PRC LAWS AND REGULATIONS

We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section sets out a summary of the most significant relevant laws, regulations, rules and policies that are applicable to our current business activities in the PRC.

REGULATIONS ON DRUG ADMINISTRATION

Drug Regulatory Regime

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the "**Drug Administration Law**") was promulgated by the Standing Committee of the National People's Congress (the "**SCNPC**") on September 20, 1984, latest amended on August 26, 2019 and became effective on December 1, 2019. 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》) (the "**Implementation Regulations**") was promulgated by the State Council on August 4, 2002, and was latest amended on December 6, 2024 and became effective on January 20, 2025. The Drug Administration Law and the Implementation Regulations have jointly established the legal framework for the administration of pharmaceutical products in the PRC, including the research, development and manufacturing of drugs. The Drug Administration Law applies to entities and individuals engaged in the development, production, trade, application, supervision and administration of pharmaceutical products, which regulates and provides a framework for the administration of pharmaceutical manufacturers, pharmaceutical trading companies and medicinal preparations of medical institutions, and the development, research, manufacturing, distribution, packaging, pricing and advertisements of pharmaceutical products. The Implementation Regulations, at the same time, provides the detailed implementation regulations on the Drug Administration Law.

Non-clinical Research

The non-clinical safety evaluation study for drugs for the purpose of applying for drug registration shall be conducted in accordance with the Good Laboratories Practice for Drug Non-Clinical Laboratory Studies (《藥物非臨床研究質量管理規範》), which was promulgated on August 6, 2003 and latest amended on July 27, 2017 by the China Food and Drug Administration (currently known as the NMPA) and effective from September 1, 2017. In April 2007, the China Food and Drug Administration issued the Administrative Measures for Administration of Certification of Drug 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》), amended on January 19, 2023 and taking effect on July 1, 2023, which set forth the requirements for an institution to apply for a Certification of Good Laboratory Practice to undertake non-clinical research on drugs.

Application for Clinical Trial

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》) promulgated by the China Food and Drug Administration (currently known as the NMPA) on March 17, 2017, the decision on the approval of clinical trials of drugs shall be made by the Center for Drug Evaluation ("**CDE**") from May 1, 2017. According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the "**Registration Measures**"), which was promulgated on January 22, 2020 and took effect on July 1, 2020, drug clinical trials shall be divided into Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial, and bioequivalence trial. After the completion of the pharmaceutical, pharmacological and toxicological research of the drug clinical trial, the applicant may submit relevant research materials to CDE for applying for the approval to conduct drug clinical trial. The CDE will organize pharmaceutical, medical and other technicians to review the application and to decide whether to approve the drug clinical trial within 60 business

days of the date of acceptance of the application. Once the decision is made, the result will be notified to the applicant through the website of the CDE and if no notice of decision is issued within the aforementioned time limit, the application of clinical trial shall be deemed as approval.

Accelerated Approval for Clinical Trial and Registration

According to the Registration Measures, the NMPA shall establish a system for accelerated marketing authorization of drugs to support clinically value-oriented drug innovation. For qualified drug registration applications, applicants may apply for the application of procedures for breakthrough therapy drugs, conditional approval, priority review and approval, and special approval. In the process of drug development and registration, drug regulatory authorities and their professional technical institutions shall provide necessary policy and technical support, such as technical guidance, communication, priority resource allocation, and shortening of review time limits.

Conduct of Clinical Trial

After obtaining clinical trial approval, the applicant shall conduct clinical trials at qualified clinical trial institutions. The qualified clinical trial institution refers to institutions that have the conditions to conduct clinical trials in accordance with the requirements and technical guidelines set forth in the Regulations for the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which came into effect on December 1, 2019. Such clinical trial institutions shall be subject to filing requirements, with the exception of institutions that only engage in analysis of biological samples which shall not be subject to such filing requirements. The NMPA is responsible for setting up a filing management information platform for the registration, filing and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information from the supervision and inspection activities conducted by the drug regulatory authorities and competent healthcare authorities.

The Announcement on Issuing the Guidelines for General Considerations for Clinical Trials on Drugs (《關於發佈藥物臨床試驗的一般考慮指導原則的通告》) promulgated by the China Food and Drug Administration (currently known as the NMPA) on January 18, 2017 provides technical guidelines for applicants and investigators in formulating overall research and development plan of drugs and separate clinical trial and provides references for evaluation of the technical standards of the drugs.

According to the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (《藥物研發與技術審評溝通交流管理辦法》), revised by the CDE on December 10, 2020, during the research and development periods and in the registration applications of, among others, the innovative new drugs, the applicants may propose to conduct communication meetings with the CDE. The communication meetings can be classified into three types. Type I meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are held during the key research and development stages of drugs, mainly including meetings before submitting the clinical trial application, meetings upon the completion of Phase II trials and prior to Phase III trials, meetings before submitting the marketing application for a new drug, and meetings for risk evaluation and control. Type III meetings refer to other meetings not classified as Type I or Type II.

Good Clinical Practices

Clinical trials must be conducted in accordance with the Good Clinical Practice for Drugs (《藥物臨床試驗質量管理規範》) (the "**GCP Rules**") promulgated by CFDA, amended by NMPA and the National Health Commission of the PRC (the "**NHC**") on April 23, 2020 and effective on July 1, 2020, which stipulates the requirements for the procedures of conducting clinical trials, including trial protocols, protection of subjects' rights and interests, duties of researchers, sponsors

and monitors, as well as data management and statistical analysis. According to the GCP Rules, clinical trial means systematical investigation of drugs conducted on human subjects (patients or healthy volunteers) to prove or reveal the clinical, pharmacological and other pharmacodynamic effects, adverse reactions or absorption, distribution, metabolism and excretion of the drug being investigated. In order to ensure the quality of clinical trials and the safety of human subjects, the GCP Rules provides comprehensive and substantive requirements on the design and conduct of clinical trials in the PRC. In particular, the GCP Rules enhances the protection for study subjects and tightens the control over bio-samples collected under clinical trials.

New Drug Registration

Pursuant to the Registration Measures, upon completion of clinical trials, determination of quality standards, completion of validation of commercial-scale production processes and completion of other related preparation works, the applicant may apply with the NMPA for the marketing authorization. The NMPA then determines whether to approve the application according to applicable laws and regulations. The applicant must obtain the marketing authorization for a new drug before the drug can be manufactured and sold in the China market.

Marketing Authorization Holder Mechanism

Pursuant to the Drug Administration Law, the PRC implements the marketing authorization holder mechanism for management of the drug industry. The drug marketing authorization holder (the "**MAH**") refers to an enterprise or a drug research and development institution that has obtained the drug registration certificate. The MAH shall be responsible for non-clinical research, clinical trials, production and operation, post-marketing research, adverse reaction monitoring, reporting and processing of drugs in accordance with the provisions of the law.

