

REGULATORY OVERVIEW

OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section summarizes the major PRC regulatory authorities and PRC laws and regulations that we believe are relevant to our business and operations in the PRC.

REGULATIONS ON FOREIGN INVESTMENT

Investment activities in the PRC by foreign investors are principally governed by the *Catalog of Encouraged Industries for Foreign Investment (2025 version)* (《鼓勵外商投資產業目錄》(2025年版)) (the “**Encouraged Catalog**”), and the *Special Administrative Measures (Negative List) for Foreign Investment Access (2024 version)* (《外商投資准入特別管理措施(負面清單)》(2024年版)) (the “**2024 Negative List**”), which are promulgated and amended from time to time by the Ministry of Commerce of the PRC (中華人民共和國商務部) (the “**MOFCOM**”) and the National Development and Reform Commission (中華人民共和國國家發展和改革委員會) (the “**NDRC**”), and together with the Foreign Investment Law of PRC (《中華人民共和國外商投資法》) (the “**FIL**”) and its respective implementation rules and ancillary regulations.

In March 2019, the FIL was promulgated by National People’s Congress (中華人民共和國全國人民代表大會) (the “**NPC**”) and came into effect on January 1, 2020, which replaced three then existing laws on foreign investments in China, namely, the *Sino-Foreign Equity Joint Venture Enterprise Law of PRC* (《中華人民共和國中外合資經營企業法》), the *Sino-Foreign Cooperative Joint Venture Enterprise Law of PRC* (《中華人民共和國中外合作經營企業法》) and the *Wholly Foreign-owned Enterprise Law of PRC* (《中華人民共和國外資企業法》). The FIL, by means of legislation, establishes the basic framework for the access, promotion, protection and administration of foreign investment in view of investment protection and fair competition. According to the FIL, foreign investment shall enjoy pre-entry national treatment, except for those foreign invested entities that operate in industries deemed to be either “restricted” or “prohibited” in the 2024 Negative List, and the State Council (中華人民共和國國務院) shall promulgate or approve a list of special administrative measures for access of foreign investments. To ensure the effective implementation of the FIL, the *Regulations on Implementing the Foreign Investment Law of the PRC* (《中華人民共和國外商投資法實施條例》), was promulgated by State Council in December 2019 and came into effect on January 1, 2020, which further clarified that the state encourages and promotes foreign investment, protects the lawful rights and interests of foreign investors, regulates foreign investment administration, continues to optimize foreign investment environment, and advances a higher-level opening.

In December 2019, the MOFCOM and the State Administration for Market Regulation (國家市場監督管理總局) (the “**SAMR**”) promulgated the *Measures on Reporting of Foreign Investment Information* (《外商投資信息報告辦法》), which came into effect on January 1, 2020. After the *Measures on Reporting of Foreign Investment Information* came into effect, the *Interim Measures for the Administration of Filing for Establishment and Changes in Foreign Investment Enterprises* (《外商投資企業設立及變更備案管理暫行辦法》) have been repealed simultaneously. Since January 1, 2020, for foreign investors carrying out investment activities directly or indirectly in China, the foreign investors or foreign-invested enterprises shall submit investment information to the relevant commerce administrative authorities according to the *Measures on Reporting of Foreign Investment Information*.

According to the *Measures for the Security Review of Foreign Investment* (《外商投資安全審查辦法》) promulgated by the NDRC and the MOFCOM on December 19, 2020 and became effective on January 18, 2021, any foreign investment that has or may have an impact on national security shall be subject to security review in accordance with the provisions hereof. A foreign investor or a party concerned in China shall take the initiative to make a declaration to the working mechanism office prior to making the investment in any important infrastructure, important transportation services and other important fields that concern national security while obtaining the actual control over the enterprises invested in.

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REGULATIONS ON PHARMACEUTICAL PRODUCT

The pharmaceutical manufacturing industry in the PRC is primarily subject to regulatory oversight by the following departments under the State Council, namely, the National Medical Products Administration of the PRC (中華人民共和國國家藥品監督管理局) (the “NMPA”, formerly the China Food and Drug Administration (國家食品藥品監督管理總局) (the “CFDA”), the National Healthcare Security Administration of the PRC (中華人民共和國國家醫療保障局), the National Health Commission of the PRC (中華人民共和國國家衛生健康委員會) (the “NHC”), the NDRC, the Ministry of Industry and Information Technology of the PRC (中華人民共和國工業和信息化部), the Ministry of Human Resources and Social Security of the PRC (中華人民共和國人力資源和社會保障部), and the Ministry of Ecology and Environment of the PRC (中華人民共和國生態環境部).

