochemical drugs and drug substance.

Good Manufacturing Practices

The Good Manufacturing Practices (《藥品生產質量管理規範》) sets the basic standards for the manufacture of pharmaceuticals, covering issues such as the production plant and facilities, the qualification of the personnel at the management level, documentation, material packaging and labeling, inspection, production management, sales and return of products and customer complaints.

According to the Notice on Issuing the Administrative Rules Governing the Certification of Good Manufacturing Practice for Drugs (《關於印發藥品生產質量管理規範認證管理辦法的通知》), a new pharmaceutical manufacturer, or a pharmaceutical manufacturer that extends its manufacturing scope or establishes a new workshop shall apply for GMP certification for drugs in compliance with the Implementing Rules for the Drug Administration Law. For any pharmaceutical

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manufacturer holding GMP certification for drugs, the certificate shall be renewed no later than six months before the expiry of its valid term. The Notice on Matters concerning the Implementation of Good Manufacturing Practice (《關於切實做好實施藥品生產質量管理規範有關工作的通知》) provides that drug manufacturers failing to obtain the GMP certificates will not be issued with the drug manufacturing license.

The Circular on the Relevant Issues concerning the Implementation of the Drug Administration Law of the PRC (《關於貫徹實施〈中華人民共和國藥品管理法〉有關事項的公告》) confirms that since December 1, 2019, the GMP certifications have been cancelled, applications for GMP certifications are no longer accepted, and GMP certificates are no longer issued. However, according to the Drug Administration Law, when engaging in drug manufacturing activities, a manufacturer shall comply with the GMP and establish a sound GMP system, so as to ensure that the entire process of drug manufacturing always meets the statutory requirements.

After the Administrative Measures for the Inspection of Pharmaceuticals (Trial) (《藥品檢查管理辦法(試行)》) was promulgated, the Certification Measures for Good Manufacturing Practice for Drugs (《藥品生產質量管理規範認證管理辦法》) was repealed simultaneously. The Administrative Measures for the Inspection of Pharmaceuticals (Trial) stipulated that if a drug manufacturer applies for a drug manufacturing license for the first time, it will be subject to on-site inspection under relevant contents of the GMP; if a drug manufacturer applies for re-issuance of drug manufacturing license, relevant authorities shall conduct examination pursuant to risk management principle, taking into account the enterprise’s compliance with pharmaceutical administration laws and regulations, operation status of GMP and quality system, and may conduct GMP compliance inspection where necessary.

Drug Operation Permit

According to the Drug Administration Law, a drug operation permit shall be obtained for drug wholesale activities upon approval by the drug regulatory departments of the local people’s governments of the provinces, autonomous regions or municipalities directly under the central government, and a drug operation permit shall be obtained for drug retailing activities upon approval by the drug regulatory departments of the local people’s governments above the county level. Those who do not have a drug operation permit shall not trade in drugs. The drug operation permit shall indicate the validity period and the business scope of drug operation, and is renewable upon expiry after re-examination.

China’s National Medical Insurance System

The National Reimbursement Drug List for Basic Medical Insurance, Work Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》) (the “NRDL”) sets out the standards for payment of medicines by the basic medical insurance (“BMI”), work injury insurance and maternity insurance funds. The scope of the use of drugs covered by BMI is administered through the formulation of the BMI Drug Catalog (《基本醫療保險藥品目錄》). The BMI Drug Catalog is managed by generic names, and medicines under the same generic name as those already included in the NRDL will automatically share the same scope of medical insurance reimbursement.

NRDL Negotiation

Since 2017, the NHSA in China has implemented a systematic and value-based drug evaluation mechanism to assess innovative therapies seeking inclusion in the NRDL. It conducts price negotiations with pharmaceutical companies to secure reasonable payment standards for exclusive or high-value drugs covered by public healthcare. Under the current regulatory regime, the negotiated drug contract lasts for two years, after which the contract needs to be renewed.

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NRDL Renewal

The following sets forth the current renewal pathways under the applicable NRDL renewal rules:

- *Routine Catalog Management.* Under existing rules, non-exclusive drugs and exclusive drugs that have been continuously in the “negotiated drugs” section for eight years (as of December 31 of the adjustment year, applicable to drugs included in 2017) are eligible for the transition into “routine catalog” management and will not be subject to re-negotiations.
- *Simplified Renewal.* Exclusive drugs that meet certain criteria are eligible for a simplified renewal pathway, a streamlined alternative to the full re-negotiation process. A critical condition is that the actual fund expenditure during the agreement period must not exceed 200% of the projected budget (i.e., calculation of “Ratio A”). When the Ratio A is greater than 110% and does not exceed 200% during the renewal, the company may choose to proceed with a simplified renewal process or apply for a re-negotiation to determine the reduction ratio.
- *Re-negotiation.* Exclusive drugs that do not meet the conditions for routine management or simplified renewal will be subject to re-negotiation. Failure in the re-negotiation process will result in the drug being removed from the scope of negotiated drugs, and the drug will no longer be eligible for the negotiated medical insurance reimbursement.

More importantly, the NHSA has shown a more innovation-friendly stance in its recent update of the renewal rules for older drugs negotiated under the NRDL. As described above, negotiated drugs listed in the NRDL for more than eight years will no longer be subject to further negotiations or price reductions until their generic counterparts become available. In addition, negotiated drugs listed in the NRDL for more than four years will experience a halved price reduction ratio in their payment standard. Prior to the rule update, these older drugs were subjected to the same renewal price reduction schedule as newer negotiated entries (i.e., those listed for less than four years). In the recent update of the renewal rules, the risk of double price reduction due to indication expansion during listing renewal was also removed. Moreover, starting from 2025, the calculation of renewal price reduction will be based on the cost of drugs included in the payment scope rather than 65% of the drug sales. Innovative drug manufacturers will also have a genuine opportunity to negotiate a lower price reduction than the simplified renewal reduction. Before the rule change, drug price reduction during re-negotiation had to be equal to or higher than the simplified renewal reduction.

