

REGULATORY OVERVIEW

This section sets out the major laws and regulations that may have material impact on our business and operations.

REGULATORY SYSTEM FOR RADIOPHARMACEUTICALS IN CHINA

1. Major Regulatory Authorities

The National Medical Products Administration (國家藥品監督管理局) (the “NMPA”), subordinated to the State Administration of Market Supervision (國家市場監督管理總局), is the core regulatory authority for drugs in China. It takes up the drug regulatory functions of its predecessors, the State Food and Drug Administration (國家食品藥品監督管理局) and the China Food and Drug Administration (國家食品藥品監督管理總局) (the “CFDA”), and is mainly responsible for the safety supervision and administration, standard management, registration management, quality management, post-marketing risk management, supervision and inspection of drugs, medical devices and cosmetics. The Center for Drug Evaluation (藥品審評中心) (the “CDE”) is a unit directly under the NMPA, and its main responsibilities include, among others, accepting and conducting technical reviews of drug clinical trials and application for drug marketing authorization, conducting technical reviews of evaluation for quality and efficacy consistency of generic drugs, and organizing the formulation and implementation of drug evaluation specifications and technical guidelines.

The National Health Commission (國家衛生健康委員會) (the “NHC”) is a constituent department of the State Council, and is mainly responsible for healthcare work. Its functions related to drug regulation include organizing the formulation of national drug policies and national essential drug systems, carrying out drug use monitoring, comprehensive clinical evaluation and the issue of early warning of drug shortages, putting forward suggestions on the pricing policy of national essential medicine, and participating in the formulation of national pharmacopoeia.

The National Healthcare Security Administration (國家醫療保障局) (the “NHSA”) is an authority directly under the State Council and is primarily responsible for healthcare security. Its functions related to drug regulation include organizing the formulation of medical insurance catalog and payment standards on drugs, organizing the formulation of policies for drug price, formulating and supervising the implementation of bidding and tendering policies for drugs, and guiding the construction of drug bidding and procurement platforms.

In view of the special nature of radiopharmaceuticals, in addition to the drug supervision and administration department, its regulatory authorities also include the competent department of science, technology and industry for national defense and competent department of ecological environment.

2. Principal Laws and Regulations

(1) Basic Laws and Regulations

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the “**Drug Administration Law**”) shall apply to activities involving research and development, manufacturing, operation, use, supervision and administration of drugs within the territory of China. The law was formulated by the Standing Committee of the National People’s Congress (the “SCNPC”) and first promulgated on September 20, 1984, last amended and promulgated on August 26, 2019 and became effective on December 1, 2019. The Drug Administration Law is the basic law of drug administration in China, which contain provisions on drug research and development and registration, drug marketing authorization holders, drug production, drug operation, pharmaceutical administration of medical institutions, drug post-marketing administration, drug price and advertising, drug reserve and supply, supervision and administration, legal liability, etc. According to the Drug Administration Law, China encourages research and development of new drugs, and protects the legitimate rights and interests of citizens, legal persons and other organizations in research and development of new drugs.

In order to implement the Drug Administration Law in detail, the State Council first promulgated the Regulations for the Implementation of the Drug Administration Law of the People’s Republic of China (《中華人民共和國藥品管理法實施條例》) on August 4, 2002, which was last amended and promulgated on January 16, 2026, and became effective on May 15, 2026.

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In order to strengthen the administration of radiopharmaceuticals, the State Council first promulgated the Measures for the Administration of Radiopharmaceuticals (《放射性藥品管理辦法》) on January 13, 1989, which was last amended and promulgated on December 6, 2024, and became effective on January 20, 2025. It contains special provisions on the research, manufacturing, operation, transportation, use, inspection, supervision and administration of radiopharmaceuticals (radionuclide agents used for clinical diagnosis or treatment or their labeled drugs).

(2) *Non-clinical Research on Drugs*

According to the Drug Administration Law, the conduct of non-clinical research on drugs shall comply with relevant regulations, abide by the good laboratory practice for non-clinical laboratory studies, with personnel, sites, equipment, instruments and management systems appropriate to the research projects in place, and ensure the authenticity of relevant data, information and samples. In accordance with the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the “**Registration Measures**”) first promulgated on a trial basis by NMPA on October 30, 2002 and last amended and promulgated by the State Administration for Market Regulation (國家市場監督管理總局) on January 22, 2020 and became effective on July 1, 2020, non-clinical safety assessment research on drugs shall be carried out in institutions certified by the good laboratory practice for non-clinical laboratory studies and shall comply with the good laboratory practice for non-clinical laboratory studies.

On February 24, 2021 and January 22, 2024, the CDE issued the Technical Guidelines for Non-clinical Research of Radioactive *In-vivo* Diagnostic Drugs (《放射性體內診斷藥物非臨床研究技術指導原則》) and the Technical Guidelines for Non-clinical Research of Radioactive Therapeutic Drugs (《放射性治療藥物非臨床研究技術指導原則》) respectively, which are not mandatory and legally binding and aim to standardize and guide the non-clinical research of radiopharmaceuticals.

Animal experiments conducted in the course of non-clinical research on drugs shall comply with the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) (first promulgated by the former State Science and Technology Commission on November 14, 1988 and last amended and implemented by the State Council on March 1, 2017) and the Administrative Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) (jointly promulgated and implemented by the former State Science and Technology Commission and the former State Bureau of Quality and Technical Supervision on December 11, 1997), and obtain a license for the use of experimental animals. According to the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》), jointly promulgated by the Ministry of Science and Technology and other relevant regulatory authorities on December 5, 2001 and became effective on January 1, 2002, the validity period of the license for the use of experimental animals is five years, and the holder shall apply for the re-examination and renewal within six months before the expiration of the validity period.