Drug Regulatory Regime

The *Drug Administration Law of the PRC* (《中華人民共和國藥品管理法》) (the “**Drug Administration Law**”) was promulgated by the Standing Committee of the NPC (全國人民代表大會常務委員會) (the “SCNPC”), in September 1984, last amended on August 26, 2019 and became effective on December 1, 2019. The *Implementation Regulations of the Drug Administration Law of the PRC* (《中華人民共和國藥品管理法實施條例》) (the “**Implementation Regulations**”) was promulgated by the State Council in August 2002, and was last amended in January 16, 2026, and will become effective on May 15, 2026. The *Drug Administration Law* and the *Implementation Regulations* have jointly established the legal framework for the administration of pharmaceutical products in the PRC, including the research, development and manufacturing of drugs. The *Drug Administration Law* applies to entities and individuals engaged in the development, production, trade, application, supervision and administration of pharmaceutical products, which regulates and provides for a framework for the administration of pharmaceutical manufacturers, pharmaceutical trading companies and medicinal preparations of medical institutions, and the development, research, manufacturing, distribution, packaging, pricing and advertisements of pharmaceutical products. The *Implementation Regulations*, at the same time, provides the detailed implementation regulations on the Drug Administration Law.

In 2017, the drug regulatory system entered a new and significant period of reform. The General Office of the State Council (中華人民共和國國務院辦公廳) and the General Committee of the Communist Party of China (中國共產黨中央委員會) jointly issued an *Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices* (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (the “**Innovation Opinions**”) in October 2017. According to the *Innovation Opinions*, institutions for drug clinical trials should establish an independent ethics committee and the clinical trial schemes are subject to examination, approval and signing with approval opinions by the ethics committee before implementation, in order to protect the rights and interests of human subjects in clinical trials. For a multi-center clinical trial conducted in the PRC, after ethical review by the leader unit of clinical trial, other member units should recognize the review results of the leader unit and may not conduct repeated review. In addition, the expedited programs, the record-filing system, the prioritized review mechanism, the acceptance of foreign clinical data under the *Innovation Opinions* and other recent reforms encourage drug marketing authorization holders to seek marketing approval in China first for the development of drugs in highly prioritized therapeutic areas such as oncology or rare disease areas.

To implement the regulatory reform introduced by *Innovation Opinions*, the SCNPC and the NMPA, as well as other authorities, are currently responsible for revising the laws, regulations and rules regulating the pharmaceutical products and the industry.

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Application for Clinical Trial

According to the *Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs* (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA on March 17, 2017, the decision on the approval of clinical trials of drugs shall be made by the Center for Drug Evaluation (國家藥品監督管理局藥品審評中心) (the “CDE”) from May 1, 2017. According to the *Administrative Measures for Drug Registration* (《藥品註冊管理辦法》) (the “**Registration Measures**”), which was promulgated on January 22, 2020 and took effect on July 1, 2020, drug clinical trials shall be divided into Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial, and bioequivalence trial. After the completion of the pharmaceutical, pharmacological and toxicological research of the drug clinical trial, the applicant may submit relevant research materials to the CDE for applying for the approval to conduct drug clinical trial. The CDE will organize pharmaceutical, medical and other technicians to review the application and to decide whether to approve the drug clinical trial within 60 days of the date of acceptance of the application. Once the decision is made, the result will be notified to the applicant through the website of the CDE and if no notice of decision is issued within the aforementioned time limit, the application of clinical trial shall be deemed as approval. In accordance with Registration Measures and the *Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs* (《關於調整藥物臨床試驗審評審批程序的公告》) issued in July 2018, if a clinical trial applicant does not receive any negative or questioned opinions from the CDE within 60 days after the date when the trial application is accepted and the fees are paid, the applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the CDE.

The Registration Measures further requires that the applicant shall, prior to conducting the drug clinical trial, register the information of the drug clinical trial plan, etc. on the Drug Clinical Trial Information Platform. After obtaining the approval of clinical trial, the applicant must complete the clinical trial registration at the Drug Clinical Trial Information Platform for public disclosure in accordance with the *Circular on Drug Clinical Trial Information Platform* (《關於藥物臨床試驗信息平台的公告》), which came into effect on September 6, 2013, and the *Standard for the Management of Drug Clinical Trial Registration and Information Disclosure (Trial)* (藥物臨床試驗登記與信息公示管理規範(試行)), which came into effect on July 1, 2020. The applicant shall complete the trial pre-registration within one month after obtaining the approval of the clinical trial application in order to obtain the trial’s unique registration number and complete registration of certain follow-up information before the first subject’s enrollment in the trial. If the registration is not completed within one year after the approval, the applicant shall submit an explanation, and if the first submission is not completed within three years, the approval of the clinical trial application shall automatically expire. During the drug clinical trials, the applicant shall update registration information continuously, and register information of the outcome of the drug clinical trial upon completion.

