

REGULATORY OVERVIEW

REGULATIONS ON DRUG RESEARCH AND DEVELOPMENT & REGISTRATION

Research and Development of New Drugs

Pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) which was promulgated by the Standing Committee of the NPC (the “NPCSC”) on September 20, 1984, effective as of July 1, 1985 and latest amended on August 26, 2019, for clinical trials on pharmaceuticals, relevant data, information and samples such as development methods, quality indicators, and pharmacological and toxicological testing results shall be truthfully submitted to in accordance with the rules of the medical products supervisory and administrative department under the State Council and be subject to its approval. Pharmaceuticals marketed in China shall be approved by the medical products supervisory and administrative under the State Council and be with a pharmaceutical registration certificate. The institutions for nonclinical safety assessment and study and clinical trial organizations shall respectively implement the Good Laboratory Practice for Non-Clinical Laboratory Studies (《藥物非臨床研究質量管理規範》), which came into effect on September 1, 2017, and Good Clinical Practice for Drugs (the “GCP (2020)”) (《藥物臨床試驗質量管理規範》), which came into effect on September 1, 2003 and was amended on April 23, 2020.

Pursuant to the Regulations of Implementation of the Drug Administration Laws of the PRC (《中華人民共和國藥品管理法實施條例》) which was promulgated by the State Council on August 4, 2002, came into effect on September 15, 2002 and latest amended on January 16, 2026 and to be effective from May 15, 2026, research and development of new drugs that require clinical trials shall be approved by the medical products supervisory and administrative department under the State Council. The applicant shall, upon obtaining the approval of the application for clinical trial of the drug from the medical products supervisory and administrative department under the State Council, choose an institution among those institutions that are qualified for conducting clinical trials of drugs in accordance with the laws to undertake the clinical trial of the drug. Before clinical trials for drugs to be conducted by institutions that will undertake such clinical trials, the subjects and their guardians shall be informed of the facts and their written consents shall be obtained.

LABORATORY REGULATIONS

The PRC conducts multi-level management of all laboratories engaged in teaching, testing, diagnosing and other activities related to bacterial and viral pathogen infection or pathogenic microbial samples. Pursuant to the regulations on the Bio-safety Management of Pathogenic Microbe Laboratories (《病原微生物實驗室生物安全管理條例》) issued by the State Council on November 12, 2004 and latest amended on December 6, 2024, the pathogenic microorganism laboratories are classified into Bio-safety Level 1, Bio-safety Level 2, Bio-safety Level 3 and Bio-safety Level 4 in accordance with its biosafety level for pathogenic microorganisms and the national standards for the bio-safety. Experimental activities involving pathogenic microorganisms shall be conducted in laboratories of the corresponding level. The biosafety level of a laboratory engaged in experimental activities involving pathogenic microorganisms shall be no lower than the level required for such experimental activities as stipulated in the catalogue of pathogenic microorganisms. Newly building, rebuilding or expanding of Bio-safety Level 1 or Level 2 laboratories shall go through the filing formalities with the relevant administrative department of health or the administrative department of veterinary of the people’s governments of the cities divided into districts. The laboratories of Bio-safety Level 3 and Level 4 shall be subject to the state accreditation for laboratories.

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Pursuant to Guidelines for Clinical Trial Bioanalytical Laboratory Management (Interim) (《藥物臨床試驗生物樣本分析實驗室管理指南(試行)》) issued by the State Food and Drug Administration (the “SFDA”) on December 2, 2011 and effective on the same date, data analysis by the clinical trial bioanalytical laboratory on drugs is an integral part of application for new drug registration and a key basis of technical review on new drugs applied for registration by drug supervisory and administrative departments. Accordingly, regulation on clinical trial bioanalytical laboratory is an important part of regulation on clinical trial on drugs. Laboratories that conduct bioanalytical activities for submitting the results to the drug supervisory and administrative departments as the data for drug registration shall comply with these Guidelines in aspects such as their organization and personnel, laboratory facilities, instruments and materials, and contract management, and shall be subject to supervision and inspection by the drug supervisory and administrative departments.