2025 NRDL

On December 7, 2025, the NHSA and the Ministry of Human Resources and Social Security jointly released the updated NRDL, which took effect on January 1, 2026. The NRDL has been updated with 114 newly added drugs. The newly added drugs cover multiple critical therapeutic areas where effective treatment options were previously lacking. This includes medicines for major diseases such as triple-negative breast cancer, pancreatic cancer, and lung cancer, as well as treatments for some rare diseases and chronic diseases like diabetes.

The updated NRDL now includes a total of 3,253 drugs, including 1,857 chemical/biologic drugs and 1,396 proprietary Chinese medicines. Drugs included in the NRDL are classified into “Class A” (fully reimbursed by the national medical insurance) and “Class B” (partially reimbursed) drugs. The proportion of out-of-pocket payments for “Class B drugs” is determined by the medical insurance administrative departments in provincial regions subject to overall planning.

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First CHIIDL

On December 7, 2025, the NHTSA and the Ministry of Human Resources and Social Security jointly released the first-ever Commercial Health Insurance Innovation Drug List (《商業健康保險創新藥品目錄》) (the “**CHIIDL**”), which took effect on January 1, 2026.

The CHIIDL is designed to create a complementary system that fills gaps in the basic medical insurance coverage. The first edition of CHIIDL includes 19 drugs from 18 pharmaceutical companies, including 9 NME drugs. The CHIIDL features cutting-edge treatments like CAR-T cell therapy and bispecific antibodies for cancer, as well as new drugs for Alzheimer’s disease and rare diseases (like neuroblastoma and Gaucher disease). The main goal is to cover highly innovative drugs that offer significant clinical value and major patient benefits, but which are currently not covered by the NRDL.

For pharmaceutical enterprises, this CHIIDL brings new market dynamics. Inclusion in the CHIIDL offers an advantage, as the potential adoption by many commercial insurance products creates a significant scale effect and substantially increases utilization volume.

VBP of Drugs

The Opinions on Promoting the Normalization and Institutionalization of the VBP of Drugs (《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》) (the “**Normalization Opinions**”) stated that various measures would be adopted to promote the normalization and institutionalization of nationwide VBP. All public medical institutions are required to participate in the VBP program. The procurement program will focus on drugs with high demand and high procurement costs in the National Essential Medicines List, gradually covering clinically necessary, reliable- quality drugs available on the domestic market. Future procurement lists are expected to include widely demanded or high-priced drugs in the National Medical Insurance List, aiming to encompass as many clinically necessary, high-quality drugs as possible.

According to the Normalization Opinions, VBP is to be carried out in a tiered manner. The state will organize centralized VBP for certain drugs that have passed consistency evaluation and conduct special procurement based on market conditions while guiding local authorities in their procurement efforts. Provincial-level regions (provinces, autonomous regions, and municipalities) are responsible for independently conducting or forming alliances with other provinces for centralized VBP of drugs not included in the national procurement scope. They are also tasked with guiding eligible prefecture-level regions to conduct procurement. Prefecture-level regions are expected to independently or collaboratively conduct VBP for drugs not covered by upper-level organizations, according to their provincial arrangements. For drugs not yet included in the government-organized VBP scope, medical institutions may independently or delegate procurement via the provincial-level drug procurement platform.

Two-invoice System

According to the Implementing Opinions on Launching the “Two-invoice System” in Drug Procurement for 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)》), 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. The wholly-owned or controlling commercial companies (limited to one commercial company nationwide) and the domestic general agents of overseas drugs (limited to one domestic general agent nationwide) set up by a pharmaceutical manufacturer or a group-type enterprise integrating science, industry and trade, which only sells drugs of their own enterprise (group), can be regarded as manufacturing enterprises. The

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appropriation of drugs within a pharmaceutical distribution group-type enterprise to a wholly-owned (holding) subsidiary or between wholly-owned (holding) subsidiaries may not be regarded as a single invoice, but is allowed to be invoiced at most once. The “two-invoice system” is gradually implemented in the procurement of drugs for public medical institutions, and other medical institutions are encouraged to implement the “two-invoice system” in the procurement of drugs. Pilot provinces (autonomous regions and municipalities) for the comprehensive medical reform and pilot cities for the public hospital reform should take the lead in implementing the “two-invoice system”, and other regions are encouraged to implement the “two-invoice system”, with a view to achieving its full-scale implementation throughout the country by 2018.

Laws and Regulations in Relation to the Medical Device Industry

Industry Classification of Medical Devices

Pursuant to the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), medical devices are classified into Class I (low risk), Class II (medium risk), and Class III (high risk) based on risk level. Medical devices of Class I refer to such devices with low level of risk, the safety and effectiveness of which can be ensured through routine administration. Medical devices of Class II refer to such devices with medium level of risk, the safety and effectiveness of which shall be strictly controlled. Medical devices of Class III refer to such devices with high level of risk, the safety and effectiveness of which shall be guaranteed and be subject to strict control through special administrative measures.

Registration and Filings of Medical Device Products

Pursuant to the Measures for the Administration of Registration and Filing of Medical Devices (《醫療器械註冊與備案管理辦法》), Class II and Class III medical devices are subject to product registration management, while Class I medical devices are subject to product filing management. Legal manufacture of domestic Class I medical devices shall submit record-filing materials to the drug regulatory authorities at the level of city divided into districts. Domestic Class II medical devices shall be reviewed by the drug regulatory authorities of provinces, autonomous regions and centrally-administered municipalities, which shall issue the Medical Device Registration Certificate upon approval after examination. Domestic Class III medical devices shall be examined by the NMPA, which shall issue the Medical Device Registration Certificate upon approval after examination. The registration certificate for a medical device is valid for five years and the registrant shall apply to the original registration departments for renewal at least six months prior to its expiration date.

Good Clinical Trial Practice for Medical Devices

The Good Clinical Trial Practice for Medical Devices (《醫療器械臨床試驗質量管理規範》) governs the entire medical device clinical trial process, including protocol design, implementation, monitoring, auditing and inspection, as well as data collection, recording, storage, analysis, summary and reporting. Clinical trials of medical devices shall be carried out in clinical trial institutions and only for medical devices that meet the corresponding conditions and have gone through requisite record-filing processes. Clinical trials of medical devices are required to be approved by an ethics committee. For Class III medical devices that require clinical trials as part of the registration process, such trials must be conducted in qualified medical institutions (e.g., Class III Grade A hospitals). It is important to note that not all Class III devices necessarily undergo clinical trials, as exemptions may apply.