Accelerated Approval for Clinical Trial and Registration

The *Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices* (《關於改革藥品醫療器械審評審批制度的意見》) issued by the State Council in August, 2015, established a reform framework of the evaluation and approval system for drugs and medical devices, and indicated the tasks of enhancing the standards of approval for drug registration, accelerating the evaluation and approval process for innovative drugs, and improving the approval for clinical trials of drugs, etc.

The CFDA released the *Circular Concerning Several Policies on Drug Registration Review and Approval* (《關於藥品註冊審評審批若干政策的公告》) in November 2015, which clarified the measures and policies regarding simplifying and accelerating the approval process of clinical trials, including but not limited to a one-time approval procedure allowing the overall approval of all phases of a drug’s clinical trials, replacing the phase-by-phase application and approval.

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The Innovation Opinions established a framework for reforming the evaluation and approval system for drugs, medical devices and equipment. The Innovation Opinions indicated enhancing the standard of approval for drug marketing registration and accelerating the evaluation and approval process for innovative drugs as well as improving the approval of drug clinical trials.

According to the *Announcement on Matters Concerning the Optimization of Drug Registration Review and Approval* (《關於優化藥品註冊審評審批有關事宜的公告》) jointly issued by the NMPA and the NHC in May 2018, the CDE will prioritize the allocation of resources for review, inspection, examination and approval of registration applications that have been included in the scope of fast track clinical trial approval.

In July 2020, the NMPA issued the *Evaluation and Approval Procedures for Breakthrough Therapeutic Drugs (Trial)* (《突破性治療藥物審評工作程序(試行)》), the *Evaluation and Approval Procedures for Conditionally Approved Drugs (Trial)* (《藥品附條件批准上市申請審評審批工作程序(試行)》) and the *Priority Review and Approval Procedures for Drug Marketing Authorizations (Trial)* (《藥品上市許可優先審評審批工作程序(試行)》) and on April 22, 2026, the NMPA further revised and promulgated the *Review and Approval Procedures for Conditional Approval of Drug Marketing Applications* (《藥品附條件批准上市申請審評審批工作程序》). These measures stipulate the applicable working procedures for drugs application that meet respective eligibility criteria. For instance, at the time of application for drug marketing authorization, the following drugs which have obvious clinical value may apply for prioritized review and approval procedures: (i) clinically and urgently needed but insufficient drugs, innovative drugs and improved new drugs for prevention and treatment of major contagious diseases and rare diseases; (ii) new pediatric use pharmaceutical products, dosage form and specifications which comply with pediatric physiological characteristics; (iii) vaccines and innovative vaccines urgently needed for prevention and control of diseases; (iv) drugs included in the procedures for breakthrough therapy designation; (v) drugs which comply with conditional approval criteria; and (vi) other circumstances entitled to prioritized review as stipulated by the NMPA. Upon communication and confirmation with the CDE, when the applicant submits the application for drug marketing authorization, the applicant shall simultaneously submit an application for prioritized review and approval. If an application satisfies one of the foregoing criteria, the CDE shall announce so and admit the application in the prioritized review and approval procedures. The following policy support shall be granted to an application for drug marketing authorization admitted in the prioritized review and approval procedures: (i) the review period shall be limited to no more than 130 days; (ii) for clinically and urgently needed imported drugs for rare diseases which are not yet marketed in the PRC, the review period shall be limited to no more than 70 days; (iii) priority shall be granted to examination, inspection and approval of the commonly used name of drugs (if applicable); and (iv) upon communication and confirmation, supplementary supporting materials may be required.

In July 2024, the State Council executive meeting considered and passed the *Implementation Plan for Supporting Innovative Drug Development Across the Whole Chain* (《全鏈條支持創新藥發展實施方案》), which requires strengthening the policy guarantee in the whole chain, coordinating the use of policies on price management, payment of medical insurance, commercial insurance, drug dispensing and use, investment and financing, etc., optimizing the review and approval and the assessment mechanism of medical institutions, and jointly boosting the breakthrough development of innovative drugs.

Conduct of Clinical Trial

After obtaining clinical trial approval, the applicant shall conduct clinical trials at qualified clinical trial institutions. The qualified clinical trial institution refers to institutions that have the conditions to conduct clinical trials in accordance with the requirements and technical guidelines set forth in the *Regulations for the Administration of Drug Clinical Trial Institutions* (《藥物臨床試驗機構管理規定》), which came into effect on December 1, 2019. Such clinical trial institutions shall be subject to filing requirements, with the exception of institutions that only engage in analysis of biological samples which shall not be subject to such filing requirements. The NMPA is

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responsible for setting up a filing management information platform for the registration, filing and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information from the supervision and inspection activities conducted by the drug regulatory authorities and competent healthcare authorities.

