

REGULATORY OVERVIEW

OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

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

Regulatory Authorities

The regulatory authorities of the drug industry in the PRC include: the National Medical Products Administration (國家藥品監督管理局) (the “**NMPA**”), the National Health Commission of the People’s Republic of China (中華人民共和國國家衛生健康委員會) (the “**NHC**”) and the National Healthcare Security Administration (國家醫療保障局) (the “**NHSA**”). The NMPA is an authority under the State Administration for Market Regulation (國家市場監督管理總局) (the “**SAMR**”) and is the primary regulator for medical products. The NHC is a component department of the State Council of the PRC (中華人民共和國國務院) (the “**State Council**”) and is the primary national regulator for public health. The NHSA is an authority directly under the State Council responsible for the management of the healthcare security system.

Laws and Regulations in Relation to New Drugs

Application for New Drug Registration

Pursuant to the provisions of the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) (the “**Measures for the Administration of Drug Registration**”), which was promulgated by the SAMR on January 22, 2020 and came into effect on July 1, 2020, the Measures for the Administration of Drug Registration shall apply to the development, registration, supervision and management activities carried out in the territory of the PRC for marketing of drugs. In accordance with the Measures for the Administration of Drug Registration, drug registration refers to activities that a drug registration applicant files an application and other supplementary applications for clinical drug trial, approval for drug marketing, and reregistration, among others, under the legal procedures and according to the relevant requirements, and that the medical products administrative department examines the safety, effectiveness, and quality controllability based on the laws and regulations, and the existing scientific cognitions, to decide whether to agree with the activities applied for.

Non-clinical Research and Animal Testing

The non-clinical safety assessment of drugs for the purpose of applying for drug registration shall be conducted in accordance with the Good Laboratory Practices for Non-clinical Drug Studies (《藥物非臨床研究質量管理規範》), which was promulgated by the State Food and Drug Administration (the “**SFDA**”) on August 6, 2003, amended by the China Food and Drug Administration (國家食品藥品監督管理總局) (the “**CFDA**”) on July 27, 2017, and came into effect on September 1, 2017. The SFDA promulgated the Administrative Measures for the Certification of Good Laboratory Practices for Non-clinical Drug Studies (《藥物非臨床研究質量管理規範認證管理辦法》) on April 16, 2007 and amended it on January 19, 2023, which specifies the requirements for institutions applying for Good Laboratory Practices (the “**GLP**”) certification of non-clinical drug studies.

According to the Regulations for the Administration of Experimental Animals (《實驗動物管理條例》) promulgated by the State Science and Technology Commission on November 14, 1988 and lastly amended in March 1, 2017 by the State Council, the Measures for the Quality Administration of Experimental Animals (《實驗動物質量管理辦法》) jointly promulgated by the State Scientific and Technological Commission of the People’s Republic of China of Quality and Technical Supervision on December 11, 1997, and the Administrative Measures on the Permits for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》), which was promulgated

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by the Ministry of Science and Technology and other regulatory authorities on December 5, 2001 and came into effect on January 1, 2002, using experimental animals and related products requires a permit for the use of experimental animals.

Application for Clinical Trial

An approval for clinical trials of drugs from the NMPA shall be obtained before the conduction of new clinical drug trials. According to the Decision on Adjusting the Approval Procedures for Certain Administrative Approval Items Concerning Drugs (《關於調整部分藥品行政審批事項審批程序的決定》), which was promulgated by the CFDA and came into effect on May 1, 2017, the approval decisions on drug clinical trials (including domestic and imported) made by the CFDA shall be adjusted to be made by the Center for Drug Evaluation of the CFDA (國家食品藥品監督管理總局藥品審評中心) (the “**CDE**”) in the name of the CFDA from May 1, 2017. Pursuant to the Drug Administration Law of the People’s Republic of China (《中華人民共和國藥品管理法》) (the “**Drug Administration Law**”), which was promulgated by the Standing Committee of the National People’s Congress (the “**SCNPC**”) on September 20, 1984, lastly amended in August 26, 2019, and came into effect on December 1, 2019, persons conducting clinical trials of drugs shall, pursuant to the provisions of the drug administrative department of the State Council, submit the relevant data, materials and samples such as research and development methods, quality indicators, pharmacological and toxicological test results and etc. truthfully, and be subject to approval by the drug administrative department of the State Council.