The sponsor of a medical device clinical trial shall establish a quality management system covering the whole process of the clinical trial of medical devices to ensure the clinical trial complies with relevant laws and regulations and protect the rights and interests and safety of subjects.

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Production of Medical Devices

According to the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) and the Measures on the Supervision and Administration of Medical Devices Production (《醫療器械生產監督管理辦法》), in order to engage in the production of medical devices, an entity shall meet the following conditions: (i) having the production site, environmental conditions, production equipment and professional technicians that meet the needs of the medical devices to be produced; (ii) having the facility or full-time personnel and testing equipment capable of testing the quality of the medical devices to be produced; (iii) having a system of internal control that can ensure the quality of medical devices; (iv) having the after-sale service capabilities that meet the needs of the medical devices to be produced; and (v) having the capability to meet the requirements as prescribed in the documents on product research and development and production techniques.

To engage in the production of Class II and Class III medical devices, an entity shall apply for a manufacturing license to the drug regulatory department of the people’s government of the province where it is located and submit the relevant materials and the registration certificate of the medical devices to be produced. The manufacturing permit for medical devices is valid for five years. When it is necessary to renew the permit upon its expiration, the formalities for renewal shall be completed in accordance with the relevant laws on administrative licensing.

Operation of Medical Devices

In order to strengthen the supervision and management of medical devices operation, regulate medical device operation activities, and ensure the safety and effectiveness of medical devices, the State Administration for Market Regulation has formulated the Measures for the Supervision and Administration of Medical Devices Operation (《醫療器械經營監督管理辦法》) (the “**2022 Supervisory and Administrative Measures for Operations**”) in accordance with the 2024 Medical Devices Regulations. According to the 2022 Supervisory and Administrative Measures for Operations, an enterprise engaging in the operation of medical devices shall have business premises and storage conditions suitable for the operation scale and scope, and shall have a quality control department or personnel suitable for the medical devices it operates. An enterprise engaged in the operation of Class II medical devices shall file with the competent municipal level drug supervision and administration department and provide proofing materials for satisfying the relevant conditions of engaging in the operation of Class II medical devices, while an enterprise engaged in the operation of Class III medical devices shall apply for a Business Operation Licence of Medical Devices (醫療器械經營許可證) to the competent municipal level drug supervision and administration department and provide proofing materials for satisfying the relevant conditions of engaging in the operation of such medical devices. The competent drug supervision and administration department which receives operation permit application shall grant the Business Operation Licence of Medical Devices if the enterprise meets the prescribed requirements. A Business Operation Licence of Medical Devices is valid for five years and may be renewed pursuant to the relevant regulations. An enterprise engaging in medical devices operation shall not operate any medical device that has not been legally registered or filed for record, without qualification certificate, outdated, invalid or disqualified.

Other Laws and Regulations in the PRC

Product Liability and Protection of Consumer Rights and Interests

According to the Product Quality Law of the PRC (《中華人民共和國產品質量法》), producers and sellers shall establish a sound internal product quality control system and strictly adhere to a job responsibility system in relation to quality standards and quality liabilities together with implementing corresponding examination and inspection measures. Producers and sellers shall bear liability for product quality in accordance with this Law.

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According to the Civil Code of the PRC (《中華人民共和國民法典》), in the event of damage to others arising from a defective product, the infringed may seek compensation from either the producer or seller of the said product. If the product defect is caused by the producer, the seller shall be entitled to seek reimbursement from the producer upon compensation. If the product defect is caused through the fault of the seller, the producer shall be entitled to seek reimbursement from the seller upon compensation. If a defect is found in a product after it has been put into circulation, the producer and the seller shall take remedial measures in a timely manner including stopping selling, alerts and recalls. In the event of more damage arising from a failure to take remedial measures in a timely manner or inadequate remedial measures, they shall bear tort liability. A patient may seek compensation from the drug marketing authorization holder, producer or medical institution for any damage arising from defects of drugs. If the said patient seeks compensation from the medical institution, the medical institution shall have the right to, after compensation, claim reimbursement from the drug marketing authorization holder and the producer liable for the damage.

Safety Production

The Production Safety Law of the PRC (《中華人民共和國安全生產法》) is the basic law for governing production safety. It provides that, any entity whose production safety conditions do not meet the requirements may not carry out production and operation activities. Production and operation entities shall educate and train employees regarding production safety so as to ensure that the employees have the necessary knowledge of production safety, are familiar with the relevant regulations and rules for safe production and the rules for safe operation, master the skills of safe operation in their own positions, understand the emergency measures, and know their own rights and duties in terms of production safety. Employees who fail the education and training programs on production safety may not commence working in their positions. Safety facilities of new building, rebuilding or expanding project shall be designed, constructed and put into operation simultaneously with the main body of the project. Investment in safety facilities shall be included in the budget of the construction project.

Environmental Protection

According to the Code of the PRC on the Ecological Environment (《中華人民共和國生態環境法典》) (“**Ecological Environment Code**”), the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》), and the Administrative Regulations on the Environmental Protection of Construction Project (《建設項目環境保護管理條例》), enterprises which plan to construct projects shall engage qualified professionals to provide the assessment reports, assessment form, or registration form on the environmental impact of such projects. The assessment reports, assessment form, or registration form shall be filed with or approved by the relevant environmental protection bureau prior to the commencement of any construction work.