(3) *Clinical Trial of Drugs*

According to the Drug Administration Law, when conducting the clinical trial of drugs, relevant data (such as research methods, quality indicators, pharmacological and toxicological test results), materials and samples shall be truthfully submitted in accordance with the provisions of the drug supervision and administration department under the State Council, and approved by the drug supervision and administration department under the State Council; the drug supervision and administration department under the State Council shall decide whether to approve or not and notify the applicant of the clinical trial within 60 working days from the date of accepting the clinical trial application. Failure to notify within the time limit shall be deemed as consent; drug clinical trials shall be carried out in accordance with the good laboratory practice for non-clinical laboratory studies and shall be conducted in clinical trial institutions that satisfy the necessary conditions. According to the Measures for the Administration of Radiopharmaceuticals (《放射性藥品管理辦法》), the research unit shall submit application and deliver the materials and samples as required to the drug supervision and administration department under the State Council before conducting clinical trials or verification for a new radiopharmaceutical. Upon approval by the drug supervision and administration department under the State Council, clinical research shall be conducted in the drug clinical trial institutions designated by the drug supervision and administration department under the State Council.

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According to the Registration Measures, drug clinical trials are divided into phase I clinical trials, phase II clinical trials, phase III clinical trials, phase IV clinical trials and bioequivalence trials; an applicant authorized to carry out clinical drug trial shall, before carrying out subsequent clinical drug trial by phases, develop a corresponding plan for clinical drug trial and carry out clinical drug trial upon examination and approval by the ethics committee, and submit the corresponding plan for clinical drug trial and supporting materials on the website of the CDE; drug clinical trials shall be carried out within three years after approval. If there are no subjects signing of the informed consent form within three years from the date of approval of drug clinical trial application, the drug clinical trial license shall automatically expire.

On October 13, 2020 and February 6, 2023, the CDE issued the Technical Guidelines for Clinical Evaluation of Radioactive *In Vivo* Diagnostic Drugs (《放射性體內診斷藥物臨床評價技術指導原則》) and the Technical Guidelines for Clinical Evaluation of Radioactive *In Vivo* Therapeutic Drug (《放射性體內治療藥物臨床評價技術指導原則》) respectively. These guidelines are not mandatory and legally binding and aim to standardize and guide the clinical research of radiopharmaceuticals.

According to the Registration Measures, applicants may communicate with CDE and other professional and technical institutions on major issues at critical stages such as prior to application for drug clinical trial, during the process of drug clinical trial, and prior to application for drug marketing authorization.

According to the Registration Measures, upon obtaining the clinical trial approval, the applicant shall, prior to conducting the drug clinical trial, register the information of the drug clinical trial plan, etc. on the Drug Clinical Trials Registration and Information Publicity Platform. During the drug clinical trials, the applicant shall update registration information continuously, and register information about the results of the drug clinical trial upon completion. The applicant shall be responsible for the authenticity of the drug clinical trial information published on the platform.

(4) Drug Registration and Marketing Authorization

According to the Drug Administration Law, drugs to be marketed in the territory of the People's Republic of China shall be subject to approval by the drug supervision and administration department under the State Council to obtain the drug registration certificate. To apply for drug registration, data, materials, and samples that are true, adequate, and credible shall be provided to prove the safety, efficacy, and quality management of the drug.

According to the Measures for the Administration of Radiopharmaceuticals, after completing the clinical research on a new radioactive drug, the development entity shall submit application to the drug supervision and administration department under the State Council. Upon soliciting opinions from the competent departments for national defense science and technology industry under the State Council and after examination and approval by the drug supervision and administration department under the State Council, a new drug certificate shall be issued. To put a new radioactive drug into production, the production entity or the development entity holding a radioactive drug manufacturing license shall submit application for production of the drug to the drug supervision and administration department under the State Council using the duplicate copy of the new drug certificate and provide samples. The drug supervision and administration department under the State Council shall examine and issue an approval number. According to the Opinions on Reforming and Improving the Review and Approval Management System for Radiopharmaceuticals (《關於改革完善放射性藥品審評審批管理體系的意見》) issued and implemented by the NMPA on April 21, 2023, China encourages clinical value-oriented innovation in radiopharmaceuticals; prioritizes the review and approval of application for marketing authorization for radiopharmaceuticals in urgent clinical needs, gives priority to handling communication and meeting requests related to radiopharmaceuticals, and establishes a dedicated channel for radiopharmaceuticals during the review phase, assigning them to a separate review queue.

According to the Registration Measures, after completing studies to support the drug marketing registration including CMC, pharmacological and toxicological studies and drug clinical trials, establishing the specifications and completing commercial-scale manufacturing process validation and preparation for drug registration inspection and testing, the applicant shall file application for drug marketing authorization and submit related study data as per

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application dossier requirements. The application shall be accepted when the application dossiers comply with requirements and pass the preliminary review. The CDE shall organize CMC, medical and other technical personnel to evaluate accepted application for drug marketing authorization as required. If the comprehensive review is passed, the drug shall be approved for marketing and a Drug Approval License shall be issued; if not, the drug shall be disapproved. The Drug Approval License shall bear the drug approval number, marketing authorization holder, manufacturer and other information. The validity period for the Drug Approval License is 5 years. The holder shall continually ensure the safety, efficacy and quality of the drug during the validity period and apply for registration renewal 6 months prior to the expiration date.