PRECLINICAL STUDIES

Nonclinical Research

The nonclinical safety assessment of drugs for marketing approval shall be conducted in accordance with the Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) promulgated by the SFDA in August 8, 2003 and latest amended by the SFDA in July 27, 2017 and came into effect on September 1, 2017. The SFDA promulgated the Administrative Measures for the Certification of Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》) in April 2007, which specifies the requirements for institutions applying for Good Laboratory Practices certification of non-clinical laboratory studies. On January 19, 2023, the National Medical Products Administration (the “NMPA”) amended the Administrative Measures for the Certification of Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》), which came into effect on July 1, 2023.

Animal Testing

According to the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) promulgated by the State Science and Technology Commission on November 14, 1988 and amended on January 8, 2011, July 18, 2013 and March 1, 2017 respectively by the State Council, the Administrative Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) jointly promulgated by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision on December 11, 1997, and the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》) promulgated by the Ministry of Science and Technology of the People’s Republic of China and other regulatory authorities on December 5, 2001, performing experimentation on animals requires a Certificate for Use of Laboratory Animals. A Certificate for Utilization of Laboratory Animals shall be valid for five years, and the holder shall apply for renewal six months prior to the expiry of the validity period. A Certificate for Utilization of Laboratory Animals shall be inspected annually by the local Science and Technology Bureau.

According to the Measures for the administration of the Domestication and Breeding License of Wild Animals under Special State Protection (《國家重點保護野生動物馴養繁殖許可證管理辦法》) promulgated by National Forestry Administration on January 9, 1991 and amended on April 30, 2015, any entity or individual must obtain a domestication and breeding license of wild animals under special state protection before being engaged in the domestication and breeding activities.

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CLINICAL STUDIES

Clinical Trials on Drugs

Pursuant to the Measures for the Administration of Drug Registration (2020) (《藥品註冊管理辦法》), clinical trials are divided into Phase I, Phase II, Phase III and Phase IV and bioequivalence trial. The CDE shall be responsible for reviewing applications for drug clinical trials, applications for marketing authorization, supplementary applications and applications for re-registration of drugs manufactured overseas, among others. An applicant that applies for a drug clinical trial after completion of the pharmaceutical, pharmacological and toxicological research, etc., which support the drug clinical trial, shall submit relevant research materials according to the requirements for application materials. The application materials shall be accepted if they are deemed acceptable upon formal examination. The CDE shall organize pharmaceutical, medical and other technicians to review the accepted application for the drug clinical trial.

Pursuant to the GCP (2020), the GCP (2020) is a quality standard for the whole process of clinical drug trials involving protocol design, organization and implementation, monitoring, auditing, recording, analysis, summary and reporting. A trial protocol shall be distinct, explicit and operable and may be executed only upon the consent of the ethics committee. An investigator shall abide by the relevant trial protocol during a clinical trial, and each medical judgment or clinical decision-making involved shall be made by clinicians. Researchers participating in the implementation of a clinical trial shall have the corresponding education, training background and relevant experience necessary to undertake the clinical trial.

Pursuant to the Announcement on Adjusting the Review & Approval Procedures of Drug Clinical Trials (《關於調整藥物臨床試驗審評審批程序的公告》) issued by NMPA on July 24, 2018, the matters related to the review and approval of drug clinical trials shall be adjusted as follows: for applications of drug clinical trials in China, an applicant can conduct the drug clinical trial as per the submitted protocols should the Center for Drug Evaluation of the NMPA failed to issue an opinion of rejection or questioning within 60 days as from its acceptance of the application and the receipt of corresponding administrative fees.

Pursuant to the Announcement on Issuing the Guidelines for Ethical Review Work of Drug Clinical Trials (《關於印發藥物臨床試驗倫理審查工作指導原則的通知》) issued by SFDA on November 2, 2010, the ethics committee shall carry out a review on the project of clinical trial on the drug to decide if it is rational in terms of science and ethics, and shall be subject to guidance and supervision under the drug supervisory and administrative departments.