According to the Ecological Environment Code and the Regulation on Administration of Discharge Permit (《排污許可管理條例》), enterprises, public institutions and other producers and operators that are subject to the administration of discharge permit shall discharge pollutants in accordance with the requirements of the discharge permit; and those who have not obtained the discharge permit shall not discharge pollutants. The competent authorities in charge of environmental protection shall impose different administrative penalties on individuals or enterprises that violate the Ecological Environment Code. According to the Measures for Pollutant Discharge Permitting Administration (《排污許可管理辦法》), enterprises, public institutions and other producers and business operators shall, in accordance with factors such as the amount of pollutants produced, the amount of pollutants discharged and the extent of their impact on the environment, carry out the management of pollutant discharge permits with a focus, simplified management and pollutant discharge registration. The specific scope of pollutant discharging entities under priority pollutant discharge permitting administration or those under summary

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pollutant discharge permitting administration shall be governed by the classification administration list of pollutant discharge permitting for fixed pollution sources. The pollutant discharging entity that, in accordance with the law, shall apply for a pollutant discharge permit in accordance with the law and discharge pollutants in accordance with the relevant provisions.

Labor

According to the Labor Law of the PRC (《中華人民共和國勞動法》), the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), and the Implementation Regulations of the Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》), an employer and an employee shall enter into a written labor contract when establishing an employment relationship. The employer shall, in accordance with the provisions of the labor contract and relevant laws and regulations, pay the labor remuneration to the employee in full and in a timely manner. At the same time, the wages of workers must not be lower than the local minimum wage.

Social Insurance and Housing Provident Funds

As required under the Regulation of Insurance for Labor Injury (《工傷保險條例》), the Provisional Measures for Maternity Insurance of Employees of Corporations (《企業職工生育保險試行辦法》), the Decisions on the Establishment of a Unified Program for Basic Old-Aged Pension Insurance of the State Council (《國務院關於建立統一的企業職工基本養老保險制度的決定》), 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》), the Unemployment Insurance Measures (《失業保險條例》), the Interim Regulations Concerning the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》), and the Social Insurance Law of the PRC (《中華人民共和國社會保險法》), enterprises are obliged to provide their employees in Chinese Mainland with welfare schemes covering basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and basic medical insurance. These payments are made to local administrative authorities. Any employer that fails to make social insurance contributions may be ordered to rectify the non-compliance and pay the required contributions within a prescribed time limit and be subject to a late fee. If the employer still fails to rectify the failure to make the relevant contributions within the prescribed time, it may be subject to a fine ranging from one to three times the amount overdue.

Pursuant to the Regulation on the Administration of Housing Provident Funds (《住房公積金管理條例》), an employer shall pay the housing provident funds for its employees in accordance with the relevant provisions of the state. Employers failing to process registration of provident fund accounts for their employees within designated period will be ordered by the housing provident fund administrative center to do so within a prescribed time limit. If the employer still fails to comply upon expiration of such time limit, it will be subject to a fine ranging from RMB10,000 to RMB50,000. When employers violate those provisions and fail to pay the housing provident fund in full amount as due, the housing provident fund administrative center will order such employers to pay up the amount within a prescribed period; if those employers still fail to comply with the regulations upon the expiration of the above time limit, further application will be made to the court for mandatory enforcement.

Intellectual Property Rights

Trademark

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》), and the Implementation Provisions of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》), registered trademarks in Chinese Mainland include commodity trademarks, service

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trademarks, collective trademarks and certification trademarks. The Trademark Office of China National Intellectual Property Administration handles trademark registrations and grants a term of ten years to registered trademarks, and another ten years if requested upon expiry of the first or any renewed ten-year term.

Patents

Patents in the PRC are mainly protected by the Patent Law of the PRC (《中華人民共和國專利法》) (the “Patent Law”), which was promulgated by the SCNPC on March 12, 1984, last amended on October 17, 2020 and became effective on June 1, 2021, and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), which was promulgated by the State Council on June 15, 2001 and last amended on December 11, 2023 and became effective on January 20, 2024. The Patent Law of the PRC and its Implementation Rules provide for three types of patents, “invention,” “utility model” and “design.” The duration of a patent right for “invention” is 20 years, the duration of a patent right for “utility model” is 10 years, and the duration of a patent right for “design” is 15 years, from the date of application. According to the Patent Law, for the purpose of public health, the patent administrative department of the State Council may grant mandatory licensing to manufacture and export patented drugs to countries or regions in compliance with provisions of the relevant international treaties to which the PRC is a party.

According to the provisions of the Patent Law and its Implementation Rules, for the purpose of compensating for the time taken to examine and approve a new drug to be marketed, the patent administrative department under the State Council shall grant compensation to the validity period of patent rights for the invention patents of new drugs approved to be marketed in the PRC upon request of the patentee. The compensation period shall not exceed five (5) years, and the total validity period of patent rights after a new drug is approved to be marketed shall not exceed fourteen (14) years. During the validity compensation period of patent rights, the scope of protection of the invention patent of a new drug is limited to the new drug and its approved indications-related technical solutions; within the scope of protection, the patentee enjoys the same rights and undertakes the same obligations as those before the validity compensation period.

Customs

According to the Provisions of the Customs of the PRC on the Administration of Filing of Customs Declaration Entities (《中華人民共和國海關報關單位備案管理規定》), the term “declaration entities” refers to the consignees or consignors of import and export goods registered with the Customs, as well as customs declaration entities. The filing of a customs declaration entity is valid for a long period of time, while the provisional filing is valid for one year, and an application for re-filing must be made upon expiration.

Regulations on Foreign Investment

According to the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “**Foreign Investment Law**”) and the Implementation Regulations for the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》), foreign investment refers to any investment activity directly or indirectly carried out by foreign natural persons, enterprises or other organizations (the “**foreign investors**”) within the territory of the PRC, including the following circumstances: (i) a foreign investor establishes a foreign-funded enterprise within the territory of the PRC, either alone or together with any other investor; (ii) a foreign investor acquires shares, equities, property shares or any other similar rights and interests of a PRC enterprise; (iii) a foreign investor invests in any new project within the territory of the PRC, either alone or together with any other investor; or (iv) a foreign investor invests in any other way as stipulated under the laws or

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administrative regulations or provided by the State Council. The organization form and structure, and the operating rules of foreign-funded enterprises are subject to the provisions of the Company Law, the Partnership Enterprise Law of the PRC and other applicable laws.