According to the Registration Measures, the review timeline for application for drug marketing authorization is 200 working days; the review timeline of priority review and approval procedures is 130 working days; the review timeline for priority review and approval procedures for rare disease drugs with urgent clinical needs which have been marketed overseas is 70 working days.

According to the Drug Administration Law, China implements a marketing authorization holder (MAH) system for drug administration. A Marketing Authorization Holder (MAH) refers to an enterprise or R&D institution which holds a drug approval license. MAHs shall, in accordance with provisions of this Law, be responsible for non-clinical studies, clinical trials, manufacture and distribution, post-marketing studies, and monitoring, reporting, and handling of adverse drug reactions. MAHs may either manufacture drug products by themselves or entrust a drug manufacturer with production. MAHs may either distribute drug products that have obtained drug approval licenses or entrust a drug distributor for distribution.

(5) Drug Manufacturing

According to the Drug Administration Law (《藥品管理法》), the undertaking of drug manufacturing shall be subject to approval by the local drug supervision and administration department of the people's government of the province, autonomous region, or municipality directly under the central government, and shall obtain a Drug Manufacturing Certificate; the undertaking of drug manufacturing shall comply with the Good Manufacturing Practice for Drugs. A quality management system shall be established and improved for drug manufacturing, to ensure that the whole chain of drug manufacturing continuously complies with statutory requirements.

According to the Measures for the Administration of Radiopharmaceuticals (《放射性藥品管理辦法》), an enterprise to be established for production of radiopharmaceuticals shall be subject to examination and approval by both the competent department in charge of national defense science and technology industry of corresponding province, autonomous region, or municipality directly under the central government, and the pharmaceuticals supervisory and administrative departments of corresponding province, autonomous region, or municipality directly under the central government, the pharmaceuticals supervisory and administrative departments of corresponding province, autonomous region, or municipality directly under the central government shall issue a Radiopharmaceutical Manufacturing Enterprise Certificate (放射性藥品生產企業許可證). The validity period of the Radiopharmaceutical Manufacturing Enterprise Certificate is five years. The radiopharmaceutical manufacturing enterprise shall apply for a renewal to the original issuing administrative department six months in advance based on the expiry date. Upon approval, a new certificate shall be issued in replacement of the old one.

According to the Provisions for the Supervision and Administration of Drug Manufacturing (《藥品生產監督管理辦法》), which was first promulgated on a trial basis by the NMPA on December 11, 2002, and last amended and promulgated by the State Administration for Market Regulation on January 22, 2020, and became effective on July 1, 2020, to carry out drug manufacturing activities, approval should be obtained from the drug supervision and administration department of corresponding province, autonomous region or municipality directly under the Central Government, the Drug Manufacturing Certificate shall be obtained, and the Good Manufacturing Practice for Pharmaceutical Products should be strictly followed to ensure the manufacturing process continuously complies with statutory requirements. MAHs shall establish a drug quality assurance system, fulfill marketing release responsibilities and be responsible for the quality of drugs granted with drug approval license.

According to the Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) ("GMP"), which was first promulgated by the former Ministry of Health on March 17, 1988,

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last amended and promulgated on January 17, 2011, and became effective on March 1, 2011, the manufacturer should establish a quality management system. The system should cover all factors that influence the quality of drugs, including all organized and planned activities with the objective of ensuring that the drugs are of the quality required for their intended use. According to the Measures for the Administration of Drug Inspection (Trial) (《藥品檢查管理辦法(試行)》) first promulgated by NMPA on May 24, 2021, and last amended, promulgated and implemented on July 19, 2023, for the first application for a drug manufacturing certificate, on-site inspection shall be carried out in accordance with relevant GMP requirements, for applications for drug marketing, GMP compliance inspections shall be conducted as necessary.

(6) Radiation Safety

According to the Regulations on Safety and Protection of Radioisotopes and Radiation-emitting Devices (《放射性同位素與射線裝置安全和防護條例》) first promulgated by the State Council on September 14, 2005, and last amended and implemented on March 2, 2019, the entities producing, selling and using radioisotopes and radiation-emitting devices shall obtain the relevant licenses; except for entities using Class I radioactive sources for medical purposes or preparing radiopharmaceuticals for positron emission tomography for their own use, the licenses for entities producing radioisotopes, selling and using Class I radioactive sources or selling and using Class I radiation-emitting devices shall be issued by the Ministry of Ecology and Environment of the State Council upon examination and approval; the licenses for entities other than those whose licenses shall be issued by the Ministry of Ecology and Environment of the State Council upon examination and approval shall be issued by the Ministry of Ecology and Environment of the people's governments of provinces, autonomous regions and municipalities directly under the Central Government upon examination and approval. The validity period of a license is five years. If the validity period of a license needs to be renewed upon expiration, the entity holding the license shall, submit application for renewal to the original license-issuing authority within 30 days prior to the expiry of the validity period of the license.

To implement the radiation safety licensing system, the Measures for Administration of the Safety Licensing of Radioisotopes and Radiation-emitting Devices (《放射性同位素與射線裝置安全許可管理辦法》) was first promulgated by the former State Environmental Protection Administration on January 18, 2006, and was last amended, promulgated and implemented by the Ministry of Ecology and Environment on January 4, 2021. It stipulates matters related to the application for, issuance of, and supervision and administration of radiation safety licenses.