OTHER LAWS AND REGULATIONS IN RELATION TO MEDICAL INDUSTRY

Gathering, Collection and Filing of Human Genetic Resources

On October 17, 2020, NPCSC promulgated Biosecurity Law of the PRC (《中華人民共和國生物安全法》), and latest amended and came into effect on April 26, 2024. The Biosecurity Law establishes a comprehensive legislative framework for the pre-existing regulations in such areas as epidemic control of infectious diseases for humans, animals and plants; research, development, and application of biology technology; biosecurity management of pathogenic microorganism laboratories; security management of human genetic resources and biological resources; countermeasures for microbial resistance; and prevention of bioterrorism and defending threats of biological weapons. As per the Biosecurity Law, the R&D activities of high-risk and medium-risk biotechnology shall be carried out by a legal

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person organization established within the territory of China, upon obtaining the approval or record-filing. The establishment of a pathogenic microorganism laboratory shall be subject to approval or record-filing requirements in accordance with the law.

REGULATIONS ON IMPORT AND EXPORT OF SPECIAL GOODS

Pursuant to the Provisions on the Administration of the Health and Quarantine of Entry/Exit Special Articles (《出入境特殊物品衛生檢疫管理規定》) issued by the General Administration of Customs on January 21, 2015 and last amended and came into effect on November 23, 2018, the entry and exit of microorganisms, human tissues, biological products, blood and its products, and other special articles are subject to applicable supervision and administration of health and quarantine. The local customs office directly under the General Administration of Customs shall be responsible for the approval of health and quarantine of imported and exported special articles within their respective jurisdictions. The entity conducting import or export of special articles shall establish safety management system for special articles, and shall produce, use or sell the special articles in strict accordance with the purposes for the approval of such special articles.

REGULATIONS ON ENVIRONMENTAL PROTECTION, PRODUCTION SAFETY, ENERGY CONSERVATION

Environmental Protection

According to the Environmental Protection Law of the People’s Republic of China (《中華人民共和國環境保護法》) (the “Environmental Protection Law”) promulgated by the Standing Committee of the National People’s Congress on December 26, 1989, and last amended on April 24, 2014 and came into effect on January 1, 2015, any entity that discharges or will discharge pollutants in the course of operation or other activities must implement effective environmental protection measures to control and properly handle hazardous substances such as waste gas, waste water, waste residues, dust, malodorous gases, radioactive substances, noise, vibration and electromagnetic radiation generated in the course of such activities. The State implements a pollutant discharge permit management system in accordance with the law.

According to the Regulation on the Administration of Environmental Protection of Construction Projects (《建設項目環境保護管理條例》) promulgated by the State Council on November 29, 1998, amended on July 16, 2017 and came into effect on October 1, 2017, the Interim Measures for Environmental Protection Acceptance Examination Upon Completion of Construction Projects (《建設項目竣工環境保護驗收暫行辦法》), which was promulgated by the former Ministry of Environmental Protection on November 20, 2017 and came into effect on the same day, and the Environmental Impact Assessment Law (《中華人民共和國環境影響評價法》), which was promulgated by the Standing Committee of the National People’s Congress on December 29, 2018 and came into effect on the same day, the PRC implements a system to assess the environmental impact of construction projects. The construction entity shall submit an environmental impact report or an environmental impact statement for approval prior to the commencement of the construction project, or an environmental impact registration form as required by the environmental protection administrative department of the State Council for record. In addition, after the completion of a construction project for which an environmental impact report or an environmental impact statement has been prepared, the construction entity shall, in accordance with the standards and procedures prescribed by the competent administrative department of environmental protection under the State Council, conduct acceptance checks on the supporting environmental protection facilities and prepare an acceptance report. For construction projects that are constructed in phases or put into

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production or used in phases, the corresponding environmental protection facilities shall be inspected and accepted in phases. The construction projects can only be put into production or use after the completed supporting environmental protection facilities have passed the acceptance inspection. Facilities that have not been carried out or have not passed the acceptance examination shall not be put into production or use.