According to the Special Administrative Measures for Access of Foreign Investment (Negative List) (《外商投資准入特別管理措施(負面清單)》) (2024 edition) (the “**Negative List**”), the development and application of human stem cells, genetic diagnosis and therapy technologies fall into the field where foreign investments are prohibited. However, as of the Latest Practicable Date, there was no official interpretation clarifying the specific connotation and scope of human stem cells, gene diagnosis and therapy technologies. Pursuant to the Notice of the MOFCOM, NHC and the NMPA on Launching Pilot Programs for Further Opening-Up in the Medical Field (《商務部國家衛生健康委國家藥監局關於在醫療領域開展擴大開放試點工作的通知》), effective from September 7, 2024, foreign-invested enterprises are permitted to engage in the R&D and application of human stem cell and gene diagnosis and therapy technologies in the China (Beijing) Pilot Free Trade Zone, the China (Shanghai) Pilot Free Trade Zone, the China (Guangdong) Pilot Free Trade Zone and the Hainan Free Trade Port, for the purpose of product registration, listing and manufacturing.

During the Track Record Period, we entered into a collaboration with YolTech Therapeutics to develop YOLT-101 (also known as SAL061), a gene-editing therapy targeting PCSK9, in Chinese Mainland. For details, see “Business—Material Collaboration and Licensing Agreements—Collaboration and Licensing Agreement with YolTech.” The R&D activities of SAL061 are carried out through a qualified subsidiary located in a designated pilot free trade zone. Based on interviews we conducted with the relevant competent authorities, such qualified subsidiary is permitted to engage in the development and application of gene diagnosis and therapy technologies, and its business complies with the applicable provisions on foreign investment access. Except as disclosed above, as of the Latest Practicable Date, our business did not fall within the scope of the Negative List and was not subject to any special management measures thereunder.

Regulations on Foreign Trade

According to the Foreign Trade Law of the People’s Republic of China, promulgated by the NPC Standing Committee, China allows import and export of goods and technologies, unless otherwise stipulated by laws and administrative regulations. On December 21, 2023, the MOFCOM and the Ministry of Science and Technology issued the Catalog of Technologies Prohibited and Restricted From Export in China, and the catalog was last amended on July 15, 2025. As of the Latest Practicable Date, we primarily exported cefepime to overseas markets. As advised by our PRC Legal Advisor, export of cefepime is not prohibited or restricted according to the above laws and administrative regulations.

Regulations on Human Genetic Resources

In May 2019, the State Council promulgated the Regulation on the Administration of Human Genetic Resources of the PRC (《中華人民共和國人類遺傳資源管理條例》) (the “**HGR Regulation**”), which was last amended and became effective on May 1, 2024. On May 26, 2023, the Ministry of Science and Technology (the “**MOST**”) issued the Implementing Rules for HGR Regulation (《人類遺傳資源管理條例實施細則》) (“**HGR Implementing Rules**”), which took effect on July 1, 2023.

The HGR Regulation and the Implementing Rules prohibit foreign entities or individuals or such entities established or actually controlled thereby, or “Foreign Persons,” from collecting or preserving Chinese human genetic resources in China, or providing such human genetic resources abroad, whereas activities of collection and preservation of organs, tissues and cells for purposes

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of clinical diagnosis and treatment, service of blood collection and provision, investigation of illegal activities, doping test and funeral service, are required to be conducted in accordance with other relevant laws and regulations.

Foreign Persons, however, are permitted to use such human genetic resources in limited circumstances, including to carry out scientific research activities through collaboration with Chinese scientific research institutions, higher education institutions, medical institutions, or enterprises, collectively, the “Chinese Entities.” Such activities must be approved by the competent authority for HGR, and the application for approval must be filed jointly by the Foreign Person and the relevant Chinese Entity. The only exception to the approval requirement is “international collaboration in clinical trials” that do not involve the outbound transfer of Chinese human genetic resource materials such as organs, tissues, or cells comprising the human genome, genes, or other genetic substances. Such clinical trial collaboration, however, must still be pre-registered with the competent authority for HGR.

On October 17, 2020, the Standing Committee of the NPC promulgated the Biosecurity Law of the PRC (《中華人民共和國生物安全法》), which was last amended and became effective on April 26, 2024. The Biosecurity Law of the PRC, among other things, restates relevant approval or pre-registration requirements of HGR collection, preservation, utilization and external provision, as provided in the HGR Regulation.

As advised by our PRC Legal Advisor, our Company is controlled by Salubris HK, an organization established outside of Chinese Mainland, and therefore our Company is deemed as a Foreign Person under the HGR Regulation and the HGR Implementing Rules. During the Track Record Period and as of the Latest Practicable Date, we had completed the pre-registration with the competent authority for HGR of all our clinical trials which may be deemed “international collaboration in clinical trials,” and we had not engaged in any outbound transfer of Chinese human genetic resources. During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any penalties from the competent governmental authorities for our business operations or clinical studies involving the use of Chinese human genetic resources.

Regulations on Information Security and Data Privacy

Data Security and Data Export

The Data Security Law of the PRC (《中華人民共和國數據安全法》) (the “**Data Security Law**”) provides for the establishment of a data classification and grading protection system to conduct classified and hierarchical protection of data. Entities engaged in data processing activities shall, in accordance with laws and regulations, establish a sound full-process data security management system, organize data security education and training, and take corresponding technical measures and other necessary measures to ensure data security. According to the Measures on Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》), a data processor that provides data overseas under any of the following circumstances shall apply to the national cyberspace administration for the security assessment of the outbound data transfer through local provincial cyberspace administration: (i) a data processor provides important data abroad; (ii) the critical information infrastructure operator or the data processor that has processed the personal information of more than 1 million people provides personal information abroad; (iii) the data processor that has provided the personal information of over 100,000 people or the sensitive personal information of over 10,000 people cumulatively since January 1 of the previous year provides personal information abroad; and (iv) any other circumstance where an application for the security assessment of outbound data transfer is required by the national cyberspace administration.