To strengthen the management of safety and protection for radioisotopes and radiation-emitting devices, the former Ministry of Environmental Protection promulgated the Measures for the Management of Safety and Protection for Radioisotopes and Radiation-emitting Devices (《放射性同位素與射線裝置安全和防護管理辦法》) on April 18, 2011, which became effective on May 1, 2011. The measures covers matters such as facility safety and protection, personnel safety and protection, management of spent radioactive sources and items contaminated by radiation, supervision and inspection, emergency reporting and handling, and exemption management.

(7) Drug or Drug Technology Transfer

According to the Registration Measures, if the applicant changes during a drug clinical trial, the new applicant shall assume the relevant responsibilities and obligations for the drug clinical trial.

According to the Drug Administration Law, a marketing authorization holder may, upon approval by the drug supervision and administration department under the State Council, transfer its drug marketing authorization. The transferee shall be capable of quality management, risk control, and compensation for liability to ensure drug safety, efficacy and quality management, and shall fulfill the obligations of the marketing authorization holder.

OTHER PRINCIPAL PRC LAWS AND REGULATIONS AFFECTING OUR BUSINESS OPERATIONS AND THE [REDACTED]

1. Project Construction

(1) Environmental Protection

According to the Law on Environmental Impact Assessment of the People's Republic of China (《中華人民共和國環境影響評價法》) formulated by the SCNPC, first promulgated on

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October 28, 2002, and last amended, promulgated and implemented on December 29, 2018, China manages environmental impact assessments of construction projects through classification: for projects likely to cause significant environmental impacts, an environmental impact report shall be prepared; for projects likely to cause gentle environmental impacts, an environmental impact report form shall be prepared; for projects causing minimal environmental impact that do not require an environmental impact assessment, an environmental impact registration form shall be filled out.

According to the Administration Rules on the Environmental Protection of Construction Projects (《建設項目環境保護管理條例》) first promulgated by the State Council on November 29, 1998, last amended and promulgated on July 16, 2017, and became effective on October 1, 2017, as to construction projects for which an environmental impact report or the environmental impact report form is required according to the law, the construction entity shall, before the commencement of construction, submit the environmental impact report or the environmental impact report form for approval to the competent administrative department of environmental protection. If the environmental impact assessment documents of the construction project have not been examined by the approval authority in accordance with the law or approved upon examination, the construction entity shall not commence the construction. Construction projects requiring an environmental impact report or report form may only be put into production or use after passing acceptance inspection for the supporting environmental protection facilities; if the supporting environmental protection facilities have not undergone acceptance inspection or fail the acceptance inspection, such projects may not be put into production or use.

(2) Safety Facilities

In accordance with the Measures for the Supervision and Administration of “Three Simultaneities” of Safety Facilities in Construction Projects (《建設項目安全設施「三同時」監督管理辦法》), the interim measures for which were first promulgated by the former State Administration of Work Safety (國家安全生產監督管理總局) on December 14, 2010, and which was last amended and promulgated on April 2, 2015, and became effective on May 1, 2015, the production and operation entity is the responsible entity for the construction of safety facilities in construction projects. The safety facilities of construction projects must be designed, constructed, and put into production and use simultaneously with the main project. During the preliminary design of a construction project, the production and operation entity shall entrust a qualified design entity to design the safety facilities simultaneously and prepare the safety facility design. Before a construction project is completed and put into production or use, the production and operation entity shall organize the completion acceptance of safety facilities and form a written report for inspection. Safety facilities must pass the completion acceptance before they can be put into production and use.

(3) Fire Protection Design

In accordance with the Fire Protection Law of the People’s Republic of China (《中華人民共和國消防法》) first promulgated by the SCNPC on April 29, 1998, last amended, promulgated and became effective on April 29, 2021, the fire protection design and the project construction shall meet the national technological standards for fire protection in respect of project construction. Developers, designers, constructors, construction supervisors, etc. shall, according to law, be responsible for the fire protection design and for the quality of construction projects.

In accordance with the Interim Provisions on the Administration of Fire Protection Design Review and Final Inspection of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) first promulgated by the Ministry of Housing and Urban-Rural Development (住房和城鄉建設部) on April 1, 2020, last amended and promulgated on August 21, 2023, and became effective on October 30, 2023, for construction projects that require a fire protection design according to the national fire protection technical standards other than special construction projects, the project owner shall provide fire protection design drawings and technical information as needed for construction when applying for a construction license or approval of the construction commencement report. The project owner shall, within 5 working days from the date of passing the completion acceptance, file with the competent fire protection design review and acceptance department. Upon receiving the archive materials from the project owner, the fire protection design review and acceptance department shall issue an archive-filing certificate if it found the materials are complete. The competent fire protection design review and acceptance department shall conduct random checks on other construction projects that are required to be filed.

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(4) Construction Permit and Completion Acceptance

In accordance with the Management Measures on Construction Permits for Construction Projects (《建築工程施工許可管理辦法》) first promulgated by the former Ministry of Construction on October 15, 1999, and last amended, promulgated and implemented by the Ministry of Housing and Urban-Rural Development on March 30, 2021, the project owner who is engaged in the construction, renovation, or decoration of various buildings and their ancillary facilities, the installation of the supporting lines, pipelines, and equipment, and the construction of urban municipal infrastructure projects within the territory of the People’s Republic of China shall apply for a construction permit prior to the commencement of construction to the housing and urban-rural development department of the local government at or above county-level of the place where the project is located. For a construction project with an investment amount of less than RMB300,000 or with a GFA of less than 300 sq.m., no application for construction permit is required.