On March 12, 2026, the NPC promulgated the Code of the PRC on the Ecological Environment. The Code of the PRC on the Ecological Environment will take effect on August 15, 2026 and supersede 10 existing environmental protection laws, serving as the comprehensive and unified fundamental law governing ecological and environmental protection in the PRC.

Solid Waste

According to the Law of the PRC on Prevention and Control of Environmental Pollution Caused by Solid Wastes (《中華人民共和國固體廢物污染環境防治法》) promulgated by the Standing Committee of the National People’s Congress on October 30, 1995, which was last amended on April 29, 2020 and came into effect on September 1, 2020, any entity or individual that produces, collects, stores, transports, utilizes, or disposes solid wastes shall take measures to prevent or reduce environmental pollution caused by solid wastes, and be liable for resultant environmental pollution in accordance with the law.

Pollution Permit and Drainage Permit

According to the Environmental Protection Law and the Regulation on the Administration of Pollutant Discharge Licensing (《排污許可管理條例》), which was promulgated by the State Council on January 24, 2021, and came into effect on March 1, 2021, enterprises, business units and other producers and operators that implement the pollutant discharge licensing management shall discharge pollutants according to the requirements of the pollutant discharge license, and shall not discharge pollutants without obtaining the pollutant discharge license. The competent environmental protection authorities impose various administrative penalties on individuals or enterprises in violation of the Environmental Protection Law.

According to the Administrative Measures for the Permits for Discharge of Urban Sewage into the Drainage Pipeline (《城鎮污水排入排水管網許可管理辦法》) issued by the Ministry of Housing and Urban-Rural Development on January 22, 2015 and amended on December 1, 2022 and became effective on February 1, 2023, the discharge of sewage from drainage facilities shall be subject to supervision and management. Without a drainage permit, any entity engaged in industry, construction, catering, medical and other activities shall not discharge sewage into urban drainage facilities.

REGULATIONS RELATED TO LABOR AND SOCIAL SECURITY

Labor Relations

According to the Labor Law of the PRC (《中華人民共和國勞動法》), which was promulgated by the Standing Committee of the National People’s Congress on July 5, 1994, became effective on January 1, 1995, and was last amended on December 29, 2018, the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), which was promulgated by the Standing Committee of the National People’s Congress on June 29, 2007, last amended on December 28, 2012, and became effective on July 1, 2013, and the Implementation Regulations on the Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》), which were promulgated by the State Council and came into effect on September 18, 2008, labor

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contracts in written form shall be executed to establish labor relationships between employers and employees. In addition, wages cannot be lower than local minimum wage. The employers must establish a system for labor safety and sanitation, strictly abide by state rules and standards, provide education regarding labor safety and sanitation to its employees, provide employees with labor safety and sanitation conditions and necessary protection materials in compliance with state rules and carry out regular health examinations for employees engaged in work involving occupational hazards.

Social Insurance and Housing Provident Fund

In accordance with the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) which was promulgated by the Standing Committee of the National People’s Congress on October 28, 2010 and was latest amended on December 29, 2018, with the latest revision effective on the same date, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance, and maternity insurance. Employers who fail to promptly contribute social security premiums in full amount shall be ordered by the social security premium collection agency to make or supplement contributions within a stipulated period, and shall be subject to a late payment fine computed from the due date at the rate of 0.05% per day; where the payment is not made within the stipulated period, the administrative authorities shall impose a fine ranging from one to three times of the amount in arrears.