The applicant filing an application for clinical drug trial after completing the pharmaceutical research, pharmacological and toxicological research, and other researches supporting clinical drug trial shall submit relevant research materials according to the requirements for the application materials. The applicant who intends to carry out a bioequivalence test shall, after undergoing the recordation formalities for bioequivalence test at the website of the CDE as required, carry out relevant research work according to the plan recorded. The applicant who is approved to carry out clinical drug trial shall, before carrying out subsequent clinical drug trial by stages, develop corresponding plan for clinical drug trial, carry out clinical drug trial upon examination and with consent of the ethics committee, and submit corresponding plan for clinical drug trial and supporting materials on the website of the Center for Drug Evaluation. Where indications (or functions) are intended to be added for a drug approved for clinical drug trial and the use of a drug in combination with other drugs is added, the applicant shall file a new application for clinical drug trial, and may only carry out new clinical drug trial with approval.

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

According to the *Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs* (《關於調整藥物臨床試驗審評審批程序的公告》), where the application for clinical trial of new investigational drug has been approved, upon the completion of Phase I and Phase II clinical trials and prior to Phase III clinical trial, the applicant shall submit the application for communication meetings to the CDE to discuss with the CDE the key technical questions including the design of the Phase III clinical trial protocol. According to the *Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs* (《藥物研發與技術審評溝通交流管理辦法》), revised by the NMPA on April 1, 2026, during the research and development periods and in the registration applications of, among others, the innovative new drugs, the applicants may propose to conduct communication meetings with the CDE. The communication meetings can be classified into three types. Type I meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are held during the key research and development stages of drugs, mainly including meetings before submitting the clinical trial application, meetings upon the completion of Phase II trials and prior to the Phase III trials, meetings before submitting the marketing application for a new drug, and meetings for risk evaluation and control. Type III meetings refer to other meetings not classified as Type I or Type II.

Multi-Regional Clinical Trials and Acceptance of Overseas Clinical Trial Data

On January 30, 2015, the CFDA promulgated the *Multi-Regional Clinical Trial Guidelines (Trial)* (《國際多中心藥物臨床試驗指南(試行)》) (the “**MRCT Guidelines**”), which took effect on March 1, 2015, to provide guidance for the regulation of application, implementation and administration of international multi-center clinical trials in China. Pursuant to the MRCT Guidelines, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicant plans to make use of the data derived from the international multi-center clinical trials for application for approval of new drug registration, such international multi-center clinical trials shall satisfy the requirements set forth in the Drug Administration Law and its implementation regulations and relevant laws and regulations.

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On October 8, 2017, the General Office of the CPC Central Committee and the General Office of the State Council jointly issued the *Opinion on Strengthening the Reform of the Drug and Medical Device Review and Approval Process to Encourage Drug and Medical Device Innovation* (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) which stipulates that overseas clinical trial results are acceptable in China. Data derived from overseas clinical trials can be used in application for registration of drugs and medical devices if the data satisfy the registration requirement for drugs and medical devices in China. For initial application for marketing of pharmaceutical products and medical devices in China, the applicants are required to provide clinical trial data to indicate whether there will be difference of trial results among different ethnic groups.

On July 6, 2018, the NMPA issued the *Technical Guiding Principles for the Acceptance of the Overseas Clinical Trial Data of Drugs* (《接受藥品境外臨床試驗數據的技術指導原則》) (the “**Guiding Principles**”), which provides that overseas clinical data can be submitted for all kinds of registration applications in China, including the clinical trial authorization and new drug registration. The Guiding Principles clearly list the basic principles and requirements on the acceptance of overseas clinical trial data, and distinguish different levels of acceptance based on the quality of the data itself and different circumstances. The Guiding Principles require that the applicant shall ensure that the overseas clinical trial data are truthful, complete, accurate and traceable, and the generating process of the overseas clinical trial data shall comply with the relevant requirements of the Good Clinical Practice (臨床試驗質量管理規範) provided by the *International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use* (人用藥品註冊技術國際協調會議).

Good Clinical Practices

Clinical trials must be conducted in accordance with the *Good Clinical Practice for Drug Trials* (《藥物臨床試驗質量管理規範》) (the “**GCP Rules**”) promulgated by NMPA and NHC on April 23, 2020 and became effective on July 1, 2020, which stipulates the requirements for the procedures of conducting clinical trials, including pre-clinical trial preparation, trial protocols, protection of testees’ rights and interests, duties of researchers, sponsors and monitors, as well as data management and statistical analysis. According to the GCP Rules, clinical trial means systematical investigation of drugs conducted on human subjects (patients or healthy volunteers) to prove or reveal the clinical, pharmacological and other pharmacodynamic effects, adverse reactions or absorption, distribution, metabolism and excretion of the drug being investigated. In order to ensure the quality of clinical trials and the safety of human subjects, the GCP Rules provides comprehensive and substantive requirements on the design and conduct of clinical trials in the PRC. In particular, the GCP Rules enhances the protection for study subjects and tightens the control over bio-samples collected under clinical trials.