The MAH may manufacture drugs by themselves or entrust a pharmaceutical manufacturing enterprise to manufacture drugs. Likewise, they may sell drugs by themselves or entrust a pharmaceutical distribution enterprise to sell drugs. However, the MAH may not entrust a pharmaceutical manufacturing enterprise to produce blood products, narcotic drugs, psychotropic drugs, medical-use toxic drugs or pharmaceutical precursor chemicals, except as otherwise stipulated by the drug regulatory department under the State Council.

Drug Manufacturing

According to the Drug Administration Law and the Implementing Regulations, a drug manufacturing enterprise is required to obtain a Drug Manufacturing Permit from the relevant provincial drug administration authority of the PRC. The grant of such permit is subject to an inspection of the manufacturing facilities, and an inspection to determine whether the sanitary condition, quality assurance systems, management structure and equipment meet the required standards. According to the Measures for the Supervision and Administration of Drug Manufacturing (《藥品生產監督管理辦法》) (the "**Drug Manufacturing Measures**"), last amended on January 22, 2020 and came into effect on July 1, 2020, the Drug Manufacturing Permit is valid for five years and shall be renewed at least six months prior to its expiration date upon a re-examination by the original issuing authority. In addition, the name, unified social credit code, registered address (business premises) and legal representative specified in the drug manufacturing permit shall be the same as that set forth in the business license as approved and issued by the local counterparts of the SAMR. According to the Drug Manufacturing Measures, if the MAH does not manufacture the drug but entrusts others to manufacture the drug, the MAH shall enter into 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 competent provincial counterpart of the NMPA where the MAH is located to apply for the Drug Manufacturing Permit.

The Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) (the "**GMP Rules**") was last amended on January 17, 2011 and came into effect on March 1, 2011. The GMP Rules comprise a set of detailed standard guidelines governing the manufacture of drugs, including institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, raw material management, maintenance of sales records and management of customer complaints and AE reports. Under the Drug Manufacturing Measures, a GMP certification is no longer required for drug manufacturing enterprises, but drug manufacturing enterprises shall comply with the GMP Rules in their drug manufacturing activities.

Drug Distribution

According to the Drug Administration Law, the engagement in drug distribution, including drug wholesale and drug retail, is prohibited without a drug distribution license. A drug distribution license shall state the validity period and the scope of business and be subject to review and reissuance upon expiry of the validity period.

The Measures for the Supervision and Management of Drug Distribution and Use Quality (《藥品經營和使用質量監督管理辦法》) promulgated by the SAMR on September 27, 2023 and came into effect on January 1, 2024, and the Measures for the Administration of Drug Distribution License (《藥品經營許可證管理辦法》) was simultaneously repealed. The Measures for the Supervision and Management of Drug Distribution and Use Quality stipulates the conditions, procedures, changes and supervision and administration of the drug distribution license.

The Good Supply Practice for Pharmaceutical Products (《藥品經營質量管理規範》) (the "**GSP Rules**") was last amended and came into effect on July 13, 2016. The GSP Rules set forth the basic standards in management of distribution quality of drugs and apply to enterprises engaged in drug distribution in the PRC, which require drug distributors to implement strict controls on its distribution of pharmaceutical products, including standards regarding staff qualifications, premises, warehouses, inspection equipment and facilities, management and quality control. Under the Drug Administration Law, the GSP certification is no longer required for drug distributors, but drug distributors are still required to comply with the GSP Rules.

Approval or Filing of Human Genetic Resources

The Regulations 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》), promulgated by the State Council on May 28, 2019, latest amended in March 10, 2024 and came into effect on May 1, 2024, stipulates that in order to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China's human genetic resources at clinical institutions without export of human genetic resource materials. However, the type, quantity and usage of the human genetic resources to be used shall be filed with the administrative department of health under the State Council before clinical trials. On May 26, 2023, the Ministry of Science and Technology issued 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》), which came into effect on July 1, 2023, optimizing the scope of administrative licensing and record-keeping, enhancing the operability of the human genetic resources administration system, and implementing the registration and reporting system for the management of human genetic resources.

REGULATIONS ON COMPANY, FOREIGN INVESTMENT AND OVERSEAS INVESTMENT

Company Law

The establishment, operation and management of companies within the territory of the PRC are governed by the Company Law of the PRC (《中華人民共和國公司法》) (the "**Company Law**"). The Company Law was promulgated by the SCNPC on December 29, 1993, latest amended on December 29, 2023 and became effective on July 1, 2024. The Company Law governs the establishment, operation, corporate structure, and management of legal person entities within the PRC. According to the Company Law, companies established in the PRC can take the form of limited liability companies and joint-stock companies. Each company has the status of a legal person and owns its own assets. The Company Law also applies to foreign-invested enterprises.

According to the Company Law, companies shall contribute 10% of the profits into their statutory capital reserve upon distribution of their post-tax profits of the current year. A company may discontinue the contribution when the aggregate sum of the statutory capital reserve is more than 50% of its registered capital. Where the balance of the statutory capital reserve of a company is insufficient to make up its losses in the previous year, the company shall make up such losses using its profits of the current year before making contribution to the statutory capital reserve. Upon contribution to the statutory capital reserve with its post-tax profits, a company may make further contribution to the capital reserve with its post-tax profits. After making up its losses and accrued reserves, a company may distribute post-tax profits to its shareholders.

Foreign Investment

Investment activities in the PRC by foreign investors are principally governed by the Catalog of Encouraged Industries for Foreign Investment (2025) (《鼓勵外商投資產業目錄》(2025年版)) (the "**Encouraged Catalog**"), and the Special Administrative Measures (Negative List) for Foreign Investment Access (2024) (《外商投資准入特別管理措施(負面清單)(2024年版)》) (the "**Negative List**"), which are promulgated and amended from time to time by the MOFCOM and the NDRC, and together with the Foreign Investment Law of PRC (《中華人民共和國外商投資法》) (the "**FIL**") and its respective implementation rules and ancillary regulations.

On March 15, 2019, the FIL was promulgated by National People's Congress and came into effect on January 1, 2020, which established the basic framework for the access, promotion, protection and administration of foreign investment in view of investment protection and fair competition. According to the FIL, foreign investment shall enjoy pre-establishment national treatment, except for those foreign invested entities that operate in industries deemed to be either "restricted" or "prohibited" in the Negative List, and the State Council shall promulgate or approve a list of special administrative measures for access of foreign investments. To ensure the effective implementation of the FIL, the Regulations on Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》) (the "**Implementation Regulations**"), was promulgated by State Council on December 26, 2019 and came into effect on January 1, 2020, which further clarified that the state encourages and promotes foreign investment, protects the lawful rights and interests of foreign investors, regulates foreign investment administration, continues to optimize foreign investment environment, and advances a higher-level opening.

On December 30, 2019, the MOFCOM and the SAMR promulgated the Measures on Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which came into effect on January 1, 2020. Since January 1, 2020, for foreign investors carrying out investment activities directly or indirectly in China, the foreign investors or foreign-invested enterprises shall submit investment information to the relevant commerce administrative authorities according to the Measure on Reporting of Foreign Investment Information.