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The Measures for Cybersecurity Review (《網絡安全審查辦法》) (the “**Cybersecurity Review Measures**”) stipulate, among others, that: (i) when the purchase of network products and services by a critical information infrastructure operator (關鍵信息基礎設施運營者) (the “**CIIO**”) or the data processing activities conducted by a network platform operator (網絡平台運營者) affect or may affect national security, a cybersecurity review shall be conducted pursuant to the Cybersecurity Review Measures; (ii) an application for cybersecurity review shall be made by an issuer who is a network platform operator holding personal information of more than one million users before such issuer applies to list its securities abroad; and (iii) the relevant PRC governmental authorities may initiate a cybersecurity review if such governmental authorities determine that the issuer’s network products or services, or data processing activities affect or may affect national security.

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》), 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. In addition, the Measures for Standard Contract for Outbound Transfer of Personal Information require that all Outbound Transfers of personal information that have been carried out before June 1, 2023 and do not comply with the provisions of the Measures for Standard Contract for Outbound Transfer of Personal Information be rectified within 6 months.

Personal Information Protection

According to the Civil Code of the PRC, 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 PRC (《中華人民共和國個人信息保護法》) further emphasizes the obligations and responsibilities of processors for the protection of personal information, and requests a higher level of protective measures on the processing of sensitive personal information. According to the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》) (the “**Cybersecurity Law**”), 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.

The Administrative Measures on the Standards, Security and Service of National Health and Medical Big Data (Trial) (《國家健康醫療大數據標準、安全和服務管理辦法(試行)》) on July 12, 2018 (hereinafter referred to as the “Health and Medical Big Data Measures”) stipulate the guidelines and principles for standard management, security management and service management of health and medical big data. According to the Health and Medical Big Data Measures, medical and health institutions at all levels and related enterprises and institutions should adopt data

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classification, important data backup, encryption authentication and other measures to ensure the security of health and medical big data. Health and medical big data should be used in accordance with laws and regulations. Data-related information should provide secure information query and copy channels to ensure privacy protection and data security; data access and use permissions of users at different levels should be strictly regulated to ensure that data is used within the scope of authorization. No unit or individual may use or publish health and medical big data without authorization or beyond the scope of authorization, and it is prohibited to obtain data through illegal means. When various types of medical and health institutions at all levels and related service institutions disclose health and medical big data to the public, they must abide by relevant national regulations and must not disclose state secrets, business secrets and personal data, and must not infringe on national interests, public interests and legitimate rights and interests of citizens, legal persons and other organizations.

Laws and Regulations on Anti-money Laundering, Anti-corruption and Anti-bribery

Laws and Regulations on Anti-money Laundering

According to the Anti-money Laundering Law of the PRC (《中華人民共和國反洗錢法》) (the “**Anti-money Laundering Law**”), financial institutions shall establish a sound internal control system for anti-money laundering in accordance with the provisions of the Anti-money Laundering Law. They shall also set up a special body or designate an internal body to take the lead to take charge of the anti-money laundering work. Entities and individuals in business relationship with financial institutions shall cooperate with the financial institution in conducting customer due diligence, including providing authentic and valid identity documents or other identity certificates, accurately and completely filling in identity information, 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 as required by the Anti-money Laundering 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 on Anti-corruption

According to the Criminal Law of the People’s Republic of China (《中華人民共和國刑法》), 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 on 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》) 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》), 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 that breaches the relevant anti-bribery rules may be subject to administrative punishment or criminal liability, depending on the seriousness of the cases.

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According to the Provisions on the Establishment of Adverse Records of Commercial Bribery in the Medicine Purchase and Sales Field (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》) promulgated by the National Health and Family Planning Commission (currently the NHC), an enterprise engaged in the manufacturing or distribution of medicines, medical devices or medical consumables (or its agent) that offers any items of value or other benefits to the staff of a medical institution may be listed in the Adverse Records of Commercial Bribery (“**Adverse Records**”) by the relevant government authorities. As a result, its products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies within the relevant provinces, and the scores of its products in the centralized procurement processes conducted by public medical institutions or medical and health institutions receiving financial subsidies in other provinces will be reduced. Where the relevant enterprise (or its agent) is listed in Adverse Records twice within a five-year period, its products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies across China for two years.

Regulations on Overseas Securities Offering and Listing by Domestic Enterprises

On February 17, 2023, with the approval of the State Council, the CSRC promulgated the 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》) (the “**Overseas Listing Trial Measures**”) and five relevant guidelines. According to the Overseas Listing Trial Measures, (i) PRC domestic companies that seek to offer or list securities overseas, both directly and indirectly, should fulfill the filing procedure and submit relevant information to the CSRC; if a domestic company fails to complete the filing procedure or conceals any material fact or falsifies any major content in its filing documents, it may be subject to administrative penalties, such as order to rectify, warnings and fines, and its controlling shareholders, de facto controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines; (ii) direct overseas offering and listing by domestic companies refers to the overseas offering and listing of the companies limited by shares registered and established in Chinese Mainland; and (iii) any companies limited by shares registered and established in Chinese Mainland are required to file with the CSRC within three business days after their application document of overseas listing is submitted. Failure to complete the filing under the Overseas Listing Trial Measures may subject a PRC domestic company to a rectification order issued by the CSRC, warnings, and a fine of RMB1 million to RMB10 million.

Pursuant to the Provisions on Strengthening the Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) (the “**Provisions on Confidentiality**”), when a domestic company provides or publicly discloses the documents and materials involving state secrets and working secrets of state organs to the relevant securities companies, securities service institutions, overseas regulatory authorities and other entities and individuals, or provides or publicly discloses such documents and materials through its overseas listing subjects, it shall report to the competent department with the examination and approval authority for approval, and file with the same level secrecy administration department. Domestic companies providing accounting archives or copies thereof to entities and individuals such as securities companies, securities service institutions and overseas regulatory authorities shall perform the relevant procedures according to relevant regulations. The working papers formed within the territory of the PRC by the securities companies and securities service institutions that provide related services for the overseas offering and listing of domestic enterprises shall be kept within the territory of the PRC. Cross-border transferring of such working papers shall go through the examination and approval formalities in accordance with the relevant regulations.