The GCP Rules stipulated that the sponsor shall bear the expenses for medical treatment and the corresponding compensation for any human subject who is harmed or dies due to reasons connected with the clinical trial. The sponsor and investigator shall pay the human subject the compensation or indemnification in a timely manner. However, the GCP Rules promulgated in 2020 abolishes the compulsory insurance the sponsor provides to human subjects participating in a clinical trial compared with the GCP Rules promulgated in 2003.

The GCP Rules also set out the qualifications and requirements for the investigators and centers participating in clinical trial, including: (i) professional certification at a clinical trial center, professional knowledge, training experience and capability of clinical trial, and being able to provide the latest resume and relevant qualification documents per request; (ii) being familiar with the trial protocol, investigator’s brochure and relevant information of the trial drug provided by the applicant; (iii) being familiar with and comply with the Revised GCP Rules and relevant laws and regulations relating to clinical trials; (iv) keeping a copy of the authorization form on work allocation signed by investigators; (v) investigators and clinical trial centers shall accept supervision and inspection organized by the applicant and inspection by the drug regulatory

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authorities; and (vi) in the case of investigators and clinical trial centers authorizing other individual or institution to undertake certain responsibilities and functions relating to clinical trial, they shall ensure such individual or institution are qualified and establish complete procedures to ensure the responsibilities and functions are fully performed and generate reliable data.

The GCP Rules also summarizes the role of ethic committee in clinical trial process. An ethic committee shall consist of experts working in the medical, pharmaceutical and other fields. The clinical trial protocol may not be executed unless approved by the ethic committee. 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》) promulgated by CFDA in November 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. The Regulations for the Administration of Drug Clinical Trial Institutions also stipulates that each clinical trial institution shall maintain an ethic committee responsible for the ethical review of drug clinical trial.

Non-clinical Research

The non-clinical safety evaluation study for drugs for the purpose of applying for drug registration shall be conducted in accordance with the *Administrative Measures for Good Laboratories Practice* (《藥物非臨床研究質量管理規範》), which was promulgated in August 2003 and amended in July 2017 by the CFDA. In April 2007, the CFDA issued the *Regulations on the Certification Management of Good Laboratory Practice* (《藥物非臨床研究質量管理規範認證管理辦法》), last amended on January 19, 2023 and took effect on July 1, 2023, which set forth the requirements for an institution to apply for a Certification of Good Laboratory Practice to undertake non-clinical research on drugs.

According to the *Regulations for the Administration of Affairs Concerning Experimental Animals* (《實驗動物管理條例》) promulgated by the former State Science and Technology Commission (國家科學技術委員會) in November 1988 and lastly amended in March 2017 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 former State Science and Technology Commission and the former State Bureau of Quality and Technical Supervision (國家質量技術監督局) in December 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 PRC (中華人民共和國科學技術部) (the “MST”) and other regulatory authorities in December 2001 and came into effect in January 2002, using experimental animals and related products requires a Certificate for Utilization 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.

New Drug Registration

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

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Marketing Authorization Holder Mechanism

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

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

The drug marketing authorization holder shall establish a drug quality assurance system and be equipped with special personnel to take charge of quality management on drugs independently. The drug marketing authorization holder shall regularly review the quality management system of the drug manufacturer and the drug distributor, and supervise its continuous quality assurance and control capabilities. Where the marketing authorization holder is an overseas enterprise, its designated domestic enterprise shall perform the obligations of the marketing authorization holder and jointly assume responsibilities of the marketing authorization holder with the overseas enterprise.

Pharmacovigilance

Pursuant to the *Pharmacovigilance Quality Control Specifications* (《藥物警戒質量管理規範》) issued by the NMPA on May 7, 2021, and implemented from December 1, 2021, drug marketing authorization holders and drug registration applicants who are permitted to implement drug clinical trials shall establish the pharmacovigilance system to monitor, identify, evaluate and control adverse drug reactions and other drug-related harmful reactions through the effective operation and maintenance of the system. The drug marketing authorization holders shall initiate quality objectives for pharmacovigilance and establish quality assurance system for quality management on pharmacovigilance system and activities with an aim to consistently improve the efficiency of the system and ensure the compliance of the activities with the relevant laws and regulations. The legal representative and the key person-in-charge of a drug marketing authorization holder shall be fully responsible for the pharmacovigilance activities. The drug marketing authorization holders shall complete the information registration in the National Adverse Drug Reaction Monitoring System within 30 days upon the date of obtaining the first drug approval document.