Overseas Investment

Pursuant to the Measures for the Administration of Overseas Investment (《境外投資管理辦法》) which was issued by the MOFCOM on September 6, 2014 and became effective on October 6, 2014, the MOFCOM and the commerce departments at provincial levels shall subject the overseas investment of enterprises to recordation or confirmation management, depending on the actual circumstances of investment. Overseas investment involving any sensitive country or region, or any sensitive industry shall be subject to confirmation management. Overseas investment under other circumstances shall be subject to recordation management.

Pursuant to the Measures for the Administration of Overseas Investment of Enterprises (《企業境外投資管理辦法》) which was issued by the NDRC on December 26, 2017 and became effective on March 1, 2018, an enterprise in the territory of the PRC (the "**Investor**") shall, in overseas investment, undergo the formalities for the confirmation or recordation, among others, of an overseas investment project (the "**Project**"), report the relevant information, and cooperate in supervisory inspection. Sensitive projects conducted by investors directly or through overseas enterprises controlled by them shall be subject to approval management. Non-sensitive Projects directly conducted by Investors, namely, non-sensitive Projects involving Investors' direct contribution of assets or rights and interests or provision of financing or security, shall be subject to recordation management. The aforementioned sensitive Project means a Project involving a sensitive country or region or a sensitive industry. The NDRC promulgated the Catalogue of Sensitive Sectors for Outbound Investment (2018 Edition) (《境外投資敏感行業目錄(2018年版)》), effective on March 1, 2018, to list the sensitive industries in detail.

REGULATIONS ON INTELLECTUAL PROPERTY

Trademarks

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

Patents

According to the Patent Law of the PRC (《中華人民共和國專利法》), promulgated by the SCNPC on March 12, 1984 and latest amended on October 17, 2020 which became effective on June 1, 2021 and the Implementing Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), promulgated by the State Council on June 15, 2001, and last amended on December 11, 2023 and effective from January 20, 2024, there are three types of patents in the PRC, i.e., invention

patents, utility model patents and design patents. The duration of invention patent right, design patent right and utility model patent right shall be 20 years, 15 years and 10 years, respectively, which are all calculated from the date of application. Implementation of a patent without the authorization of the patent holder shall constitute an infringement of patent rights, and shall be held liable for compensation to the patent holder and may be imposed a fine, or even subject to criminal liabilities.

Specifically, for the purpose of compensating for the time taken to evaluate and approve a new drug to be put on market, the patent administrative department under the State Council shall grant compensation for duration of patent rights for invention of a new drug approved to be put on market in the PRC upon request of the patentee. The compensation period shall not exceed five years, and the total validity period of patent rights for a new drug after being approved for marketing shall not exceed 14 years.

Trade Secrets

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by the SCNPC on September 2, 1993 and latest amended on June 27, 2025 and came into effect on October 15, 2025, the term "trade secrets" refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the Anti-Unfair Competition Law of the PRC, business persons are prohibited from infringing others' trade secrets by: (i) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (ii) disclosing, using or permitting others to use the trade secrets obtained illegally under item (i) above; (iii) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (iv) instigating, inducing or assisting others to violate confidentiality obligation or to violate a rights holder's requirements on keeping confidentiality of trade secrets, disclosing, using or permitting others to use the trade secrets of the rights holder. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others' trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties.

Copyrights

According to the Copyright Law of the PRC (《中華人民共和國著作權法》), promulgated by the SCNPC on September 7, 1990 and latest amended on November 11, 2020 which became effective on June 1, 2021, and the Implementation Regulations of the Copyright Law of PRC (《中華人民共和國著作權法實施條例》) promulgated by the State Council on August 2, 2002 and latest amended on January 30, 2013, Chinese citizens, legal persons, or other organizations shall, whether published or not, own copyright in their works, which include, among others, works of literature, art, natural science, social science, engineering technology and computer software. Copyright owners of protected works enjoy personal rights and property rights with respect to publication, authorship, alteration, integrity, reproduction, distribution, lease, exhibition, performance, projection, broadcasting, dissemination via information network, production, adaptation, translation, compilation, and other rights shall be enjoyed by the copyright owners.

Domain Names

According to the Measures on Administration of Internet Domain Names (《互聯網域名管理辦法》), which was promulgated by the Ministry of Industry and Information Technology (the "**MIIT**") on August 24, 2017 and became effective on November 1, 2017, the MIIT is responsible for supervision and administration of domain name services in the PRC. Communication

administrative bureaus at provincial levels shall conduct supervision and administration of the domain name services within their respective administrative jurisdictions. Domain name registration services shall, in principle, be subject to the principle of "first apply, first register". A domain name registrar shall, in the process of providing domain name registration services, ask the applicant for which the registration is made to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

REGULATIONS ON INFORMATION SECURITY AND DATA PROTECTION

Personal Information Protection

On August 20, 2021, the SCNPC promulgated the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), or the Personal Information Protection Law, which became effective on November 1, 2021. The Personal Information Protection Law requires, among others, that the processing of personal information should have a clear and reasonable purpose and should be limited to the minimum scope necessary to achieve the processing purpose, adopt a method that has the least impact on personal rights and interests, and shall not process personal information that is not directly related to the processing purpose.

Privacy Data Security and Data Export

On June 10, 2021, the SCNPC promulgated the Data Security Law of the PRC (《中華人民共和國數據安全法》) (the "**Data Security Law**") which became effective on September 1, 2021. The Data Security Law mainly sets forth specific provisions regarding establishing basic systems for data security management, including data classification and hierarchical protection system, risk assessment system, monitoring and early warning system and emergency disposal system. In addition, it clarifies the data security protection obligations of organizations and individuals carrying out data activities and implementing data security protection responsibility. The Data Security Law stipulates the measures to support and promote data security and development, to establish and optimize the national data security management system and to clarify organizations' and individuals' responsibilities in data security.

On December 28, 2021, the Cyberspace Administration of China (the "**CAC**"), jointly with 12 other administrative authorities, promulgated the revised Measures for Cybersecurity Review (《網絡安全審查辦法》) (the "**MCR**"), which became effective on February 15, 2022. According to the MCR, (i) the purchase of cyber products and services by the Critical Information Infrastructure Operator (the "**CIIO**"), and the data processing activities carries out online platform operators which affects or may affect national security, shall be subject to the cybersecurity review by the Cybersecurity Review Office, the department which is responsible for the implementation of cybersecurity review under the CAC; (ii) network platform operators with personal information of more than one million users that seek for listing in a foreign country are obliged to apply for a cybersecurity review by the Cybersecurity Review Office; and (iii) the relevant regulatory authorities may initiate cybersecurity review if such regulatory authorities determine that the issuer's network products or services, or data processing activities affect or may affect national security.

On July 7, 2022, the CAC promulgated the Measures for the Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》) (the "**Security Assessment Measures**"), which became effective on September 1, 2022. The Security Assessment Measures provides four circumstances, under any of which data processors shall, through the local cyberspace administration at the provincial-level, apply to the national cyberspace administration for security assessment of cross-border data transfer.

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. The provisions provide several exemptions from undergoing data security assessment, obtaining personal information protection certification or entering into standard contract for outbound transfer of personal information for businesses.