According to the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) which was promulgated by CFDA on September 6, 2013 and came into effect on September 6, 2013, and the Standard for the Administration of Registration and Information Disclosure of Drug Clinical Trials (Trial) (《藥物臨床試驗登記與信息公示管理規範(試行)》) which was promulgated by NMPA on July 1, 2020 and came into effect on July 1, 2020, all clinical trials approved by the NMPA and conducted in the PRC shall complete the clinical trial registration and continuously update information of the clinical trials on the Drug Clinical Trial Registration and Information Disclosure Platform.

Pursuant to the Administrative Regulations for Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》) which was promulgated by NMPA and NHC on November 29, 2019 and came into effect on December 1, 2019, after obtaining clinical trial approval from NMPA, the applicant shall choose institutions qualified for clinical trials of the drug to conduct clinical trials.

Conduct of Clinical Trial

In compliance with the Measures for the Administration of Drug Registration, clinical trials are divided into Phase I, Phase II, Phase III, Phase IV and bioequivalence trial.

A sponsor approved to carry out clinical drug trial shall, prior to conducting subsequent phases of clinical drug trials, formulate the corresponding scheme on clinical drug trial, carry out clinical drug trial upon examination and consent of ethics committee, and submit corresponding scheme on clinical drug trial and supporting materials on the online website of the CDE.

Clinical trials shall be conducted for the application of new drug registration and shall be implemented and governed in accordance with the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) (the “**GCP**”), which was promulgated by the NMPA and NHC on April 23, 2020 and came into effect on July 1, 2020.

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According to the Announcement on Adjusting the Review and Approval Procedures for Drug Clinical Trials (《關於調整藥物臨床試驗審評審批程序的公告》), which was promulgated by the NMPA on July 24, 2018 and came into effect on July 24, 2018, if a new drug clinical trial has been approved to be carried out, after the completion of Phase I and Phase II clinical trials and before the implementation of Phase III clinical trials, the applicant shall submit an application for a communication meeting to the CDE to discuss with the CDE on key technical issues.

New Drug Application

Pursuant to the Measures for the Administration of Drug Registration, after completing the pharmaceutical research, pharmacological and toxicological research, clinical drug trial, and other research supporting the marketing registration of a drug, determining the quality standards, completing the verification of commercial scale production process, and making sound preparation for the drug registration inspection and examination, an applicant shall file an application for drug marketing authorization, and submit relevant research materials in accordance with the requirements of the application materials. Upon formal review of the application materials, an application that satisfies the requirements shall be accepted.

The CDE shall organize pharmaceutical, medical and other technical personnel to evaluate the accepted applications for drug marketing authorization as required. Where the comprehensive evaluation conclusion is adopted, the drug shall be approved for marketing, and a drug registration certificate shall be issued.

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

According to the Opinions on Deepening the Reform of the Review and Approval Systems to Encourage Innovation of Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (the “**Opinions on Deepening the Reform of the Review and Approval Systems to Encourage Innovation of Drugs and Medical Devices**”), which was promulgated by the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council and came into effect on October 8, 2017, the clinical trial data obtained from an international multi-center clinical trials that conforms to relevant requirements for registration of drugs and medical devices in the PRC can be used for the application for registration in the PRC.

Marketing Authorization Holder System

Pursuant to the Drug Administration Law and the Measures for the Administration of Drug Registration, the drug marketing authorization holder system is implemented in the PRC 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. Pursuant to the Notice on Matters Concerning Promoting the Piloting of the Marketing Authorization Holder System for Drugs (《關於推進藥品上市許可持有人制度試點工作有關事項的通知》), which was promulgated by the CFDA on August 15, 2017, drug manufacturers, drug research and development institutions, and researchers may serve as the drug marketing authorization holder.