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UNITED STATES LAWS AND REGULATIONS

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

U.S. Government Regulation of Drug and Biological Products

In the United States, the Food and Drug Administration (“**FDA**”) regulates drugs under the Food, Drug, and Cosmetic Act (“**FDCA**”) and its implementing regulations, and the FDA regulates biologics under the FDCA and the Public Health Service Act (the “**PHSA**”) and their respective implementing regulations. Drugs and biologics also are subject to other federal, state, and local laws, such as those related to competition. The process of obtaining regulatory approvals to manufacture or market drugs and biologics in the United States and the subsequent compliance with appropriate federal, state, local, and non-U.S. applicable laws requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative or judicial enforcement actions. These actions could include, among other actions, the FDA’s refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any such action could have a material adverse effect on our business, financial condition and results of operations as well as the market’s acceptance of our products and our reputation. Outside the United States, drugs and biologics are regulated under other legal systems with which we would need to comply if we were to manufacture or market drugs or biologics outside the United States, and failure to comply there could also subject us to administrative or judicial enforcement actions.

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 the FDA’s Good Laboratory Practice regulations. A sponsor of an Investigational New Drug application (“**IND**”) must submit the results of the preclinical tests (such as animal tests), manufacturing information, analytical data, the clinical trial protocol, and any available clinical data or literature to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions and places the trial on a clinical hold within that 30-day period. The FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance. Although information a sponsor submits in an IND is confidential information, general clinical trial information such as the number of patients involved and the type of adverse events studied can be made public information and can be available for public review through publication on government websites such as www.clinicaltrials.gov.

All clinical trials, which involve the administration of the investigational product to humans, must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practice (“**GCP**”) and human subject protection regulations, including the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board (“**IRB**”), often under the auspices of a university and sometimes a private, independent organization, 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 human subject research regulations or if the product has been associated with unexpected serious harm to subjects and the IRB believes patients are at risk.

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Clinical trials generally are conducted in three sequential phases, known as Phase I, Phase II and Phase III, and may overlap. Phase I trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. Phase II trials generally involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. Phase III trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA before marketing approval is received. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than 7 calendar days after the sponsor’s initial receipt of the information. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

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 a New Drug Application (“NDA”) or a Biologics License Application (“BLA”). Unless deferred or waived, NDAs or BLAs, or supplements, must contain data adequate to assess the safety and efficacy of the product at the proposed commercial dosing regimen and administration for the claimed indications in all relevant populations, including any pediatric subpopulations. The submission of an NDA or a BLA is subject to the payment of a user fee and an annual prescription drug product program fee to the FDA, although in certain circumstances the FDA may waive the annual prescription drug product program fee if the drug qualifies for orphan drug designation.

The FDA may refuse to approve the NDA or the 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 letter describing all of the specific deficiencies that the FDA identified in the NDA or the 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 complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. The applicant may withdraw the application and resubmit the NDA or the BLA when all the data addressing all of the deficiencies identified in the letter is available, or the applicant may request an opportunity for a hearing.

The regulatory approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Furthermore, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including phase IV clinical trials, to further assess a product’s safety and effectiveness after NDA or BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

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Expedited Development and Review Programs

FDA has four programs intended to facilitate and expedite development and review of new drugs and biologics to address medical need in the treatment of a serious or life-threatening condition. The requirements and benefits of those programs—fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation—are discussed in detail in FDA, *Guidance for Industry: Expedited Programs for Serious Conditions—Drugs and Biologics* (May 2014). No drug or biologic is guaranteed eligibility for these programs.

Post-Marketing Requirements

Following the approval of a new product, the manufacturer is subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as “off-label use”) and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws.

Patent Term Restoration and Marketing Exclusivity

Subject to certain requirements, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product development and FDA review of an NDA or a BLA if approval of the application is the first permitted commercial marketing or use of a biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act, relevant portions of which are codified at 35 U.S.C. §156. The allowable patent term extension is calculated as one-half of the product’s testing phase, which is the time between IND and NDA/BLA submission, and all of the review phase, which is the time between NDA/BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration, only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended, and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug candidate for which an NDA or a BLA has not been submitted.

While the Hatch-Waxman Act addresses the development and approval of generic drugs, the Biologics Price Competition and Innovation Act of 2009 (the “**BPCIA**”), codified at 42 U.S. Code § 262 enacted in the Affordable Care Act, or the ACA, amended the Public Health Service Act to create an abbreviated licensure pathway for biological products that are demonstrated to be

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“biosimilar” to, or “interchangeable,” with an FDA-licensed reference product. BPCIA allows for approval of a biosimilar if it is “highly similar” and has no clinically meaningful differences from its approved and existing biological product.

U.S. Trade Related Regulations

Regulations on Outbound Investment

On January 2, 2025, a U.S. outbound investment security program (the “**OISP**”), implemented by the Treasury under a newly adopted rule (the “**Outbound Investment Rule**”), became effective. The U.S. OISP prohibits or requires notification of certain outbound investment transactions by “U.S. persons” involving “covered foreign persons” that are engaged in specified “covered activities” relating to certain sensitive technologies and products in the (i) semiconductors and microelectronics, (ii) quantum information technologies, and (iii) artificial intelligence (“**AI**”) sectors. Certain AI systems, depending on their end use and the computing power used to train them, fall under the definitions for prohibited and notifiable transactions under the Outbound Investment Rule.

The OISP includes exceptions, which, if applicable, exclude from its prohibitions and notification requirements certain transactions that would otherwise be either prohibited transactions or notifiable transactions if engaged in by a U.S. person. These exceptions include a “publicly traded securities exception,” which is applicable to certain U.S. person investments in publicly traded securities that are traded on a national stock exchange or the over-the-counter markets, provided that such U.S. persons are not afforded rights beyond standard minority shareholder protections with respect to the issuer. Following completion of the [REDACTED], our H Shares will be [REDACTED] and authorized to be [REDACTED] on the [REDACTED] and therefore would be considered “[REDACTED]” under the OISP, as would our A Shares traded on the Shenzhen Stock Exchange. A purchase of such “publicly traded securities” by a U.S. person or its non-U.S. person subsidiaries would be eligible for the “publicly traded securities exception,” provided that such U.S. person or its non-U.S. person subsidiaries are not afforded rights beyond standard minority shareholder protections with respect to our Company.