REGULATIONS ON LEASING

According to the Civil Code of the PRC, an owner of immovable or movable property is entitled to possession, use, earnings, and disposal of such property in accordance with the law. Subject to the consent of the lessor, the lessee may sublease the leased premises to a third party. Where a lessee subleases the premises, the lease contract between the lessee and the lessor remains valid. The lessor is entitled to terminate the lease if the lessee subleases the premises without the consent of the lessor. In addition, if the ownership of the leased premises changes during the lessee's possession in accordance with the terms of the lease contract, the validity of the lease contract shall not be affected. Moreover, pursuant to the Civil Code of the PRC, if the mortgaged property has been leased and transferred for occupation prior to the establishment of the mortgage right, the original tenancy shall not be affected by such mortgage right.

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

REGULATIONS ON FIRE PROTECTION AND ENVIRONMENTAL PROTECTION

Fire Control

Pursuant to the Fire Control Law of the PRC (《中華人民共和國消防法》) promulgated by the SCNPC on April 29, 1998, and last amended on April 29, 2021 and effective therefrom, the Department of Emergency Management under the State Council and the local people's governments at or above county level shall supervise and administer the matters of fire protection, while the fire control and rescue institutions of such people's governments shall be responsible for implementation. The design of fire control of the construction projects must comply with the national technical standards of fire control. If the design of fire control of a construction project has not been examined pursuant to the relevant laws or failed to pass the examination, the construction of such project is not allowed. If a completed construction project has not gone through the fire safety inspection or failed to satisfy the requirements of fire safety upon inspection, such project is not allowed to be put to use or business. According to the Interim Regulations on Administration of Examination and Acceptance of Fire Control Design of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) issued by the Ministry of Housing and Urban-Rural Development on April 1, 2020 and latest amended on 21 August, 2023, an examination system for fire control design and acceptance only applies to special construction projects, and for other projects, a record-filing and spot check system would be applied.

Environmental Protection

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) was promulgated by the SCNPC and effective on December 26, 1989, and most recently amended on April 24, 2014. The Environmental Protection Law of the PRC has been formulated for the purpose of protecting and improving the environment, preventing and controlling pollution and other public hazards, safeguarding people's health, advancing the construction of an ecological civilization and

promoting sustainable economic and social development. According to the provisions of the Environmental Protection Law of the PRC, in addition to other relevant laws and regulations of the PRC, the Ministry of Environmental Protection and its local counterparts are responsible for administering and supervising environmental protection matters. Pursuant to the Environmental Protection Law, construction projects that have environmental impact shall be subject to environmental impact assessment.

Environment Impact Assessment

On October 28, 2002, the SCNPC promulgated the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》), which was latest amended on December 29, 2018. The State Council implemented the environmental impact assessment to classify construction projects according to the impact of the construction projects on the environment. The Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》) was promulgated by the State Council on November 29, 1998, amended on July 16, 2017 and became effective on October 1, 2017. According to the Environmental Impact Assessment Law and the Administration Rules on Environmental Protection of Construction Projects, depending on the impact of the construction project on the environment, the construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form.

Pursuant to the Interim Measures for Environmental Protection Acceptance of Completed Construction Projects (《建設項目竣工環境保護驗收暫行辦法》) effective as of November 20, 2017 and the Regulations on the Administration Construction Project Environmental Protection, after the completion of a construction project for which an environmental impact report or an environmental impact report form is required, the construction entity shall, according to standards and procedures prescribed by the environmental protection administrative authorities, conduct environmental protection completion acceptance check and compile an acceptance check report. A construction project for which an environmental impact report or an environmental impact report form is required shall not be put into production or use until the environmental protection completion acceptance check has been passed.

Pollutant Discharges Permitting Administration

Pursuant to the provisions of the Regulation on the Administration of Permitting of Pollutant Discharges (《排污許可管理條例》) promulgated on January 24, 2021 and effective on March 1, 2021, and the Measures for Pollutant Discharge Permitting Administration (《排污許可管理辦法》) promulgated on April 1, 2024 and became effective on July 1, 2024, the PRC implements the classified pollutant discharge permit management (i.e., key management, simplified management and registration management) on pollutant discharges of enterprises based on factors such as the volume of pollutants generated, the amount of pollutant discharged and the degree of impact on the environment. Enterprises and other producers that are included in the Classification Administration List of Pollutant Discharge Permits for Fixed Pollution Sources (《固定污染源排污許可分類管理名錄》) shall apply for and obtain a pollutant discharge permit or fill in a pollutant discharge registration form within the prescribed time limit, and shall not discharge pollutants without a pollutant discharge permit or filling in a pollutant discharge registration form.

Disposal of Hazardous Waste

Pursuant to the Law on the Prevention and Control of Environmental Pollution Caused by Solid Waste of the PRC (《中華人民共和國固體廢物污染環境防治法》), which was promulgated by the SCNPC on October 30, 1995 and was latest amended on 29 April 2020 and became effective on September 1, 2020, entities generating hazardous waste shall store, utilise and dispose hazardous waste according to the relevant requirements of the state and environmental protection standards, and shall not dump or pile up hazardous waste without authorisation. Furthermore, it is forbidden

to entrust hazardous waste to entities without a permit for disposal, or else the competent ecological and environmental authorities shall order it to make rectification, impose fines, confiscate illegal gains, and in serious circumstances, order it to suspend business or close down upon the approval of the government authorities.

REGULATIONS ON EMPLOYMENT AND SOCIAL WELFARE

Employment

The major PRC laws and regulations that govern employment relationship are the Labor Law of the PRC (《中華人民共和國勞動法》), (the "**Labor Law**"), which was promulgated by the SCNPC on July 5, 1994, last amended and came into effect on December 29, 2018), the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), (the "**Labor Contract Law**"), which was promulgated by the SCNPC on June 29, 2007 and became effective on January 1, 2008, and then amended on December 28, 2012 and became effective on July 1, 2013, and the Implementation Rules of the Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》), (the "**Implementation Rules of the Labor Contract Law**"), promulgated by the State Council on September 18, 2008 and came into effect on the same day. According to the aforementioned laws and regulations, labor relationships between employers and employees must be executed in written form. The laws and regulations above impose stringent requirements on the employers in relation to entering into fixed-term employment contracts, hiring of temporary employees and dismissal of employees. As prescribed under the laws and regulations, employers shall ensure their employees have the right to rest and the right to receive wages no lower than the local minimum wages. Employers must establish a system for labor safety and sanitation that strictly abides by state standards and provide relevant education to its employees. Violations of the Labor Contract Law and the Labor Law may result in the imposition of fines and other administrative liabilities and/or incur criminal liabilities in the case of serious violations.