Approval or Filing of Human Genetic Resources

The MST promulgated the *Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC* (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) in July 2015, according to which, the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organization of China shall apply for approval of the Human Genetic Resources Management Office of the PRC through the online system. The MST and the Human Genetic Resources Management Office of the PRC further respectively promulgated

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the *Circular on Further Optimizing the Administrative Examination and Approval of Human Genetic Resources* (《關於進一步優化人類遺傳資源行政審批流程的通知》) in October 2020, which simplify the approval of sampling and collecting human genetic resources for the purpose of listing a drug in the PRC.

The *Regulations on the Administration of Human Genetic Resources of the PRC* (《中華人民共和國人類遺傳資源管理條例》), promulgated by the State Council in May 2019, latest amended in March 2024 and came into effect on May 1, 2024, further stipulates that in order to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China’s human genetic resources at clinical institutions without export of human genetic resource materials. However, the type, quantity and usage of the human genetic resources to be used shall be filed with the administrative department of health under the State Council before clinical trials. In May 2023, the MST issued the *Implementation Rules for the Administrative Regulation on Human Genetic Resources* (《人類遺傳資源管理條例實施細則》), which came into effect on July 1, 2023, optimizing the scope of administrative licensing and record-keeping, enhancing the operability of the human genetic resources administration system, and implementing the registration and reporting system for the management of human genetic resources.

On October 17, 2020, the SCNPC promulgated the *Biosecurity Law of the PRC* (《中華人民共和國生物安全法》) (the “**Biosecurity Law**”) which became effective on April 15, 2021 and latest amended and became effective on April 26, 2024, establishing a comprehensive legislative framework on the current regulations in the areas including prevention and control of outbreak of major newly-emerged infectious diseases, animal and plant epidemics, security of biotechnology research, development and application, biosafety management of pathogenic microbiology laboratories, security management of human genetic resources and biological resources, prevention of the invasion of alien species and protection of biodiversity, countermeasures against microbial resistance and prevention of bioterrorism and threat of biological weapons. According to the Biosecurity Law, the high-risk and medium-risk biotechnology research and development activities shall be carried out by legal entities lawfully established in the PRC, and shall be approved or filed. The establishment of a pathogenic microbiology laboratory shall be lawfully approved or filed. Engaging in the following activities shall be approved by the administrative department of health under the State Council, (i) collecting human genetic resources of important genetic families or specific areas in the PRC, or collecting human genetic resources of which the types and quantities are subject to provisions of the administrative department of health under the State Council, (ii) preserving human genetic resources of the PRC, (iii) using human genetic resources of the PRC to carry out international scientific research cooperation, or (iv) transporting, mailing or exiting human genetic resource materials of the PRC.

Two-invoice System

Pursuant to the Opinions on the Implementation of the “Two-invoice System” in Drug Procurement by Public Medical Institutions (for Trial Implementation) (《關於在公立醫療機構藥品採購中推行“兩票制”的實施意見(試行)》) issued on December 26, 2016 jointly by eight government departments, including the Deepen Medical and Healthcare System Reform Leading Group Office of the State Council, the “Two-invoice System” restricts multiple layers of re-sale of drug products by only allowing two invoices in the supply of drug products: one from the manufacturer (or deemed manufacturer) to the distributor, and the other from the distributor to the procuring medical institution. The policy requires public medical institutions to phase in the “Two-invoice System” in drug procurement and encourages its adoption by other healthcare institutions, with the goal of achieving nationwide implementation by 2018. The “Two-invoice System” was implemented first in pilot provinces and public hospital reform pilot cities, with the target of nationwide implementation by 2018. On March 5, 2018, six government departments, including the Deepen Medical and Healthcare System Reform Leading Group Office of the State

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Council, jointly mandated the implementation of the “Two-invoice System” for drug procurement in all provinces within 2018, and encouraged the gradual adoption of the “Two-invoice System” for other high-value medical consumables.

Pharmaceutical companies must comply with the “Two-invoice System” to participate in procurement activities with public medical institutions. As such, our products are subject to such requirement to the extent we are to supply such products to public medical institutions after commercialization. For this purpose, we plan to conduct thorough due diligence on future distributors before we supply our products to them, and impose contractual requirements for distributors to comply with the “Two-invoice System” as applicable. We also plan to implement necessary product tracking measures and conduct regular review and audits on distributors to ensure their compliance with the “Two-invoice System”. Based on the foregoing, we expect that we will engage reputable distributors with established distribution networks and industry influence, and sell our products to public medical institutions through a single tier of distributors. This is expected to help control our distribution channel costs and credit risks arising from accounts receivables due from distributors.