National Reimbursement Drug List of the PRC

Pursuant to the Social Security Law of the People’s Republic of China (《中華人民共和國社會保險法》), which was promulgated by the SCNPC on October 28, 2010, lastly amended and came into effect on December 29, 2018, drugs, treatment, medical services and facilities which

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comply with basic medical insurance and medical costs for emergencies and rescue operations shall be paid out from the basic medical insurance fund pursuant to the related laws and regulations. The National Reimbursement Drug List for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》) (the “NRDL”) sets out the standards annually for payment of drugs by the basic medical insurance, work-related injury insurance and maternity insurance funds.

Centralized Procurement of Drugs

According to the Pilot Program of the Centralized Procurement and Use of Drugs Organized by the State (《國家組織藥品集中採購和使用試點方案》) which was promulgated by the General Office of the State Council on January 1, 2019, eleven (11) pilot cities are selected to launch pilot programs of the centralized procurement and use of drugs under the organization of the government.

Gathering, Collection and Filing of Human Genetic Resources

Pursuant to the Service Guide for Administrative Licensing for the Approval of Gathering, Collection, Deal, Export and Exit of Human Genetic Resources (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) promulgated by the Ministry of Science and Technology of the PRC (the “**Ministry of Science and Technology**”) on July 2, 2015 and the Notice on the Implementation of the Administrative License for the Approval of 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 on August 24, 2015, foreign investment sponsors who gather and collect human genetic resources through clinical trials should file a record with the China Human Genetic Resources Management Office through an online system. The Ministry of Science and Technology promulgated 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》) (the “**Implementation Rules for the Administrative Regulation on Human Genetic Resources**”) on May 26, 2023, which came into effect on July 1, 2023. The Implementation Rules for the Administrative Regulation on Human Genetic Resources has further provided detailed implementation regulations for the administration of human genetic resources of the PRC.

Laws and Regulations in Relation to Drug Manufacturer

Drug Manufacturing Permit

Pursuant to the Drug Administration Law, undertaking of drug manufacturing shall be subject to approval by the drug administrative department of the provincial, autonomous regional or municipal level at its locality, and shall obtain a Drug Manufacturing Permit (《藥品生產許可證》) (the “**Drug Manufacturing Permit**”). Drug manufacturing without a Drug Manufacturing Permit is prohibited.

Entrusted Manufacturing of Drugs

Pursuant to the Measures on the Supervision and Administration of the Manufacture of Drugs (《藥品生產監督管理辦法》), which was promulgated by the SAMR on January 22, 2020 and came into effect on July 1, 2020, drug marketing authorization holders entrusting others to manufacture drugs shall enter into outsourcing agreements and quality agreements with qualified drug manufacturing enterprises and submit the relevant agreements together with the actual manufacturing site application materials to the competent drug administrative authority in order to apply for the Drug Manufacturing Permit.

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Drug Operation Permit

According to the Drug Administration Law, the Measures for the Supervision and Administration of Drug Quality in Operation and Usage (《藥品經營和使用質量監督管理辦法》), which was promulgated by the SAMR on September 27, 2023 and came into effect on January 1, 2024, whoever engages in the wholesale or retail of drugs shall be subject to the approval of the drug regulatory authority, obtain a drug operation permit in accordance with the laws, regulations, rules, standards and norms.

Other Laws and Regulations in Relation to Medical Industry

Basic Medical Insurance Policy

Pursuant to the Decision on the Establishment of the Basic Medical Insurance System for Urban Employees (《關於建立城鎮職工基本醫療保險制度的決定》), which was promulgated by the State Council and came into effect on December 14, 1998, and the Provisional Measures for the Administration of the Scope of Drugs under the Basic Medical Insurance for Urban Employees which was promulgated by the Ministry of Labor and Social Security and came into effect on May 12, 1999, all urban employers, including several types of enterprises, organs, public institutions, social organizations, private non-enterprise entities and their employees are required to participate in basic medical insurance. Pursuant to the Guiding Opinions on Carrying out the Pilot of Basic Medical Insurance for Urban Residents (《關於開展城鎮居民基本醫療保險試點的指導意見》), which was promulgated by the State Council and came into effect on July 10, 2007, non-working urban residents in the pilot areas can voluntarily participate in the basic medical insurance for urban residents.