On July 31, 2025, the PRC Supreme People’s Court promulgated the Supreme People’s Court’s Interpretation (II) on Several Issues Concerning the Application of Law in Labor Dispute Cases (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)》) (the “New Judicial Interpretation”), which took effect on September 1, 2025. The New Judicial Interpretation clarifies that if an employer and an employee agree or the employee undertakes that social insurance contributions need not be paid, the People’s Court shall deem such agreement or undertaking invalid. Furthermore, where an employer fails to pay social insurance contributions in accordance with the law, and the employee seeks to terminate the labor contract and claims economic compensation from the employer, the People’s Court shall support such claims 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》) which were promulgated by the State Council on April 3, 1999, and was latest amended on March 24, 2019, with the latest revision effective on the same date, an employer shall make registration of contribution to the housing provident fund with the housing provident fund management center, and go through the formalities of opening housing provident fund accounts on behalf of its employees. If an employer fails to undertake contribution registration of housing provident fund or fails to go through the formalities of opening housing provident fund accounts for its employees, the housing provident fund management center shall order it to go through the formalities within a prescribed time limit; where failing to do so at the expiration of the time limit, a fine of not less than RMB10,000 nor more than RMB50,000 shall be imposed. If an employer is overdue in the contribution of, or underpays, the housing provident fund, the housing provident fund management center shall order it to make the contribution within a prescribed time limit; where the contribution has not been made after the expiration of the time limit, an application may be made to a people’s court for compulsory enforcement.

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Labor Dispatch

Pursuant to the Interim Provisions on Labor Dispatch (《勞務派遣暫行規定》) issued on January 24, 2014, and effective on March 1, 2014, by the Ministry of Human Resources and Social Security, employers may only use dispatched workers for temporary, ancillary or substitute positions. Temporary positions shall mean positions lasting for no more than six months; ancillary positions shall mean positions of non-major business that serve positions of major business; and substitute positions shall mean positions that can be substituted by other workers for a certain period during which the workers who originally hold such positions are unable to work as a result of full-time study, being on leave or other reasons. Pursuant to the Interim Provisions on Labor Dispatch, employers should strictly control the number of dispatched workers, and the number of the dispatched workers shall not exceed 10% of the total amount of their employees. Pursuant to the Labor Contract Law, where rectification is not made within the stipulated period, the employers may be subject to a penalty ranging from RMB5,000 to RMB10,000 per dispatched worker exceeding the 10% threshold.

REGULATIONS ON PRODUCTION SAFETY

Production Safety

According to the Production Safety Law of the PRC (《中華人民共和國安全生產法》) promulgated by the Standing Committee of the National People's Congress on June 29, 2002, last amended on June 10, 2021 and came into effect on September 1, 2021, enterprises engaged in production activities must strengthen safety production management, establish and improve the responsibility system for safe production and ensure a safe production environment. The state establishes and implements a system for the accountability of production safety accidents. If the company fails to comply with the provisions of the Law on Work Safety, the supervisory authority on production safety may issue a rectification order, impose a fine, order the company to cease production and operation, or revoke the relevant permit.

Radiation Safety

According to the Law of the PRC on Prevention and Control of Radioactive Pollution (《中華人民共和國放射性污染防治法》), which was promulgated by the Standing Committee of the National People's Congress on June 28, 2003 and came into effect on October 1, 2003, an entity producing, selling or using radioisotope and ray devices shall, in accordance with the relevant provisions of the State Council on prevention of radioactivity from the radioisotope and ray devices, apply to obtain a permit, and make registration accordingly. An entity producing, selling, using or storing radioactive sources shall set up a sound and safe security system, designate specialized personnel to be responsible for the system, ensure the implementation of the system of accountability for safety, and formulate the necessary measures for addressing emergencies in accidents.

According to the Regulation on the Security and Protection of Radioisotope and Radioactive Ray Devices (《放射性同位素與射線裝置安全和防護條例》) promulgated by the State Council on September 14, 2005, last amended on March 2, 2019 and came into effect on the same day, and the Measures for Administration of the Safety Licensing of Radioactive Isotopes and Radioactive Equipment (《放射性同位素與射線裝置安全許可管理辦法》) promulgated by the former Ministry of Environmental Protection on January 18, 2006, last amended on January 4, 2021 and came into effect on the same day, any entity producing, selling or using radioisotopes or radiation-emitting devices shall obtain a radiation safety license.