REGULATIONS ON INFORMATION SECURITY AND DATA PROTECTION

Data Security and Data Export

The SCNPC promulgated the *Data Security Law of the PRC* (《中華人民共和國數據安全法》) on June 10, 2021, which became effective from September 1, 2021, for the establishment of a data classification and grading protection system to conduct classified and hierarchical protection of data. Entities engaged in data processing activities shall, in accordance with laws and regulations, establish a 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.

On December 28, 2021, the Cyberspace Administration of China (國家互聯網信息辦公室) (the “CAC”) and other twelve PRC regulatory authorities jointly revised and promulgated the *Measures for Cybersecurity Review* (《網絡安全審查辦法》) (the “Cyber Review Measures”), which came into effect on February 15, 2022. The Cyber Review Measures stipulate that, among others, (i) when the purchase of network products and services by a critical information infrastructures operator (the “CIIO”) (關鍵信息基礎設施運營者) or the data processing activities conducted by a network platform operator (網絡平台運營者) affect or may affect national security, a cybersecurity review shall be conducted pursuant to the Cyber Review Measures; (ii) an application for cybersecurity review shall be made by an issuer who is a network platform operator holding personal information of more than one million users before such issuer applies to list its securities abroad; and (iii) the relevant PRC governmental authorities may initiate cybersecurity review if such governmental authorities determine that the issuer’s network products or services, or data processing activities affect or may affect national security. According to the *Measures on Security Assessment of Cross-border Data Transfer* (《數據出境安全評估辦法》) issued by the CAC on July 7, 2022 and became effective on September 1, 2022, a data processor that provides data overseas under any of the following circumstances shall apply to the national cyberspace administration for the security assessment of the outbound data transfer through local provincial cyberspace administration: (i) a data processor provides important data abroad; (ii) the CIIO or the data processor that has processed the personal information of more than 1 million people provides personal information abroad; (iii) the data processor that has provided the personal information of over 100,000 people or the sensitive personal information of over 10,000 people cumulatively since January 1 of the previous year provides personal information abroad; and (iv) any other circumstance where an application for the security assessment of outbound data transfer is required by the national cyberspace administration.

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According to the *Measures for Standard Contract for Outbound Transfer of Personal Information* (《個人信息出境標準合同辦法》) issued by the CAC on February 22, 2023 and became effective from June 1, 2023, to provide personal information to an overseas recipient through the conclusion of the standard contract, a personal information processor shall meet all of the following circumstances: (i) it is not a CIIO; (ii) it has processed the personal information of less than one million individuals; (iii) it has cumulatively provided the personal information of less than 100,000 individuals to overseas recipients since January 1 of the previous year; and (iv) it has cumulatively provided the sensitive personal information of less than 10,000 individuals since January 1 of the previous year. In addition, the Measures for Standard Contract for Outbound Transfer of Personal Information require that all Outbound Transfers of personal information that have been carried out before June 1, 2023 and do not comply with the provisions of the Measures for Standard Contract for Outbound Transfer of Personal Information be rectified within 6 months.

According to the *Provisions on Promoting and Regulating Cross-border Data Flows* (《促進和規範數據跨境流動規定》), which was promulgated by the CAC on March 22, 2024 and came into effect on the same day, if the data have not been informed or publicly announced as important data by relevant departments or regions, data handlers are not required to declare security assessment for cross-border provision of the data as important data.

Personal Information Protection

According to the *Civil Code of the PRC* (《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, ensure the security of the information, and must not illegally collect, use, process, or transmit other people’s personal information or illegally buy, sell, provide, or disclose the information. The *Personal Information Protection Law of the PRC* (《中華人民共和國個人信息保護法》) promulgated by the SCNPC 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 PRC* (《中華人民共和國網絡安全法》) last amended on October 28, 2025 and took effect on January 1, 2026, network operators must follow the principles of legality, legitimacy and necessity when collecting and using personal information, 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, and 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 ON INTELLECTUAL PROPERTY

Patent Law

Pursuant to the *Patent Law of the PRC* (《中華人民共和國專利法》) latest amended by the SCNPC on October 17, 2020 and came into effect on June 1, 2021 and the *Implementation Rules of the Patent Law of the PRC* (《中華人民共和國專利法實施細則》) latest amended by the State Council on December 11, 2023 and came into effect on January 20, 2024, patents in China are divided into three types, i.e., invention patent, utility patent and design patent. The duration of a patent right for invention is 20 years, the duration of a patent right for utility model is 10 years, and the duration of a patent right for design is 15 years, all calculated from the date of application.