Medical Insurance Catalogue

Pursuant to the Provisional Measures for the Administration of the Scope of Drugs under the Basic Medical Insurance for Urban Employees, the scope of medical insurance coverage for pharmaceutical products needs to be managed through the formulation of the NRDL. A drug listed in the NRDL must be clinically necessary, safe and effective, reasonably priced, convenient to use and the supply of which can be guaranteed by the market.

Drug Price

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

Laws and Regulations in Relation to Intellectual Property

Patent

Patents in the PRC are mainly protected by the Patent Law of the People’s Republic of China (《中華人民共和國專利法》) (the “**Patent Law**”), which was promulgated by the SCNPC on March 12, 1984, latest amended on October 17, 2020 and came into effect on June 1, 2021, and the Implementation Rules of the Patent Law of the People’s Republic of China (《中華人民共和國專利法實施細則》) (the “**Implementation Rules of the Patent Law**”), which was promulgated by the State Council on June 15, 2001, latest amended on December 11, 2023 and came into effect on January 20, 2024. The Patent Law and the Implementation Rules of the Patent Law provide for three types of patents, namely “invention”, “utility model” and “design.”

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The newly amended Patent Law introduces patent extensions to patents of new drugs that launched in the PRC, and stipulates that the patent administration department under the State Council shall, upon request of the patentee, extend the patent term of relevant invention patents of the new drug that is approved to be listed on the market in the PRC, to compensate for the time spent for the review and approval of the marketing of a new drug. The compensated extension shall not exceed five (5) years, and the total valid patent term after the new drug is approved for the market shall not exceed fourteen (14) years. Such newly adopted patent term extension rule benefits the Company through providing longer protection terms of patents applied or registered in the PRC and related to our product candidates.

Trademarks

Registered trademarks in the PRC are mainly protected by the Trademark Law of the People’s Republic of China (《中華人民共和國商標法》), which was promulgated by the SCNPC on August 23, 1982, latest amended on April 23, 2019, and came into effect on November 1, 2019, and the Implementation Rules of the Trademark Law of the People’s Republic of China (《中華人民共和國商標法實施條例》), which were promulgated by the State Council on August 3, 2002, latest amended on April 29, 2014, and came into effect on May 1, 2014. The Trademark Office of China National Intellectual Property Administration shall be in charge of the registration and administration of trademarks throughout the PRC and grants a term of ten (10) years to registered trademarks from the date of registration.

Domain Names

Domain names are regulated under the Measures on the Administration of Internet Domain Names (《互聯網域名管理辦法》) issued by the Ministry of Industry and Information Technology on August 24, 2017 and effective from November 1, 2017. Persons providing Internet domain name services and undertaking related activities such as operation and maintenance, supervision and administration thereof in the PRC shall comply with the Measures on the Administration of Internet Domain Names.

The Company Law and Regulations

The Company Law of the People’s Republic of China (《中華人民共和國公司法》) (the “**Company Law**”), which was amended by the SCNPC on December 29, 2023 and became effective on July 1, 2024, provides for the establishment, corporate structure and corporate management of companies, which also applies to foreign-invested enterprises in the PRC.

Regulations in Relation to Foreign Direct Investment

Since January 1, 2020, the Foreign Investment Law of the People’s Republic of China (《中華人民共和國外商投資法》) (the “**Foreign Investment Law**”) promulgated by the National People’s Congress (the “NPC”) on the March 15, 2019 has come into effect. The Law of the People’s Republic of China on Sino-Foreign Equity Joint Ventures, the Law of the People’s Republic of China on Wholly Foreign-Owned Enterprises and the Law of the People’s Republic of China on Sino-Foreign Cooperative Joint Ventures were abolished at the same time. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors. Pursuant to the Foreign Investment Law, the organization form, the structure and the operating rules of foreign-invested enterprises shall be subject to the provisions of the Company Law and other applicable laws and regulations of the PRC.

The PRC government adopts the management system of pre-entry national treatment and the negative list for foreign investment (the “**Negative List**”). The PRC government accords national treatment to foreign investment outside of the Negative List. The current Negative List

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is the Special Administrative Measures (Negative List) for the Access of Foreign Investment (2024 Revision) (《外商投資准入特別管理措施(負面清單)(2024年版)》), which was issued by the NDRC and the Ministry of Commerce of the People’s Republic of China (the “MOFCOM”) on September 6, 2024.