In accordance with the Regulation on the Quality Management of Construction Projects (《建設工程質量管理條例》) first promulgated by the State Council on January 30, 2000, last amended, promulgated and implemented on April 23, 2019, the project owner shall, upon receiving the completion report for a construction project, organize the entities of design, construction, project supervision, etc. to conduct a completion inspection. The project owner shall, within 15 days from the day when the construction project passes the completion acceptance, submit the completion acceptance report and the approval or licensed use documents issued by the departments of planning, public security and fire prevention, environmental protection, etc. to the construction administrative department or other pertinent departments for archival purposes. Where the construction administrative department or any other relevant department finds that the project owner commits any act in violation of the relevant provisions of the state on the management of the quality of construction projects during the course of completion inspection, it shall order the project owner to stop the use of the construction project and reorganize a completion inspection.

2. Intellectual Property Rights and Trade Secrets

(1) Patent

In accordance with the Patent Law of the People’s Republic of China (《中華人民共和國專利法》) (the “**Patent Law**”) first promulgated by the SCNRC on March 12, 1984, last amended and promulgated on October 17, 2020, and became effective on June 1, 2021, any exploiting of a patent without the permission of the patentee is an infringement of his/her patent right. In accordance with the Patent Law, the duration of patent right for inventions, utility models and designs shall be twenty, ten and fifteen years from the date of filing, respectively. To compensate for the time required spent on obtaining the marketing approval of new drugs, the patent administrative department of the State Council shall, upon request by the patent holder, grant a patent term extension for the patent right of an invention related to a new drug that has obtained marketing approval in China. The compensation period shall not exceed five years, and the total effective patent term for a new drug after obtaining marketing approval shall not exceed 14 years.

To refine the implementation of the Patent Law, the Rules for the Implementation 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》) first promulgated by the former Patent Office on January 19, 1985, was last amended and promulgated by the State Council on December 11, 2023, and became effective on January 20, 2024.

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(2) *Trademark*

In accordance with the Trademark Law of the People’s Republic of China (《中華人民共和國商標法》) (the “**Trademark Law**”) formulated by the SCNPC, first promulgated on August 23, 1982, last amended and promulgated on April 23, 2019 and became effective on November 1, 2019, a trademark registrant shall have the right to exclusively use the registered trademark, which is protected by law. In accordance with the Trademark Law, a registered trademark is valid for 10 years from the date the registration is approved. If a registered trademark has to be used after expiration of its validity period, the trademark registrant shall complete renewal formalities according to regulations within twelve months before the expiration of the validity period; failing which, a six month extension period may be granted. Each renewal of registration shall be valid for a period of ten years, and shall be counted from the date of the expiration of the previous validity period. If a registered trademark has not completed renewal formalities at the expiration of the validity period, it shall be cancelled.

To refine the implementation of the Patent Law, the Regulation on the Implementation 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》) first promulgated by the State Council to replace the original 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細則》) on August 3, 2002, was last amended and promulgated on April 29, 2014, and became effective on May 1, 2014.

(3) *Trade Secret*

In accordance with the Anti-Unfair Competition Law of the People’s Republic of China (《中華人民共和國反不正當競爭法》) promulgated by the SCNPC on September 2, 1993, (last amended and promulgated on June 27, 2025 and became effective on October 15, 2025), trade secrets refer to technical information, business information and other commercial information that are not known to the public, have commercial value and have been kept confidential by the right holder. Business operators, other natural persons, legal persons and unincorporated persons shall not engage in acts that infringe upon trade secrets. If a third party knows or should know that the employee, former employee or other entity or individual of the trade secret right holder has committed the illegal acts listed in the aforesaid, and nonetheless obtains, discloses, uses or allows others to use the trade secret, it shall be deemed as an infringement of trade secret.

3. **Labor Security**

In accordance with the Labor Law of the People’s Republic of China (《中華人民共和國勞動法》) formulated by the SCNPC, first promulgated on July 5, 1994, and last amended, promulgated and implemented on December 29, 2018, the employer shall establish and perfect rules and regulations in accordance with law and ensure that workers enjoy labor right and fulfill labor obligations. Labor contracts shall be entered into if labor relationships are established. Labor contracts are agreements reached between workers and the employer to establish labor relationships and specify the rights, interests and obligations of each party. The employer shall establish and perfect its system for labor safety and sanitation, strictly abide by State rules and standards on labor safety and sanitation, educate workers about labor safety and sanitation, prevent accidents in the process of work, and reduce occupational hazards. The State shall establish a social insurance system and set up social insurance funds so that workers can receive help and compensation when they become old, suffer diseases or work-related injuries, lose their jobs, and give birth.

For the employer and workers to establish labor relationships, enter into, perform, amend, terminate, or rescind employment contracts, the Labor Contract Law of the People’s Republic of China (《中華人民共和國勞動合同法》) first promulgated by the SCNPC on June 29, 2007, last amended and promulgated on December 28, 2012 and became effective on July 1, 2013 and the Implementation Regulations for Labor Contract Law of the People’s Republic of China (《中華人民共和國勞動合同法實施條例》) promulgated and implemented by the State Council on September 18, 2008 shall be applied.

In accordance with the Social Insurance Law of the People’s Republic of China (《中華人民共和國社會保險法》) formulated by the SCNPC, first promulgated on October 28, 2010, and last amended, promulgated and implemented on December 29, 2018, employees shall participate in basic endowment insurance, basic medical insurance for employees, injury

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insurance, and unemployment insurance, and maternity insurance. The employer shall apply to a social insurance agency for social insurance registration for its employees within 30 days after employees’ employment start.