Social Insurance

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which was promulgated by the SCNPC on October 28, 2010 and latest amended on December 29, 2018, enterprises and institutions in the PRC shall provide their employees with welfare schemes covering basic pension insurance, basic medical insurance, unemployment insurance, maternity insurance, work-related injury insurance and other welfare plans. The employer shall apply to the local social insurance agency for social insurance registration within 30 days from the date of its formation. And it shall, within 30 days from the date of employment, apply to the social insurance agency for social insurance registration for the employee. Any employer who violates the regulations above shall be ordered to rectify within a prescribed time limit; if the employer fails to rectify within the time limit, the employer and its directly liable person will be fined. Meanwhile, the Interim Regulation on the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》), which was promulgated by the State Council on January 22, 1992 and came into effect on the same day, and latest amended and became effective on March 24, 2019, prescribes the details concerning the social insurance.

Housing Provident Fund

According to the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), which was promulgated by the State Council on April 3, 1999 and came into effect on the same day, and latest amended on March 24, 2019, any newly established entity shall make deposit registration at the designated administrative centers and open bank accounts for depositing employees' housing provident funds. Employers and employees are also required to pay and deposit housing provident funds, with an amount no less than 5% of the monthly average salary of the employee in the preceding year in full and on time. Any entity that fails to make payment of housing

provident funds within the time limit or has a shortfall in payment of housing provident funds will be ordered to make the payment or make up the shortfall within a prescribed time limit, otherwise, the housing provident management center is entitled to apply for compulsory enforcement with the People's Court.

REGULATIONS ON FOREIGN EXCHANGE

Regulations relating to Foreign Currency Exchange

The principal regulations governing foreign currency exchange in China are the Foreign Exchange Administration Regulations of the PRC (《中華人民共和國外匯管理條例》), most recently amended in August 5, 2008. Under the PRC foreign exchange regulations, payments of current account items, such as profit distributions, interest payments and trade and service related foreign exchange transactions, can be made in foreign currencies without prior approval from the SAFE, by complying with certain procedural requirements. By contrast, approval from or registration with appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital account items, such as direct investments, repayment of foreign currency-denominated loans, repatriation of investments and investments in securities outside of China.

The SAFE issued the Circular on Reforming of the Management Method of the Settlement of Foreign Currency Capital of Foreign-Invested Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》) (the "**SAFE Circular 19**") on March 30, 2015, and it became effective on June 1, 2015, which was partially repealed on December 30, 2019, and latest amended on March 23, 2023. The SAFE Circular 19 expands a pilot reform of the administration of the settlement of the foreign exchange capitals of foreign-invested enterprises nationwide. On June 9, 2016, SAFE further promulgated the Circular on the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《國家外匯管理局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, among other things, amends certain provisions of SAFE Circular 19 and was partially amended on December 4, 2023. Pursuant to SAFE Circular 19 and SAFE Circular 16, the flow and use of the Renminbi capital converted from foreign currency denominated registered capital of a foreign-invested company is regulated such that Renminbi capital may not be used for business beyond its business scope or to provide loans to persons other than affiliates unless otherwise permitted under its business scope.

On October 23, 2019, SAFE issued the Circular on Further Facilitating Cross-border Trade and Investment (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》) (the "**SAFE Circular 28**"), which cancels the restrictions on domestic equity investments by capital fund of non-investment foreign invested enterprises and allows non-investment foreign invested enterprises to use their capital funds to lawfully make equity investments in China, provided that such investments do not violate the Negative List and the target investment projects are genuine and in compliance with laws. According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《國家外匯管理局關於優化外匯管理支持涉外業務發展的通知》) (the "**SAFE Circular 8**"), issued by SAFE on April 10, 2020, under the prerequisite of ensuring true and compliant use of funds and compliance with the prevailing administrative provisions on use of income under the capital account, eligible enterprises are allowed to make domestic payments by using their capital funds, foreign credits and the income under capital accounts of overseas listing, without prior provision of the evidentiary materials concerning authenticity to the bank for each transaction. The handling banks shall conduct spot checks afterwards in accordance with the relevant requirements.

REGULATIONS ON TAXATION

Enterprise Income Tax

Pursuant to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得税法》) latest amended by the SCNPC and came into effect on December 29, 2018 and the Regulations on the Implementation of the EIT Law (《中華人民共和國企業所得税法實施條例》) latest amended by the State Council on December 6, 2024 and came into effect on January 20, 2025, a domestic enterprise which is established within the PRC in accordance with the laws or established in accordance with any laws of foreign countries (regions) but with an actual management entity within the PRC shall be regarded as a resident enterprise. A resident enterprise shall be subject to a EIT of 25% of any income generated within or outside the PRC. A preferential EIT rate shall be applicable to any key industry or project which is supported or encouraged by the State. High and new technology enterprises which are supported by the State may enjoy a reduced EIT rate of 15%.

Value-Added Tax

On December 25, 2024, the SCNPC issued the Value-Added Tax Law of the PRC (《中華人民共和國增值税法》), or the VAT Law, which shall become effective from January 1, 2026. According to the VAT Law, any entities and individuals (including individual businesses) engaged in the sale of goods, services, intangible assets and immovables and importation of goods within the territory of the PRC are VAT payers and shall pay VAT in accordance with the VAT Law. Except for taxpayers' export of goods, the sale of services or intangible assets within the scope as prescribed by the State Council by domestic entities and individuals across national borders and other circumstances specified for by the State Council, the rate of VAT for sale of goods, labor services of processing, repair or replacement, or tangible movable property leasing services or import of goods is 13% unless otherwise specified, such as the rate of VAT for sale of agricultural products is 9%, and the rate of VAT for sale of transportation, postal, basic telecommunications, construction, or immovable leasing services, sale of immovables, or transfer of the rights to use land is 9%. In addition to the above circumstances, the rate of VAT for sale of services or intangible assets is 6%.

Taxation Relating to Dividends

Pursuant to the EIT Law and the Implementation Regulations for the EIT Law, a non-resident enterprise is subject to enterprise income tax for its PRC-sourced income (including equity investment gains such as dividends and bonuses paid by PRC enterprises), but shall be at a reduced tax rate of 10%, if such non-resident enterprise does not have an establishment or premises in the PRC or has an establishment or premises in the PRC but the PRC-sourced income is not connected with such establishment or premises in the PRC. The aforementioned income tax which shall be paid by non-resident enterprises shall be withheld at source, with the payer of the income being the withholding agent. Such withholding tax shall be withheld by the withholding agent from the amount paid or amount due and payable upon each payment or payment due and payable.

Pursuant to the Individual Income Tax Law of the PRC (中華人民共和國個人所得税法) (the "**IIT Law**") promulgated by the SCNPC on September 10, 1980, last amended on August 31, 2018 and effective on January 1, 2019, and the Implementation Regulations for the Individual Income Tax Law of the PRC (中華人民共和國個人所得税法實施條例) (the "**Implementation Regulations for the IIT Law**") last amended by the State Council on December 18, 2018 and implemented on January 1, 2019, dividend income derived by individual investors from PRC domestic enterprises (no matter the place of payment is in the PRC or not) shall be subject to individual income tax at a tax rate of 20% and shall be withheld by the PRC domestic enterprises, except for tax-exempt income stipulated in international conventions and agreements to which the PRC Government is a party, as well as other tax-exempt income and tax reduction circumstances stipulated by the State Council.