The foreign investment information reporting is subject to the Measures on Reporting of Foreign Investment Information (《外商投資信息報告辦法》) jointly promulgated by the MOFCOM and the SAMR on the December 30, 2019, which came into effect on January 1, 2020.

Regulations on The Security Review of Foreign Investment

On December 19, 2020, the NDRC and the MOFCOM jointly promulgated the Measures on the Security Review of Foreign Investment (《外商投資安全審查辦法》), effective on January 18, 2021, setting forth provisions concerning the security review mechanism on foreign investment, including the scope of investments subject to review, the scopes of review and procedures to review, among others.

Regulations in Relation to Product Liability

According to the Product Quality Law of the People’s Republic of China (《中華人民共和國產品質量法》), which was promulgated by the SCNPC on February 22, 1993, latest amended, and came into effect on December 29, 2018 (the “**Product Quality Law**”) manufacturers shall be liable for the quality of products produced by them and sellers shall take measures to maintain the quality of the products sold by them. Pursuant to the Civil Code of the People’s Republic of China (《中華人民共和國民法典》) (the “**Civil Code**”), which was promulgated by the NPC on May 28, 2020 and came into effect on January 1, 2021, where a patient suffers damage due to defects in drugs, he may seek compensation from the drug marketing authorization holder, manufacturer or also from the medical institution.

Regulations in Relation to Environmental Protection and Fire Safety

According to the Environmental Protection Law of the People’s Republic of China (《中華人民共和國環境保護法》), which was promulgated by the SCNPC on December 26, 1989, latest amended on April 24, 2014, and came into effect on January 1, 2015, the Environmental Impact Assessment Law of the People’s Republic of China (《中華人民共和國環境影響評價法》), which was promulgated by the SCNPC on October 28, 2002, most recently amended on December 29, 2018, and came into effect on December 29, 2018, and the Administrative Regulations on the Environmental Protection of Construction Project (《建設項目環境保護管理條例》), which was promulgated by the State Council on November 29, 1998, most recently amended on July 16, 2017, and came into effect on October 1, 2017, enterprises which plan to construct projects shall engage qualified professionals to provide the environmental impact assessment reports, environmental impact assessment statements, or environmental impact registration forms of such projects. The assessment reports, assessment statements, or registration form shall be filed with or approved by the relevant competent environmental protection administrative authorities prior to the commencement of any construction work.

According to the Categorized Management Catalog of Pollutant Discharge Permits for Fixed Sources of Pollution (2019 Edition) (《固定污染源排污許可分類管理名錄(2019年版)》), the manufacturing of biological drugs and products falls into the classification management scope for fixed source pollution permits.

According to the Fire Control Law of the People’s Republic of China (《中華人民共和國消防法》) (the “**Fire Control Law**”) which was promulgated by the SCNPC on April 29, 1998, last amended and effective on April 29, 2021, and the Provisional Measures on the Administration of

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Fire Protection Design Review and Acceptance of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) which was promulgated by the Ministry of Housing and Urban-Rural Development on April 1, 2020, last amended on August 21, 2023, and came into effect on October 30, 2023, the fire protection design or construction of a project must conform to the national fire protection technical standards for project construction.

Regulations in Relation to Employment and Social Securities

Pursuant to the Labor Law of the People’s Republic of China (《中華人民共和國勞動法》), promulgated by the SCNPC on July 5, 1994, latest amended on December 29, 2018, and came into effect on the same date, and the Labor Contract Law of the People’s Republic of China (《中華人民共和國勞動合同法》), which was promulgated by the SCNPC on June 29, 2007, latest amended on December 28, 2012, and came into effect on July 1, 2013, employers shall execute written labor contracts with full-time employees. All employers shall comply with local minimum wage standards. Employers shall establish a comprehensive management system to protect the rights of their employees.

According to Social Security Law of the People’s Republic of China (《中華人民共和國社會保險法》), which was promulgated on October 28, 2010 and amended and came into effect on December 29, 2018, an employer is required to make contributions to social insurance schemes for its employees, including basic pension insurance, basic medical insurance, work injury insurance, unemployment insurance, and maternity insurance.