According to the Interpretation (II) of the Supreme People’s Court on Issues Concerning the Application of Laws in the Trial of Labour 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)》), which was promulgated by the Supreme People’s Court of the People’s Republic of China on July 31, 2025 and came into effect on September 1, 2025, if an employer and an employee reach an agreement or the employee gives an acceptance to the employer that no social insurance premiums have to be paid, the people’s court shall determine that such agreement or acceptance is invalid. If an employer fails to pay social insurance premiums in accordance with the law and the employee requests the labour contract to be terminated and demands the employer to pay economic compensation in accordance with the Labour Contract Law of the People’s Republic of China (《中華人民共和國勞動合同法》), the people’s court shall support such request and demand in accordance with the law.

In accordance with the Regulations on the Administration of Housing Provident Fund (《住房公積金管理條例》) first promulgated by the State Council on April 3, 1999, last amended, promulgated and implemented on March 24, 2019, when an employee is hired, the employer must register with the housing provident fund management center and handle the setup or transfer of the employee’s housing provident fund account within 30 days after employees’ employment start.

In accordance with the Law of the People’s Republic of China on the Prevention and Treatment of Occupational Diseases (《中華人民共和國職業病防治法》) formulated by the SCNPC, first promulgated on October 27, 2001, last amended and implemented on December 29, 2018, the employer shall establish and perfect the responsibility system of occupational disease prevention and treatment, strengthen the administration and improve the level of occupational disease prevention and treatment, and bear responsibilities for the harm of occupational diseases engendered therefrom. In accordance with the Basic Healthcare and Health Promotion Law of the People’s Republic of China (《中華人民共和國基本醫療衛生與健康促進法》) formulated and promulgated by the SCNPC on December 28, 2019 and became effective on June 1, 2020, the employer shall control occupational hazardous factors, adopt comprehensive treatment measures including but not limited to engineering technology, individual protection, and health management, and improve the work environment and working conditions.

4. Foreign Investment

The Company Law of the People’s Republic of China (《中華人民共和國公司法》) (the “**Company Law**”) formulated by the SCNPC, first promulgated on December 29, 1993, last amended and promulgated on December 29, 2023, and became effective on July 1, 2024 shall apply to limited liability companies and joint-stock companies established within the PRC. In accordance with the Company Law, a company is an enterprise legal person, has its own assets and enjoys legal person property rights. A company shall bear responsibilities for its debts with all its assets. Shareholders of a joint-stock company shall bear responsibilities to the company to the extent of the number of shares they subscribed for.

In accordance with 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**”, the Law of the People’s Republic of China on Wholly Foreign-owned Enterprises (《中華人民共和國外資企業法》) and the Law of the People’s Republic of China on Sino-Foreign Cooperative Joint Ventures (《中華人民共和國中外合作經營企業法》)) promulgated by the National People’s Congress on March 15, 2019, and became effective on January 1, 2020, foreign investment refers to the investment activity directly or indirectly carried out by a foreign natural person, enterprise or other organization (the “**foreign investors**”). Foreign investors are encouraged to make investments within China. The administration systems of pre-establishment national treatment and negative list shall be implemented for foreign investment. National treatment shall be given to foreign investment beyond the negative list. A foreign investor may, in accordance with law, freely transfer inward and outward its contributions, profits, capital gains, income from asset disposal, royalties of intellectual property rights, lawfully claimed compensation or indemnity, proceeds from liquidation and so on within China in RMB or a foreign currency.

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To refine the implementation of the Foreign Investment Law, the State Council promulgated the Regulation for Implementing the Foreign Investment Law of the People's Republic of China (《中華人民共和國外商投資法實施條例》) on December 26, 2019, which became effective on January 1, 2020.

The prevailing Special Administrative Measures for the Market Entry of Foreign Investment (Negative List) (2024 Version) (《外商投資准入特別管理措施(負面清單)(2024年版)》) (the “**Negative List**”) was promulgated by the National Development and Reform Commission and the Ministry of Commerce on September 6, 2024, and became effective on November 1, 2024. It uniformly sets forth the special administrative measures, including ownership requirements and requirements for senior executives, for the access of foreign investment. Foreign investment in the areas beyond the Negative List shall be administered in accordance with the principle of equality between domestic and foreign investment.

5. Overseas Investment

In accordance with the Measures for Overseas Investment Management (《境外投資管理辦法》) first promulgated by the Ministry of Commerce on March 16, 2009, last amended and promulgated on September 6, 2014, and became effective on October 6, 2014, overseas investment means that an enterprise legally established in China owns a non-financial enterprise overseas or acquires the rights to own, control or operate and manage, or other rights and interests of an existing non-financial enterprise overseas by way of setting up a new company, merger or acquisition or otherwise. Overseas investments by enterprises involving sensitive countries or regions and sensitive industries are subject to administration with approval; and overseas investments by enterprises in other circumstances are subject to administration with filing.

In accordance with the Measures for the Administration of Overseas Investment of Enterprises (《企業境外投資管理辦法》) promulgated by the National Development and Reform Commission on December 26, 2017 and became effective on March 1, 2018, overseas investment means the investment activities where an enterprise in the territory of China, directly or through an overseas enterprise controlled by it, acquires overseas any rights to own, control, operate and manage, or other relevant rights and interests, by contributing assets or equity, providing financing or security, or any other means. The scope of administration with approval includes sensitive projects conducted by investors directly or through overseas enterprises controlled by them, where a sensitive project means a project involving a sensitive country or region or a project involving a sensitive industry. The scope of administration with filing includes non-sensitive projects directly conducted by investors, namely, non-sensitive projects involving investors' direct contribution of assets or equity or provision of financing or security.