Taxation relating to Share Transfer

Pursuant to the EIT Law and the Implementation Regulations for the EIT Law, a non-resident enterprise is subject to enterprise income tax for its PRC-sourced income (including gains from transfers of equity investments in PRC enterprises), but shall be at a reduced tax rate of 10%, if such non-resident enterprise does not have an establishment or premises in the PRC or has an establishment or premises in the PRC but the PRC-sourced income is not connected with such establishment or premises in the PRC. The aforementioned income tax which shall be paid by non-resident enterprises shall be withheld at source, with the payer of the income being the withholding agent. Such withholding tax shall be withheld by the withholding agent from the amount paid or amount due and payable upon each payment or payment due and payable.

Pursuant to the IIT Law and the Implementation Regulations for the IIT Law, gains on transfer of properties (including gains derived by individuals from the transfer of priced securities, equity, shares of property in a partnership enterprise) in subject to individual income tax at the rate of 20%. Pursuant to the Circular on Declaring that Individual Income Tax Continues to Be Exempted over Individual Gains from Transfer of Shares (Cai Shui Zi [1998] No. 61) (關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知(財稅字[1998]61號)) issued jointly by the Ministry of Finance and the SAT on March 30, 1998 and implemented therefrom, from January 1, 1997, gains of individuals from the transfer of shares of listed companies continue to be exempted from individual income tax. However, the aforesaid provisions have not expressly stipulated whether to levy individual income tax on the transfer of shares of PRC resident enterprises listed on overseas securities exchanges by individuals.

Tax Policies for Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect

On October 31, 2014 and November 5, 2016, the Ministry of Finance, the SAT, and the CSRC jointly promulgated the Circular on Tax Policies concerning the Pilot Program of the Shanghai-Hong Kong Stock Market Trading Interconnection Mechanism (《關於滬港股票市場交易互聯互通機制試點有關稅收政策的通知》) and the Circular on Tax Policies concerning the Pilot Program of the Shenzhen-Hong Kong Stock Market Trading Interconnection Mechanism (《關於深港股票市場交易互聯互通機制試點有關稅收政策的通知》), pursuant to which, the gains from the transfer of shares and income from dividends and bonuses obtained by PRC enterprise investors from investing in stocks listed on the Hong Kong Stock Exchange through the Shanghai-Hong Kong Stock Connect or Shenzhen-Hong Kong Stock Connect shall be included in their total income and subject to EIT in accordance with the law. Among which, income from dividends and bonuses received by PRC resident enterprises from continuously holding H Shares for at least 12 months is exempt from EIT by law. H Share companies are not required to withhold and pay taxes on the income from dividends and bonuses for PRC enterprise investors. The taxable amount shall be declared and paid by the enterprises themselves.

For dividends and bonuses received by individual PRC investors from investing in H Shares listed on the Hong Kong Stock Exchange through the Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect, the H Share company shall apply to China Securities Depository and Clearing Co., Ltd. (the "**CSDC**"), and CSDC shall provide a list of individual PRC investors to the H Share company, which shall then withhold and pay individual income tax at a rate of 20%. Individual investors who have already paid withholding tax outside the PRC may apply to the competent tax authority of CSDC for a tax credit upon presentation of a valid tax reduction certificate. For income from dividends and bonuses obtained by PRC securities investment funds from investing in stocks listed on the Hong Kong Stock Exchange through the Shanghai-Hong Kong Stock Connect or Shenzhen-Hong Kong Stock Connect, individual income tax shall be levied in accordance with the above provisions.

On December 4, 2019, the MOF, the SAT and the CSRC jointly issued the Announcement on the Continued Implementation of the Individual Income Tax Policies on the Interconnection Mechanisms for Transactions in Shanghai and Hong Kong Stock Markets and for Transactions in Shenzhen and Hong Kong Stock Markets (MOF Announcement 2019 No. 93) (《關於繼續執行滬港、深港股票市場交易互聯互通機制和內地與香港基金互認有關個人所得稅政策的公告》 (財政部公告2019年第93號)). It stipulates that for PRC individual investors, the transfer difference income derived from investing in stocks listed on the Hong Kong Stock Exchange through Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect and the trading of Hong Kong fund units through mutual recognition of funds will continue to be exempt from individual income tax on a temporary basis from December 5, 2019 to December 31, 2022.

In addition, pursuant to the Announcement on Continuing the Implementation of the Individual Income Tax Policies Concerning the Shanghai-Hong Kong Stock Connect and the Shenzhen-Hong Kong Stock Connect and the Mutual Recognition of Funds between Chinese Mainland and Hong Kong (《關於延續實施滬港、深港股票市場交易互聯互通機制和內地與香港基金互認有關個人所得稅政策的公告》(財政部公告2023年第23號)) (Announcement of the MOF No. 23 of 2023) jointly issued by the MOF, the SAT and the CSRC on August 21, 2023, the period for the implementation of the individual income tax exemption policy has been further extended to December 31, 2027.

REGULATIONS ON OVERSEAS LISTING

CSRC Filing

Pursuant to the Overseas Listing Trial Measures, promulgated by the China Securities Regulatory Commission (the "**CSRC**") on 17 February 2023, which became effective on 31 March 2023, where a PRC domestic company seeks to directly or indirectly offer and list securities in overseas markets, the issuer or the designated entity shall file the required documents with the CSRC within three business days after its application for initial public offering is submitted.

The Overseas Listing Trial Measures also stipulate the circumstances where the overseas offering and listing is explicitly prohibited, including: (i) financing through listing is expressly prohibited by laws, administrative regulations or relevant rules of the state; (ii) the overseas offering and listing may endanger national security as determined by the relevant competent department under the State Council after examination according to the law; (iii) a domestic enterprise or its controlling shareholder or actual controller has committed a criminal crime of corruption, bribery, embezzlement, misappropriation of property or disrupting the economic order of the socialist market in the last three years; (iv) domestic enterprise is under formal investigation according to the law for being suspected of any crime or major violation of laws and regulations, but no clear conclusions have been made; (v) there is a major dispute over ownership of the equity held by the controlling shareholder or a shareholder controlled by the controlling shareholder or the actual controller.

CSRC Requirements on Confidentiality and Archives Administration

On 24 February 2023, the CSRC, the MOF, National Administration of State Secrets Protection and National Archives Administration of China jointly released the revised 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 "**Archives Administration Provisions**"), which came into effect on 31 March 2023. The Archives Administration Provisions shall apply to both (i) the PRC companies seeking direct listing on the overseas stock exchange and (ii) the PRC operating entities of a foreign company seeking listing on the overseas stock exchange that qualifies as an "indirect listing" (above (i) and (ii) collectively, "**Domestic Companies**").

According to the Archives Administration Provisions, the Domestic Companies shall establish and implement a solid confidentiality and archives administration system. If a Domestic Company decides to disclose any documents or materials containing state secrets, work secrets of governmental agencies or any information that may be detrimental to national security or public interest once leaked, proper governmental approval procedures should be followed. After obtaining the governmental clearance, the Domestic Company disclosing such information, as one party, and the securities companies and securities services providers receiving such information, as the other party, shall also enter into non-disclosure agreements, setting forth the confidentiality obligations of the securities companies and securities services providers. When providing above information to the securities companies and securities services providers retained by it, the Domestic Companies are also required to issue a written statement outlining its compliance with the relevant regulatory requirements and procedures.