According to the Administrative Regulations on Housing Provident Funds (《住房公積金管理條例》), which was promulgated on April 3, 1999 and latest amended and came into effect on March 24, 2019, employers are required to make contributions to housing provident funds for their employees.

The interpretation (II) issued by the Supreme People’s Court of the PRC on Legal Issues in the Trial of Labor Dispute Cases (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)》), promulgated by the Supreme People’s Court (“SPC”) on July 31, 2025 and came into effect as of September 1, 2025, further set forth detailed provisions for protecting employees’ rights in areas including social insurance and labour relations between employees and employers. Article 19 thereof stipulates that where an employer and an employee agree, or an employee undertakes, that there is no need to pay social insurance contributions, the People’s Court shall determine such agreement or undertaking invalid. Furthermore, where an employer fails to pay social insurance contributions in accordance with the law, and an employee seeks to terminate the labour contract and claims economic compensation from the employer pursuant to Article 38 (iii) of the Labor Contract Law, the People’s Court shall support such claims in accordance with the law. This clarification affirms that employees are entitled to request termination of their labour contracts and receive corresponding economic compensation under the Labor Contract Law if the employer fails to make social insurance contributions as required by law.

Regulations in Relation to Cybersecurity Information Security and Data Privacy

The SCNPC promulgated the Data Security Law of the People’s Republic of China (《中華人民共和國數據安全法》) on June 10, 2021 (effective from September 1, 2021), 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 full-process data security management system and take corresponding technical and other necessary measures to ensure data security.

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The Personal Information Protection Law of the People’s Republic of China (《中華人民共和國個人信息保護法》), promulgated by the SCNPC on August 20, 2021 and effective on November 1, 2021, emphasizes the obligations of processors for the protection of personal information and requires higher protective measures on the processing of sensitive personal information.

According to the Cybersecurity Law of the People’s Republic of China (《中華人民共和國網絡安全法》), promulgated by the SCNPC on November 7, 2016 and effective on June 1, 2017 as amended on October 28, 2025 and effective on January 1, 2026, network operators must follow the principles of legality, legitimacy and necessity when collecting and using personal information, 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 leak, tamper with, destroy, or provide personal information to others without consent, except 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.

According to the Cyber Data Security Regulations (《網絡數據安全管理條例》), promulgated by the State Council on September 24, 2024 and effective as of January 1, 2025, the State establishes a data classification and hierarchical protection system. Data processors shall establish security management systems using encryption, backups, and access controls to prevent data tampering, leaks, or misuse. Before processing personal information, rules must be formulated and individuals informed.

According to the Cybersecurity Review Measures (《網絡安全審查辦法》), promulgated by the CAC and twelve other PRC regulatory authorities on December 28, 2021 and effective on February 15, 2022, the purchase of cyber products and services by critical information infrastructure operators (“CIIO”) shall be reported to the Cybersecurity Review Office if the CIIO anticipates that the operation of such products or services will affect or may affect national security. In addition, network platform operators holding personal information of more than one million users that seek listing in a foreign country are required to apply for cybersecurity review. As of the Latest Practicable Date, we had not received any notification regarding our identification as a CIIO and, as advised by our PRC Legal Advisor, “listing in a foreign country” does not include listing in Hong Kong. Accordingly, we were not required to apply for a cybersecurity review.

On July 7, 2022, the CAC promulgated the Measures on Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》), effective on September 1, 2022, which set out the requirements for security assessment for outbound transfer of important data or personal information collected in mainland China. 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》), issued on February 22, 2023 and effective from June 1, 2023, a personal information processor may provide personal information to an overseas recipient through the standard contract where it is not a CIIO and the volume of personal information processed and provided overseas both do not exceed the thresholds prescribed therein. On March 22, 2024, the CAC promulgated the Provisions on Promoting and Regulating Cross-Border Data Flows (《促進和規範數據跨境流動規定》), effective on the date of promulgation, which provide exemptions from certain compliance requirements and specify circumstances where data processors are required to apply for security assessment or adopt other compliance mechanisms. During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any cross-border transfer of personal information of trial subjects. Accordingly, as advised by our PRC Legal Advisor, the cross-border data transfer regulatory requirements under PRC law were not applicable to our Group.