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Regulations on Occupational Disease Prevention

Pursuant to the Law on Prevention and Control of Occupational Diseases of the PRC (《中華人民共和國職業病防治法》), which was promulgated by the Standing Committee of the National People's Congress on October 27, 2001 and came into effect on May 1, 2002, and last amended and came into effect on December 29, 2018, in order to strengthen the management, raise the standard of prevention and control of occupational diseases and assume the responsibilities for the occupational disease hazards happening in the unit, the employment unit shall establish and improve the responsibility system for prevention and control of occupational diseases by implementing the following requirements: 1) In addition to the establishment of employing entity that have occupational disease hazards shall meet the establishing conditions required by the law and administrative regulations, its workplace shall also meet the occupational health requirements; 2) The employing entity shall truthfully report the hazardous item to the local supervisory department on health administration in a timely manner and accept supervision if any hazardous factor causing an occupational disease listed in the Occupational Diseases Catalogue exists at the workplace; 3) Construction enterprises shall conduct preliminary assessment of occupational disease hazards during the stage of feasibility study, if a construction project may cause occupational disease hazards.

REGULATIONS ON FOREIGN INVESTMENT IN THE PRC

Foreign Investment Law and its Implementation Rules

According to the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) promulgated by the National People's Congress on March 15, 2019 and taking effect on January 1, 2020, and the Implementation Rules for the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》) promulgated by the State Council on December 26, 2019 and taking effect on January 1, 2020, the State adopts the pre-entry national treatment and negative list management system for foreign investment. Foreign investors are prohibited from investing in any areas specified in the negative list, and must meet the conditions listed in the negative list before investing in any restricted areas. Investments, profits, and other legitimate rights and interests of foreign investors in China are protected by law, and various national policies supporting the development of enterprises are equally applicable to foreign-funded enterprises. The State guarantees the equal participation of foreign-funded enterprises in the formulation of standards and strengthens the information disclosure and social supervision of standard formulation. Except under special circumstances, the State shall not expropriate any overseas investment.

Foreign Investment Industrial Policy

Investments activities in China by foreign investors are principally governed by the Encouraged Industries Catalog for Foreign Investment (2025 version) (《鼓勵外商投資產業目錄(2025年版)》) which was promulgated by the Ministry of Commerce and the National Development and Reform Commission on December 15, 2025 and became effective on February 1, 2026, and the Special Administrative Measures for Foreign Investment Access (Negative List 2024) (《外商投資准入特別管理措施(負面清單)(2024年版)》) which were promulgated by the Ministry of Commerce and the National Development and Reform Commission on September 6, 2024 and became effective on November 1, 2024. This catalog and negative list set forth the industries in which foreign investments are encouraged, restricted and prohibited. Industries that are not listed in any of these three categories are generally open to foreign investment unless otherwise specifically restricted by other PRC rules and regulations.

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Pursuant to the Measures for the Administration of Overseas Investment (《境外投資管理辦法》) which was issued by the Ministry of Commerce of the People’s Republic of China on September 6, 2014 and became effective on October 6, 2014, the Ministry of Commerce of the People’s Republic of China 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》) promulgated by the National Development and Reform Commission on December 26, 2017 and effective on March 1, 2018, companies established within the PRC (each, an “investor”) that intend to make overseas investments are required to complete the necessary procedures for verification or filing of the relevant overseas investment project (the “project”). In addition, investors must submit the requisite information and cooperate with ongoing regulatory oversight. Sensitive projects conducted by investors directly or through overseas enterprises controlled by them shall be subject to confirmation 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.