6. Foreign Exchange

In accordance with the Regulations of the People's Republic of China on Foreign Exchange Administration (《中華人民共和國外匯管理條例》) first promulgated by the State Council on January 29, 1996, and last amended, promulgated and implemented on August 5, 2008, China shall not impose restrictions on current international payments and transfers. For direct investment in China by overseas institutions or individuals, registration shall be completed with the foreign exchange administration authorities after obtaining approval from the relevant competent authorities. Domestic institutions or individuals engaging in overseas direct investment shall complete registration in accordance with the provisions of the foreign exchange administration department under the State Council.

The Circular on Further Simplifying and Improving Policies for Foreign Exchange Administration for Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》), issued by the SAFE on February 13, 2015 and became effective on June 1, 2015 (which was partially amended or abolished thereafter), decided to further simplify and improve the policies for foreign exchange administration of direct investment across the country, including but not limited to: cancellation of two administrative approval items, namely, registration and verification of foreign exchange under domestic and overseas direct investment. Instead, banks shall directly verify and handle the registration of foreign exchange under domestic and overseas direct investment, while the SAFE and its branches shall conduct through banks indirect regulation over registration of foreign exchange for direct investment.

Pursuant to the Notice on Issues Concerning Fund Management for Overseas Listings of Domestic Enterprises (《關於境內企業境外上市資金管理有關問題的通知》) promulgated by

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the People’s Bank of China and the SAFE on December 24, 2025 and taking effect on April 1, 2026, a domestic enterprise conducting an overseas listing shall, within 30 working days from the date of the first trading day of its overseas listing or the completion of over-allotment, apply for overseas listing registration with a bank in the locality where it domiciles. Funds raised by a domestic enterprise from an overseas listing shall, in principle, be repatriated to China in a timely manner. Following an overseas listing, where a domestic shareholder of such domestic enterprise reduces its holdings of the overseas-listed shares, the shareholder shall, either before or within 30 working days after the share reduction, apply for share reduction registration with a bank at the shareholder’s location. Proceeds obtained by a domestic shareholder from reducing or transferring its holdings in the overseas shares of a domestic enterprise shall, in principle, be repatriated to China in a timely manner.

In accordance with the Circular on Relevant Issues Concerning Foreign Exchange Administration over Involvement of Domestic Individuals in Equity Incentive Plans of Overseas Listed Companies (《關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》) issued and implemented by the SAFE on February 15, 2012, individuals involving in an equity incentive plan of an overseas listed company shall, through the domestic company with which they are affiliated, entrust a domestic agency to centrally handle matters relating to, among others, foreign exchange registration, account opening, and fund transfer and exchange; and the matters of the above individuals relating to, among others, exercise of options, purchases and sales of relevant stocks or equities, and relevant fund transfers shall be centrally handled by an overseas institution.

7. Taxation

(1) Enterprise Income Tax

In accordance with the Enterprise Income Tax Law of the People’s Republic of China (《中華人民共和國企業所得稅法》) (the “EIT Law”) formulated by the SCNPC and first promulgated on March 16, 2007, last amended, promulgated and implemented on December 29, 2018, enterprises are classified into resident enterprises and non-resident enterprises. Resident enterprises refer to enterprises that are legally established in China, or are established under the laws of a foreign country (region) but whose actual management bodies are located in China.

To refine the implementation of the EIT Law, the Implementation Rules of the Enterprise 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》) was first promulgated by the State Council on December 6, 2007, last amended and promulgated on December 6, 2024 and became effective on January 20, 2025. In accordance with the EIT Law and its implementation rules, a resident enterprise shall pay enterprise income tax on its income derived from sources both within and outside China at a tax rate of 25%.

(2) Value-Added Tax

In accordance with the Value-Added Tax Law of the People’s Republic of China (《中華人民共和國增值稅法》) formulated by the SCNPC and promulgated on December 25, 2024, and taking effect on January 1, 2026, entities and individuals (including individual business owners) selling goods, services, intangible assets, immovable property, or importing goods in China are VAT taxpayers and shall pay value-added tax.

8. Information and Data Security

(1) General provisions

In accordance with the Cybersecurity Law of the People’s Republic of China (《中華人民共和國網絡安全法》) (the “Cybersecurity Law”) formulated by the SCNPC and first promulgated on November 7, 2016, last amended and promulgated on October 28, 2025, and taking effect on January 1, 2026, network operators must keep users’ personal information that they have collected strictly confidential, and establish and maintain their system for the protection of users’ information. To collect and use personal information, network operators must follow the principles of legitimacy, integrity and necessity, disclose their rules of collection and use, clearly express the purpose, means and scope of collecting and using the information, and obtain the consent of the persons whose data is gathered. Network operators shall neither collect the personal information irrelevant to the services provided by

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them nor collect or use the personal information in violation of the provisions of any law or administrative regulation or the agreement between both parties, and shall dispose of personal information retained by them in accordance with the provisions of laws, administrative regulations and agreements with users.

In accordance with the Data Security Law of the People’s Republic of China (《中華人民共和國數據安全法》) (the “**Data Security Law**”) formulated and promulgated by the SCNPC on June 10, 2021, and became effective on September 1, 2021, closer risk monitoring shall be applied in data processing. Where data security defects, bugs, or other risks are discovered, remedial measures shall be taken immediately. Where a data security incident occurs, measures shall be taken immediately to address it, and users shall be notified and reports made to relevant competent departments in a timely manner in accordance with relevant provisions.