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REGULATIONS ON TAXATION

Enterprise Income Tax

According to the Corporate Income Tax Law of the People’s Republic of China (《中華人民共和國企業所得稅法》), which was promulgated by the SCNPC and was latest amended and came into effect on December 29, 2018, and the Implementing Regulations for the Corporate Income Tax Law of the People’s Republic of China (《中華人民共和國企業所得稅法實施條例》), which was promulgated by the State Council and was latest amended in December 6, 2024 and came into effect on January 20, 2025, a uniform twenty-five percent (25%) enterprise income tax rate is imposed to both foreign invested enterprises and domestic enterprises, except where tax incentives are granted to special industries and projects. The enterprise income tax rate is reduced to 20% for qualifying small low-profit enterprises. High-tech enterprises that are key targets of national support shall enjoy a reduced tax rate of 15% for enterprise income tax.

Value-added Tax

Pursuant to the Value-added Tax Law of the People’s Republic of China (《中華人民共和國增值稅法》) which was promulgated by the SCNPC came into effect on January 1, 2026, and the Regulations for the Implementation of the Value-Added Tax Law of the People’s Republic of China (《中華人民共和國增值稅法實施條例》), which was promulgated by the State Council came into effect on January 1, 2026, entities and individuals engaging in selling goods, providing processing, repairing or replacement services or importing goods within the territory of the PRC shall be taxpayers of the value-added tax.

REGULATIONS ON FOREIGN EXCHANGE

Foreign Exchange Regulation

On January 29, 1996, the State Council promulgated the Administrative Regulations on Foreign Exchange of the People’s Republic of China (《中華人民共和國外匯管理條例》), which was latest amended and came into effect on August 5, 2008. Foreign exchange payments under current account items shall, pursuant to the administrative provisions of the foreign exchange control department of the State Council on payments of foreign currencies and purchase of foreign currencies, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in conversion and sale of foreign currencies by presenting the valid document. Domestic entities and domestic individuals making overseas direct investments or engaging in issuance and trading of overseas securities and derivatives shall process registration formalities pursuant to the provisions of the foreign exchange control department of the State Council.

On May 10, 2013, the SAFE issued the Administrative Regulations on Foreign Exchange in Domestic Direct Investment by Foreign Investors (《外國投資者境內直接投資外匯管理規定》), which specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC must be conducted by way of registration and banks shall process foreign exchange business relating to the direct investment in the PRC based on the registration information provided by SAFE and its branches.

According to the Notice of the People’s Bank of China and the State Administration of Foreign Exchange on Issues Concerning the Administration of Funds Raised by Domestic Enterprises Listed Overseas (《中國人民銀行國家外匯管理局關於境內企業境外上市資金管理有關問題的通知》), which was issued by the People’s Bank of China and SAFE and came into effect on April 1, 2026, a domestic enterprise that conducts an overseas listing shall, within thirty (30) working days from the first trading day of the overseas listing or the completion of the over-allotment option, apply to a bank within the province or the separately-listed

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municipality where it is registered for overseas listing registration. In principle, funds raised by domestic enterprises through overseas listings shall be remitted back to the territory in a timely manner. Where such funds are retained overseas for the conduct of overseas direct investment, overseas securities investment, overseas lending and other businesses, the domestic enterprise shall obtain the approval or filing documents from the business competent authorities before the date of completion of the overseas issuance or the over-allotment option, and shall comply with relevant cross-border funds administration provisions. The purposes of funds raised through an overseas listing shall be consistent with the relevant contents set out in publicly disclosed documents, such as the document or offering circular for corporate bonds, shareholder circulars, or resolutions of the board of directors or shareholders’ meetings.

According to the Notice on Reforming the Administration of Foreign Exchange Settlement of Capital of Foreign-Invested Enterprises (《關於改革外商投資企業外匯資本金結匯管理方式的通知》) firstly promulgated on March 30, 2015, came effective on June 1, 2015 and partially abolished on December 30, 2019 and March 23, 2023, foreign-invested enterprises could settle their foreign exchange capital on a discretionary basis according to the actual needs of their business operations.