Of the three technology sectors implicated as “covered activities” under the OISP, we are engaged only in AI. In respect of AI, under the OISP specified end uses and certain specified computing power used to train an AI system can implicate the OISP’s notification requirements and prohibitions. We have built an AI-driven or computer-aided drug design (“**AIDD/CADD**”) platform to support the R&D of various modalities of drugs. For details, see “Business—Research and Development—Technology Platforms—AIDD/CADD Platform.” These AI systems are only used for drug design and R&D purposes and are not used for any of the specified end uses covered under the OISP, and the computing power used to train these AI systems is well below the threshold of 10^{23} computational operations of the notification requirement. Accordingly, our U.S. counsel, based on these facts and circumstances and its due diligence into our business, concluded that (i) our Company is not a “covered foreign person” under the Outbound Investment Rule, and (ii) the acquisition of the Company’s shares through the [REDACTED] is not a prohibited or a notifiable transaction under the Outbound Investment Rule.

U.S. Tariffs and Other Trade Restrictions

Since early 2025, U.S. President Trump has implemented significant changes to U.S. trade policy with China, including imposing additional tariffs on Chinese imports. On February 20, 2026, the U.S. Supreme Court struck down tariffs imposed by U.S. President Trump under the International Emergency Economic Powers Act. Following that decision, the administration rescinded the IEEPA-based tariffs but concurrently imposed a 10% temporary import surcharge under Section 122 of the Trade Act of 1974 on imports from all U.S. trading partners for a 150-day

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period, which expired on July 24, 2026. During the Track Record Period and up to the Latest Practicable Date, we did not have any exports to, or generate any revenue from, the United States, and therefore were not subject to these additional U.S. tariffs on Chinese imports. In 2023, 2024, 2025, and the six months ended June 30, 2025 and 2026, our revenue from exports to overseas markets accounted for 2.7%, 3.2%, 2.0%, 2.1% and 1.8% of our total revenue for the respective periods, which was primarily generated from sales of cefepime to emerging markets. In terms of sales revenue, our largest overseas market was India in 2023 and 2024, Brazil in 2025, and Egypt in the six months ended June 30, 2026. Neither country imposed tariffs or trade restrictions on these exports during the Track Record Period and up to the Latest Practicable Date. Our Directors are of the view that there was not any development of international tariffs that had any material adverse impact on our business, financial condition, or results of operations during the Track Record Period and up to the Latest Practicable Date. The Sponsors are not aware of any information to the contrary that would cause them to cast doubt on the Directors’ views set out above.

In recent years, the U.S. government has also implemented other measures, such as the expansion of export controls in respect of China, including controls on items manufactured outside the United States that are the direct product of certain controlled U.S.-origin technology or software, to specific destinations and end-users (such as certain companies on the export control Entity List), and the end-use restrictions on U.S.-origin semiconductor manufacturing and advanced computing items. The U.S. has also placed certain entities, including an increasing number of entities in China, on the Entity List under U.S. export control regulations, which imposes licensing requirements for exports, reexports, or transfers of items on lists of controlled items maintained by the U.S. government, which in most cases prevents these named entities from receiving essentially any item subject to U.S. export controls, including in some cases those produced wholly outside the United States that rely on U.S. technology for their production. During the Track Record Period and up to the Latest Practicable Date, we did not rely on key components or materials that are broadly prohibited or subject to heightened trade restrictions under U.S. export control regimes.

On December 18, 2025, the U.S. Senate passed the BIOSECURE Act as a part of the National Defense Authorization Act for Fiscal Year 2026, which was signed into law by the U.S. President. The BIOSECURE Act prohibits the U.S. government from procuring biotechnology equipment or services from designated “biotechnology companies of concern,” and prohibits government contracts, loans and grants to any entity that uses biotechnology equipment or services from a designated “biotechnology company of concern (“BCC”).” Entities may be included on the list of BCC published by the Office of Management and Budget (“OMB”) in three ways: (i) inclusion in the annual 1260H list issued by the Department of War; (ii) designation by OMB as a BCC; or (iii) as subsidiaries, parents, affiliates, or successors of the foregoing entities. OMB is required to publish the designated BCC list by December 2026, and issue implementing guidance. Subsequently, the Federal Acquisition Regulatory Council must revise the Federal Acquisition Regulation within one year. For 1260H entities, the prohibitions under the BIOSECURE Act will take effect 60 days after the FAR is revised; for other designated BCCs, the prohibitions will take effect 90 days after designation. The prohibitions in the BIOSECURE Act will go into effect for new contracts, grants and loans issued 60 days after the Federal Acquisition Regulation is updated for entities drawn from the 1260H list, and within 180 days after the Federal Acquisition Regulation is updated for entities not included on the 1260H list. As advised by the legal advisor to Salubris Bio, the BIOSECURE Act prohibits U.S. federal agencies from entering into, extending, or renewing any “contract” with an entity that uses “biotechnology equipment or services” from a BCC in performance of that contract. It also prohibits using federal loan or grant funds to procure or use biotechnology equipment or services from a BCC. During the Track Record Period and up to the Latest Practicable Date, Salubris Bio had not contracted with, or otherwise received funding from, the U.S. government. Neither had it engaged with, or planned to engage with, any company listed on the current 1260H list.

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During the Track Record Period and up to the Latest Practicable Date, the foregoing regulatory developments did not have any material adverse effect on (i) our ongoing clinical development, business operations, and overseas strategies, (ii) our relationships with customers and suppliers, (iii) our U.S. subsidiary, or (iv) our relationships with Directors who are U.S. citizens. We continually monitor the global trade environment for new and changing tariffs, retaliatory actions, trade agreements, export restrictions, sanctions or other restrictions that may impact us or our business operations, supply chain, or customers. However, we cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. For associated risks, see “Risk Factors—Risks Related to Doing Business in the Jurisdictions Where We Operate—The current global geopolitical tension, particularly with regard to Sino-U.S. political and economic relations, may adversely impact our business, financial condition, and results of operations.”