In accordance with 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》) (the “**Personal Information Protection Law**”) formulated promulgated by the SCNPC on August 20, 2021, and became effective on November 1, 2021, personal information processing shall be based on explicit and reasonable purposes and directly related to those purposes, and shall exert the minimum impacts on the rights and interests of individuals. The collection of personal information shall be limited to the minimum scope required by the purpose of processing, and personal information may not be collected excessively. The quality of personal information shall be guaranteed in personal information processing, to avoid adverse impacts on the rights and interests of individuals caused by inaccurate and incomplete personal information. No organization or individual shall illegally collect, use, process, or transmit the personal information of other persons, or illegally trade, provide or disclose the personal information of other persons, or engage in personal information processing activities that endanger national security or harm public interests.

(2) Information and Cross-border Data Transfer Security

In accordance with the Cybersecurity Law, critical information infrastructure operators shall, during their operations in China, store within the PRC the personal information and important data collected and generated within the territory of the PRC, and where cross-border transfer of such data is necessary for business, a security assessment shall be conducted in accordance with the measures formulated by the national cyberspace authority in conjunction with the relevant departments under the State Council. Where there are other provisions in laws and administrative regulations, such provisions shall prevail.

In accordance with the Data Security Law, without the approval of the competent authorities of China, organizations or individuals in China shall not provide data stored within the territory of China to any overseas judicial or law enforcement body.

In accordance with the Personal Information Protection Law, a personal information processor that truly needs to provide personal information for a party outside the territory of China for business or other reasons, shall meet any of the following conditions: (i) passing the security assessment organized by the national cyberspace department in accordance with the provisions of the law; (ii) obtaining personal information protection certification from a specialized institution in accordance with the provisions of the national cyberspace department; (iii) concluding a contract stipulating both parties’ rights and obligations with the overseas recipient in accordance with the standard contract formulated by the national cyberspace department; (iv) meeting other conditions set forth by laws and administrative regulations and by the national cyberspace department. The personal information processor shall take necessary measures to ensure that the personal information processing activities of the overseas recipient meet the personal information protection standards set forth in the law. Where a personal information processor provides personal information for any party outside the territory of China, the processor shall inform the individuals of the overseas recipient’s name and contact information, the purposes and means of processing, the categories of personal information to be processed, as well as the methods and procedures for the individuals to exercise their rights as provided in the law over the overseas recipient, etc., and shall obtain individual’s separate consent.

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In accordance with the Provisions on Promoting and Regulating Cross-border Data Flows (《促進和規範數據跨境流動規定》) issued by the Cyberspace Administration of China on March 22, 2024 and became effective on the same day, the security assessment of outbound data transfer, the standard contract for outbound transfer of personal information, the certification of personal information protection and other systems governing the outbound transfer of data were further standardized. Pursuant to this provision, data processors must identify and report important data in accordance with relevant regulations. If the data has not been designated or publicly announced as important data by relevant authorities or regions, data processors are not required to report it for a data export security assessment as important data.

9. Overseas Spin-off and Full Circulation

To regulate the spin-off of subsidiaries by listed companies for separate listing both domestically and overseas, the China Security Regulatory Commission (the “CSRC”) promulgated and implemented the Rules for the Spin-off of Listed Companies (For Trial Implementation) (《上市公司分拆規則(試行)》) on January 5, 2022, which covers the conditions for spin-off, prohibited spin-off scenarios, review procedures, and information disclosure requirements.

To regulate Chinese domestic companies that seek to offer or list securities overseas, both directly and indirectly, the CSRC promulgated the Trial Administrative Measures of the 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》) and five guidelines on the application of regulatory rules (監管規則適用指引) on February 17, 2023, which became effective on March 31, 2023. Initial public offerings or listings in overseas markets shall be filed with the CSRC within 3 working days after the relevant application is submitted overseas. For a domestic company directly offering and listing overseas, shareholders of its domestic unlisted shares applying to convert such shares into shares listed and traded on an overseas trading venue shall conform to the relevant regulations issued by the CSRC, and authorize the domestic company to file with the CSRC on their behalf. If the filing materials are complete and meet the requirements, the CSRC shall complete the filing within 20 working days from the date of receiving the filing materials, and publicize the filing information through the website.

In accordance with the Guidelines on Application for “Full Circulation” of Domestic Unlisted Shares of H-share Companies (《H股公司境內未上市股份申請「全流通」業務指引》) first promulgated by the CSRC on November 14, 2019, last amended, promulgated and implemented on August 10, 2023, shareholders of domestic unlisted shares may determine by themselves through negotiation the amount and proportion of shares, for which an application will be filed for circulation, provided that the requirements laid down in the relevant laws and regulations and set out in the policies for state-owned asset administration, foreign investment and industry regulation are met, and the corresponding H-share listed company may be entrusted to file with the CSRC. An unlisted domestic joint stock company may file with the CSRC for “full circulation” at the time of its initial public offering and listing overseas.

In accordance with the Provisions on Strengthening the Confidentiality and Archives Administration Concerning the Overseas Securities Offering and Listing by Domestic Enterprises (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) jointly promulgated by the CSRC and other relevant regulatory authorities on February 24, 2023 and became effective on March 31, 2023, in the overseas offering and listing activities of domestic enterprises, domestic enterprises, securities companies and securities service institutions that provide corresponding services shall strictly comply with the applicable laws and regulations of China and satisfy the requirements of the provisions, enhance the legal awareness of safeguarding state secrets and strengthening archives administration, establish and maintain the confidentiality and archives work system, and take necessary measures to fulfill the confidentiality and archives administration obligations, and shall not divulge state secrets or work secrets of state organs, or harm the interests of the state or the public.