On June 9, 2016, SAFE issued the Notice on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《關於改革和規範資本項目結匯管理政策的通知》), (the “**SAFE Circular 16**”), which came into effect on the same day and was partially amended on December 4, 2023 and effective since then. The SAFE Circular 16 provides that discretionary foreign exchange settlement applies to foreign exchange capital, foreign debt and repatriated funds raised through overseas listing. However, there remain substantial uncertainties with respect to SAFE Circular 16’s interpretation and implementation in practice.

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

According to 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》) issued by the China Securities Regulatory Commission (the “**CSRC**”) on February 17, 2023 and effective from March 31, 2023 (the “**Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies**”), where a domestic company seeks overseas securities issuance and listing, the issuer shall file with the CSRC in accordance with the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies. If an issuer procures an overseas initial public offering or listing, it shall file with the CSRC within three (3) business days after submitting application documents for overseas securities issuance and listing.

According to the Provisions on Strengthening 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 Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies**”) jointly issued by the CSRC and other departments on February 24, 2023 and effective on March 31, 2023, in the overseas offering and listing activities of domestic enterprises, domestic enterprises, and securities companies and securities service institutions that provide corresponding services shall strictly comply with the applicable laws and regulations of the PRC and satisfy the requirements of such Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies.

REGULATORY OVERVIEW

Regulations in Relation to the “Full Circulation” of H-share

In accordance with the Guidelines for the Application by H-share Companies for “Full Circulation” of Unlisted Shares (《H股公司境內未上市股份申請“全流通”業務指引》) which was promulgated by the CSRC on 14 November 2019, came into effect on the same date, and was subsequently partly revised on August 10, 2023 according to the Decision on Revising and Abolishing Part of Securities and Futures Policy Documents by CSRC (《中國證券監督管理委員會關於修改、廢止部分證券期貨制度文件的決定》), the term “full circulation” means the listing and circulation of domestically unlisted shares (including domestically unlisted shares held by domestic shareholders prior to the listing abroad, additional domestically unlisted shares issued domestically after listing abroad and unlisted shares held by foreign shareholders) of H-share companies on the Hong Kong Stock Exchange. On the premise of complying with relevant laws and regulations as well as policies governing state-owned asset management, foreign investment and industrial supervision, the shareholders of domestically unlisted shares may determine the number and proportion of shares under application for circulation through negotiation at their discretion and entrust a H-share company to file an application for “full circulation” with CSRC. After the domestically unlisted shares are listed for circulation on the Hong Kong Stock Exchange, they shall not be transferred back to the domestic market. A shareholder of domestically unlisted shares may reduce or increase its holding of the shares involved that are circulating on the Hong Kong Stock Exchange according to relevant rules. The H-share company shall submit a report on the relevant information to the CSRC within fifteen (15) days from completion of trans-market re-registration of the shares involved in the application to China Securities Depository and Clearing Corporation Limited (the “CSDC”).

In accordance with the Notice on Promulgation of the Implementing Rules for “Full Circulation” of H-shares (《關於發佈〈H股“全流通”業務實施細則〉的通知》) which was promulgated by CSDC and Shenzhen Stock Exchange on December 31, 2019 and came into effect on the same date, it shall apply to the relevant business involved in “full circulation” of H-shares.

In accordance with the Business Guide on H-Share “Full Circulation” of China Securities Depository and Clearing Corporation Limited Shenzhen Branch (《中國證券登記結算有限責任公司深圳分公司H股“全流通”業務指南》) which was promulgated by CSDC Shenzhen Branch on June 27, 2025 and came into effect on June 30, 2025, it specified the business preparation, cross-border transfer registration, initial maintenance of overseas deposit and domestic holding details of shares, subsequent maintenance of domestic holding details of shares, corporate action management, clearing and settlement, risk management and fee arrangement. CSDC also promulgated the Business Guidelines on H-Share “Full Circulation” by China Securities Depository and Clearing (Hong Kong) Company Limited (《中國證券登記結算(香港)有限公司H股“全流通”業務指南》) on September 20, 2024, which came into effect on September 23, 2024 to specify the relevant escrow, custody, agent service, clearing and settlement, risk management and fee arrangement of CSDC HK.