H Share Full Circulation

"Full circulation" refers to the listing and circulation of the domestic unlisted shares of an H-share listed company on the Stock Exchange of Hong Kong Limited, including unlisted domestic shares held by domestic shareholders prior to overseas listing, unlisted domestic shares additionally issued after overseas listing, and unlisted shares held by foreign shareholders. On November 14, 2019, the CSRC issued the Guidelines on the Application of "Full Circulation" of Domestic Unlisted Shares by H-share Companies (Announcement of the CSRC [2019] No. 22) (H股公司境內未上市股份申請"全流通"業務指引) (the "**Guidelines on 'Full Circulation'**") and last amended on August 10, 2023. According to the Guidelines on "Full Circulation", provided that the requirements set out in the relevant laws and regulations and in the policies for state-owned assets management, foreign investments and industry regulation are satisfied, the shareholders of domestic unlisted shares may decide at their own discretion through negotiation the amount and proportion of shares applying for circulation, and entrust the H-share Listed Company to submit the application for "full circulation." The H-share Listed Company shall apply to the CSRC for "full circulation" in accordance with the administrative licensing procedures required for the "examination and approval of overseas public offering and listing of shares (including additional issuance) by joint stock companies." Upon approval of the application for "full circulation" by the CSRC, the H-share Listed Company shall submit a report to the CSRC within 15 days after completion of the registration of shares involved in the application with the CSDC. Pursuant to the Overseas Listing Trial Measures, for a domestic company seeking direct overseas listing, the shareholders holding the domestic unlisted shares of such domestic company who apply for the conversion of the domestic unlisted shares into overseas listed shares shall comply with the relevant provisions of the CSRC and entrust such domestic company to file with the CSRC.

On December 31, 2019, the CSDC and Shenzhen Stock Exchange jointly issued the Implementation Measures for H-share "Full Circulation" Business (H股"全流通"業務實施細則), which applied to the cross-border transfer registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission, settlement, management of settlement participants, services of nominee holders and other businesses in relation to H-share "full circulation" business.

In order to fully promote the reform of H-share "full circulation" and specify the business arrangements and procedures for registration, custody, settlement and delivery of relevant shares, the CSDC Shenzhen Branch issued the Guidance for H-share "Full Circulation" (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) on September 20, 2024, last amended on June 27, 2025, which specified the business preparation, account arrangements, cross-border share transfer registration and overseas centralized custody, etc.

OVERVIEW OF LAWS AND REGULATIONS IN THE U.S.

Laws and Regulations Regarding Drug and Biological Products

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and biologics under both the FD&C Act and the Public Health Service Act, together with their implementing regulations. Both drugs and biologics are also subject to other federal, state, and local statutes. The process of obtaining regulatory approvals and subsequent compliance requires the expenditure of substantial time and financial resources. Failure to comply with applicable U.S. requirements at any time may subject an applicant to administrative or judicial sanctions, including the FDA's refusal to approve pending applications, withdrawal of approval, clinical holds, warning letters, product recalls, injunctions, and civil or criminal penalties.

Preclinical and Clinical Development

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

A sponsor must submit the results of preclinical testing, manufacturing information, analytical data, and the clinical trial protocol to the FDA as part of an Investigational New Drug application ("IND"). The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the trial on clinical hold. The FDA may also impose clinical holds at any time during clinical trials due to safety concerns or non-compliance. All clinical trials must be conducted under qualified investigators in accordance with Good Clinical Practice regulations, and an Institutional Review Board ("IRB") must review and approve each clinical trial plan before it commences at any institution.

Clinical trials are generally conducted in three sequential phases: Phase I trials involve a small number of patients and assess pharmacologic action, tolerability, and safety; Phase II trials evaluate proof of concept and dose selection in disease-affected patients, while collecting safety and pharmacokinetic data; Phase III trials involve larger patient populations at multiple sites and are designed to demonstrate effectiveness, safety, and the overall benefit/risk profile of the product.

Progress reports must be submitted at least annually to the FDA. Safety reports must be submitted within 15 calendar days, or within 7 calendar days for unexpected, fatal, or life-threatening suspected adverse reactions. Sponsors are required to register and disclose certain clinical trial information at **www.clinicaltrials.gov**.

Review and Approval Process

The results of preclinical studies and clinical trials, together with manufacturing and labeling information, are submitted to the FDA as part of a Biologics License Application ("BLA"). The submission of a BLA is subject to substantial user fees. Within 60 days of receipt, the FDA reviews the BLA to ensure it is sufficiently complete for substantive review. The FDA then conducts an in-depth review to determine whether the product is safe and effective and whether its manufacturing complies with current Good Manufacturing Practice ("cGMP") requirements. The FDA typically inspects manufacturing facilities before approving a BLA and may refer the application to an advisory committee for review.

If the applicable regulatory criteria are not satisfied, the FDA will issue a complete response letter describing deficiencies that must be addressed before approval can be granted. The regulatory approval may also be limited to specific indications, and the FDA may require post-approval studies and may impose a Risk Evaluation and Mitigation Strategy.

Expedited Development and Review Programs

Accelerated Approval. The FDA may approve a biologic for a serious or life-threatening condition that provides meaningful therapeutic benefit over existing treatments based on a surrogate endpoint reasonably likely to predict clinical benefit, or on an intermediate clinical endpoint measurable earlier than irreversible morbidity or mortality. Products approved under this pathway are subject to rigorous post-marketing requirements, including confirmatory trials to verify clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require confirmatory trials to be underway at the time of accelerated approval, and Congress streamlined the procedures for withdrawal if clinical benefit is not verified. All promotional materials for products receiving accelerated approval are subject to prior FDA review.

Breakthrough Therapy Designation. A biologic may be eligible for breakthrough therapy designation if it is intended to treat a serious or life-threatening condition and preliminary clinical evidence indicates it may demonstrate substantial improvement over currently approved therapies on clinically significant endpoints. The FDA must respond to designation requests within 60 days. If designated, the FDA expedites development and review, including frequent meetings with the sponsor throughout development.

Orphan Drug Designation. Under the Orphan Drug Act, the FDA may grant orphan drug designation to biologics intended to treat a rare disease or condition generally affecting fewer than 200,000 individuals in the U.S. The first applicant to receive FDA approval for an orphan-designated indication is entitled to seven years of exclusive marketing, during which the FDA generally may not approve another application to market the same product for the same indication.

The BIOSECURE Act

On December 18, 2025, the BIOSECURE Act became law as part of the Fiscal Year 2026 National Defense Authorization Act. The Act prohibits U.S. executive agencies from contracting with, or providing funds to, "Biotechnology Companies of Concern" ("BCOCs"), which include entities on the Department of Defense's Section 1260H list and companies designated by the Office of Management and Budget ("OMB") through a national security review process. Subsidiaries, parents, affiliates, and successors of designated BCOCs may also be covered if they independently satisfy the same national security criteria.