Pursuant to the Circular of the State Administration of Foreign Exchange on Further Improving and Adjusting Foreign Exchange Administration Policies for Direct Investment (《國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知》) which was promulgated by the State Administration of Foreign Exchange, on November 19, 2012, became effective on December 17, 2012 and was further amended on May 4, 2015, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts, and deposits accounts, the reinvestment of RMB proceeds derived by foreign investors within the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of the State Administration of Foreign Exchange, and multiple capital accounts for the same entity may be opened in different provinces. In February 2015, the State Administration of Foreign Exchange promulgated the Notice on Further Simplifying and Improving Foreign Exchange Administration Policies on 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》), part of which was abolished in December 2019. This notice stipulates that banks shall, on behalf of the State Administration of Foreign Exchange, directly examine and handle foreign exchange registration under domestic direct investment and overseas direct investment, and the State Administration of Foreign Exchange and its branches shall exercise indirect supervision over foreign exchange registration of direct investment through banks. On April 3, 2024, the State Administration of Foreign Exchange promulgated the Guidelines of Capital Account Foreign Exchange Business (2024 Version) (《資本項目外匯業務指引(2024年版)》), which came into effect on May 6, 2024, and stipulate guidelines for the capital account foreign exchange business.

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REGULATIONS ON INTELLECTUAL PROPERTY RIGHTS

Trademarks

Trademarks are protected by the Trademark Law of the PRC (《中華人民共和國商標法》) promulgated by the Standing Committee of the National People’s Congress on August 23, 1982 and subsequently amended on February 22, 1993, October 27, 2001, August 30, 2013 and April 23, 2019, respectively, as well as the Implementation Regulations on the Trademark Law of the PRC (《中華人民共和國商標法實施條例》) promulgated by the State Council on August 3, 2002 and amended on April 29, 2014. The Trademark Office handles trademark registrations and grants a term of ten years to registered trademarks and another ten years if requested upon expiry of the first or any renewed ten-year term.

Patent

In accordance with the Patent Law of the PRC (《中華人民共和國專利法》) which was promulgated by the Standing Committee of the National People’s Congress on March 12, 1984 and latest amended on October 17, 2020, with the latest revision effective on June 1, 2021, and the Implementation Regulations on the Patent Law of the PRC (《中華人民共和國專利法實施細則》) which were promulgated by the State Council on December 21, 1992 and January 9, 2010 and latest amended on December 11, 2023, patent in the PRC shall be categorized as invention, utility model and design. The duration of patent rights for an invention shall be 20 years, the duration of patent rights for a utility model shall be 10 years and the duration of patent rights for a design shall be 15 years, commencing from the filing date.

Copyright and Software Products

On September 7, 1990, the Standing Committee of the National People’s Congress promulgated the Copyright Law of the PRC (《中華人民共和國著作權法》), which took effect on June 1, 1991, and was amended on October 27, 2001, February 26, 2010 and November 11, 2020, respectively. The Copyright Law of the PRC provides that Chinese citizens, legal persons, or other organizations shall, whether published or not, enjoy copyright in their works, which include, among others, works of literature, art, natural science, social science, engineering technology and computer software. In addition, internet activities, products disseminated over the internet and software products also enjoy copyright. There is a voluntary registration system administered by the Copyright Protection Center of China.

REGULATIONS RELATING TO DATA SECURITY AND PRIVACY PROTECTION

The Data Security Law of the PRC (《中華人民共和國數據安全法》) was promulgated on June 10, 2021 and became effective on September 1, 2021. It establishes a data protection system based on the category and security level of the data in terms of its importance for economic and social development and the potential harm caused by illegal use of such data to national security, public interest or rights and interests of individuals and organizations. Entities engaged in data processing activities shall, in accordance with laws and regulations, establish a sound full-process data security management system, organize data security education and training, and take corresponding technical measures and other necessary measures to ensure data security.

The Cybersecurity Review Measures (《網絡安全審查辦法》), which was promulgated on December 28, 2021, and effective from February 15, 2022, stipulates that operators of critical information infrastructure purchasing network products and services, and network platform operators carrying out data processing activities that affect or may affect national

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security, shall conduct cybersecurity review. The Cybersecurity Review Measures further specifies that network platform operators who hold personal information of more than 1 million users, when applying for listing abroad, must report to the Cybersecurity Review Office for a cybersecurity review.

According to the Regulations on the Security Management of Network Data (《網絡數據安全管理條例》) issued by the State Council on September 24, 2024, and effective from January 1, 2025, network data handlers conducting network data processing activities that affect or may affect national security shall undergo national security review in accordance with the relevant national regulations.

On July 7, 2022, the Cyberspace Administration of China promulgated the Security Assessment Measures for Outbound Data Transfer (《數據出境安全評估辦法》), which became effective on September 1, 2022. According to these measures, where a data processor transfers data overseas, the data processor shall apply to the Cyberspace Administration of China for a data cross-border transfer security assessment (“Security Assessment”) through the local branch at the provincial level for a data outbound transfer security assessment when: (1) a data processor transfers important data overseas; (2) a critical information infrastructure operator or a data processor processing the personal information of more than one million individuals transfers personal information abroad; (3) a data processor has transferred overseas a total of 100,000 individuals’ personal information or 10,000 individuals’ sensitive personal information since January 1 of the previous year (the quantity thresholds for personal information is superseded by the Provisions on Promoting and Regulating Cross-Border Data Flows); and (4) other circumstances in which the data processor shall apply for a outbound data transfer security assessment as stipulated by the Cyberspace Administration of China. On March 22, 2024, the Cyberspace Administration of China 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. These exemptions include, among others, the scenario where a data processor, other than a critical information infrastructure operator, has cumulatively transferred overseas personal information, excluding sensitive personal information, of fewer than 100,000 individuals since January 1 of the current year. A data processor, other than a critical information infrastructure operator, shall enter into a standard contract with overseas recipients for the cross-border transfer of personal information or obtain certification for personal information protection if the data processor has cumulatively transferred to overseas recipients (a) personal information of more than 100,000 but less than 1,000,000 individuals, excluding sensitive personal information, or (b) sensitive personal information of less than 10,000 individuals since January 1 of the current year. A data processor, other than a critical information infrastructure operator, shall apply to Security Assessment if the data processor has cumulatively transferred to overseas recipients (a) personal information of more than 1,000,000 individuals, excluding sensitive personal information, or (b) sensitive personal information of more than 10,000 individuals since January 1 of the current year. The provisions also explicitly state that data processors are not required to conduct data security assessment for cross-border transfer of important data if the data has not been notified or published as important data by relevant departments or regions.

According to the PRC Civil Code (《中華人民共和國民法典》), personal information of natural persons is protected by law. If any organization or individual needs to obtain other people’s personal information, they should obtain it in accordance with the law and ensure the security of the information. They must not illegally collect, use, process, or transmit other people’s personal information, and must not illegally buy, sell, provide, or disclose the

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information. The Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) promulgated by the Standing Committee of the National People’s Congress on August 20, 2021 and implemented on November 1, 2021, further emphasizes the obligations and responsibilities of processors for the protection of personal information, and requests higher level of protective measures on the processing of sensitive personal information.

According to the Cybersecurity Law of the People’s Republic of China (《中華人民共和國網絡安全法》) promulgated by the Standing Committee of the National People’s Congress on November 7, 2016 which was amended on October 18, 2025 and became effective on January 1, 2026, network operators must follow the principles of legality, legitimacy and necessity when collecting and using personal information, and publicly disclose the rules for collection and use, clearly state the purpose, method and scope of collecting and using information, and obtain the consent of the person whose data is being collected. Network operators shall not collect personal information unrelated to the services they provide. Network operators are not allowed to leak, tamper with, or damage the personal information they collect; they are not allowed to provide personal information to others without the consent of the person whose data is being collected. However, this does not apply to cases where a specific individual cannot be identified and the identity cannot be recovered after processing. Network operators should take technical measures and other necessary measures to ensure the security of the personal information they collect and prevent leakage, damage and loss of information.

REGULATIONS IN RELATION TO OVERSEAS SECURITIES OFFERING AND LISTING BY DOMESTIC COMPANIES

According to the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) issued by the CSRC on February 17, 2023 and effective from March 31, 2023, where a domestic company issuer procures an overseas initial public offering or listing, it shall file with the CSRC within three (3) business days after submitting application documents for overseas securities issuance and listing.