The Act's requirements are subject to phased implementation. OMB must publish its initial BCOC list within one year of enactment, followed by implementing guidance and Federal Acquisition Regulation updates. At maximum, full restrictions for 1260H list entities may not take effect for approximately 970 days after enactment, with 60 days after the FAR revision for 1260H entities and 90 days for other designated BCOCs. A five-year grandfathering provision protects pre-existing contracts entered into before the applicable effective date.

Laws and Regulations Concerning International Trade

Importation of goods into the customs territory of the United States is governed principally by the Tariff Act of 1930, as amended, the Customs Modernization Act of 1993, as amended, and the regulations of U.S. Customs and Border Protection ("CBP"). Under these laws and regulations, U.S. importers have primary legal responsibility for initially valuing, classifying, and determining the rate of duty applicable to imported merchandise. The importer is required to exercise "reasonable care" in entering merchandise into the United States. This includes when providing CBP information and documentation necessary for it to assess duties on imported merchandise, collect accurate import statistics, and determine whether an import complies with applicable laws.

The United States imposes a variety of tariffs on imported goods. While the U.S. Constitution grants Congress the authority to impose tariffs, several statutes have shifted that authority to the President under certain circumstances. Within the United States, agencies involved in international trade regulation include the CBP, the U.S. International Trade Commission ("ITC"), and the Office of the U.S. Trade Representative ("USTR"). CBP is responsible for collecting tariffs on goods imported to the United States during the customs clearance process. The ITC is a quasi-judicial agency that administers U.S. laws governing trade remedies and provides analysis, information, and other support concerning tariffs and other international trade matters for the President, U.S. Congress, and the USTR. The ITC also investigates alleged violations of U.S. trade law, including unfair trade practices under Section 337 of the Tariff Act of 1930, illegal foreign financial subsidies, and violations, and Section 201 of the Trade Act of 1974 (imports of goods into the U.S. at an increased quantity that is a substantial cause of serious injury to a U.S. domestic industry). The USTR is a cabinet-level position within the office of the President of the United States, and serves as the President's principal adviser, negotiator, and spokesperson regarding matters of international trade.

The USTR is authorized to take certain action under Section 301 of the Trade Act of 1974 ("Section 301"), including without limitation the imposition of tariffs or other restrictions on imports, if it determines after investigation that a foreign government has engaged in unfair trade practices. In 2018, following a USTR investigation and report, the United States imposed tariffs on certain imported goods of Chinese origin. Section 301 tariffs are assessed and collected in addition to any other duties that may apply (including, without limitation, anti-dumping duties, countervailing duties and Section 232 tariffs for aluminum and steel from the Trade Expansion Act of 1962). Both the United States and China have brought claims against one another before the World Trade Organization in connection with this trade dispute.

In early 2025, President Trump separately invoked the International Emergency Economic Powers Act ("IEEPA") to impose additional tariff measures, including tariffs on imports from China, Canada, and Mexico based on concerns regarding illicit trade in fentanyl, as well as broader "reciprocal" tariff measures covering a wide range of products imported from most countries. On April 9, 2025, the United States implemented a 90-day pause on the varying reciprocal tariffs except for those on Chinese goods, leaving the 10% baseline tariff in place. On May 12, 2025, China and the United States jointly announced a 90-day suspension of certain trade restrictions, under which the United States imposed tariffs of 30% on most Chinese imports during such period, while China imposed tariffs of 10% on U.S. imports. On July 29, 2025, China and the United States jointly announced a 90-day extension of the tariff suspension. On November 1, 2025, the White House announced that the United States would reduce the tariffs on Chinese imports imposed to curb fentanyl flows by removing 10 percentage points from the cumulative rate, effective November 10, 2025, and would maintain its suspension of heightened reciprocal tariffs on Chinese imports until November 10, 2026.

On February 20, 2026, the U.S. Supreme Court issued its decision in *Learning Resources, Inc. v. Trump*, holding that IEEPA does not authorize the President to impose tariffs. The ruling invalidated tariffs imposed under IEEPA, including the fentanyl-related tariffs and reciprocal tariff measures. Tariffs imposed under other statutory authorities, including Section 301, Section 232 of the Trade Expansion Act of 1962 ("Section 232"), and antidumping and countervailing duty orders, were unaffected by the ruling.

Following the Supreme Court's ruling, President Trump imposed a 10% global tariff under Section 122 of the Trade Act of 1974 ("Section 122"), effective February 24, 2026. Section 122 permits the imposition of tariffs for up to 150 days absent further congressional authorization; accordingly, the Section 122 tariff is currently scheduled to expire at the end of the 150-day period unless extended by legislation. The President has indicated that his administration intends to use other available authorities, including Section 301 and Section 232, to impose longer-term replacement measures. Specific details of such replacement measures have not been announced as of the date hereof.

Employment Laws

The employment of individuals in the United States is governed by federal, state and sometimes local laws. Federal laws set the minimum legal standard for employee rights; state and local laws may set different standards. Most employees in the United States are hired "at-will," meaning that their employment can be terminated at any time, with or without notice or cause. At-will employment can be modified by an employment agreement between an employee and employer, but in no event may an employee be terminated for an illegal reason (such as discrimination or harassment), nor may an employee be terminated or retaliated against for engaging in a legally protected activity. Individual verification of eligibility to work in the United States is required. In addition, employers are required to maintain workplaces that are free of harassment based on protected characteristics such as sex, race, etc.

Intellectual Property Laws

Intellectual property protection in the United States is primarily governed by federal law. Patent rights are governed by the Patent Act, which grants the patent owner the right to exclude others from making, using, offering for sale, selling, or importing the patented invention in the United States. Copyright protection is governed by the Copyright Act, under which original works of authorship fixed in a tangible medium are protected upon creation. Trademark rights are governed by the Lanham Act, which provides for federal registration with the U.S. Patent and Trademark Office. Trade secrets are protected under the Defend Trade Secrets Act and analogous state laws.

Regulations on Data Protection and User Privacy

Data protection and user privacy in the United States are governed by a combination of federal and state laws, as well as common law principles. At the federal level, key laws include the Children's Online Privacy Protection Act and the Federal Trade Commission Act, under which the Federal Trade Commission enforces prohibitions against unfair or deceptive acts or practices. At the state level, laws such as the California Consumer Privacy Act, as amended by the California Privacy Rights Act, impose additional obligations on businesses regarding the collection, use, and disclosure of personal information of California residents, including transparency, consumer rights, and data governance requirements.

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the regulations promulgated thereunder, including the Privacy Rule (45 C.F.R. Parts 160 and 164), the Security Rule, and the Breach Notification Rule, impose obligations on "covered entities" (which include healthcare providers that conduct certain electronic transactions) and their "business associates" with respect to the use, disclosure, and safeguarding of individually identifiable health information. Violations of HIPAA may result in civil monetary penalties and, in cases of willful neglect, criminal penalties.