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In terms of patent covering a pharmaceutical product, the *Trial Implementation Measures for the Mechanism for Early-Stage Settlement of Drug Patent Disputes* (《藥品專利糾紛早期解決機制實施辦法(試行)》), promulgated by the NMPA and China National Intellectual Property Administration on July 4, 2021 and effective on the same day, establishes a special mechanism to protect pharmaceutical patents from infringement of chemical generic drugs. Under this mechanism, the marketing authorization holders (the “MAH”) shall register information about the drug and the corresponding patent of the drug. When applying for drug marketing authorization, the applicant of a chemical generic drug shall, by reference to the patent information registered by the MAH, make a declaration on each relevant drug patent of the generic drug. Any patentee or interested party who has an objection to the patent declaration may, within 45 days as of the date when the application for marketing authorization is made public by the national drug evaluation agency, lodge a lawsuit to a court regarding whether the relevant technical solution of the drug applied for marketing falls within the scope of protection of the relevant patent rights or request an administrative ruling from the patent administrative department of the State Council.

Trademark Law

In accordance with the *Trademark Law of the PRC* (《中華人民共和國商標法》) which was latest amended by the SCNPC on April 23, 2019, with the latest revision effective on November 1, 2019, and the *Implementation Regulations for the Trademark Law of the PRC* (《中華人民共和國商標法實施條例》) which was latest amended by the State Council on April 29, 2014, with the latest revision effective on May 1, 2014, trademarks approved and registered by the Trademark Office of the National Intellectual Property Administration are registered trademarks, including commodity trademarks, service marks, collective trademarks, and certification marks; the validity period of a registered trademark is 10 years, calculated from the date of approval of registration. A trademark registrant intending to continue to use the registered trademark upon expiry of the period of validity shall undergo the renewal formalities within 12 months before expiry according to the relevant provisions. Each renewal is valid for 10 years and is calculated from the day after the previous validity period of the trademark expires.

Copyright and Software Copyright

Copyright, including copyrighted software, is mainly protected under the *Copyright Law of the PRC* (《中華人民共和國著作權法》), the “**Copyright Law**”, which was adopted by the SCNPC on September 7, 1990 and last amended with effect from June 1, 2021, and *Implementation Regulations for the Copyright Law of the PRC* (《中華人民共和國著作權法實施條例》), which was promulgated by the State Council on August 2, 2002 and last amended with effect from March 1, 2013. These rules provide that Chinese citizens, legal persons or other organizations will, 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.

Domain Names

The Administrative Measures on Internet Domain Names (《互聯網域名管理辦法》), which were promulgated by the Ministry of Industry and Information Technology on August 24, 2017 and became effective on November 1, 2017, provides that “.CN” and “.zhongguo (in Chinese character)” are China’s national top level domains. Any party that engages in internet information services must use its domain name in compliance with laws and regulations and in line with relevant provisions of the telecommunications authority and shall not use its domain name to commit any violation.

REGULATIONS ON LEASING

According to the *Civil Code of the PRC* (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and implemented on January 1, 2021, the creation, modification, transfer, and extinction of real property rights that are subject to registration in accordance with the law shall

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take effect when they are recorded in the real estate registration book. A real estate ownership certificate is the proof that the owner has the right to the real estate. Pursuant to the *Administrative Measures for Commodity Housing Leasing* (《商品房屋租賃管理辦法》) promulgated by the Ministry of Housing and Urban-Rural Development (中華人民共和國住房和城鄉建設部) on December 1, 2010 and came into effect on February 1, 2011, the parties to house leasing shall, within 30 days after the execution of the house leasing contract, go through the house leasing registration and filing formalities with the competent construction (real-estate) departments of the People’s Government of the municipality directly under the Central Government, city or county at the place where the leased house is located. If a violation of the measures occurs, the party shall be ordered to rectify within a prescribed time limit. and if any party fails to do so, it shall be imposed of a fine of more than RMB1,000 and less than RMB10,000.

Furthermore, *Regulation on Housing Leasing* (《住房租賃條例》), which was promulgated by the State Council and came into effect on September 15, 2025, stipulates that the lessors shall file the housing lease contract with the real estate administration department at the location of the leased housing through the housing leasing management service platform or other means.

REGULATIONS ON FIRE PROTECTION AND ENVIRONMENTAL PROTECTION

Fire Control

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

Environmental Protection

The *Environmental Protection Law of the PRC* (《中華人民共和國環境保護法》) was promulgated and effective on December 26, 1989, and most recently amended on April 24, 2014. The *Environmental Protection Law* has been formulated for the purpose of protecting and improving both the living and the ecological environment, preventing and controlling pollution and other public hazards and safeguarding people’s health. According to the provisions of the *Environmental Protection Law*, in addition to other relevant laws and regulations of the PRC, the former Ministry of Environmental Protection (中華人民共和國環境保護部) and its local counterparts are responsible for administering and supervising environmental protection matters. Pursuant to the *Environmental Protection Law*, construction projects that have environmental impact shall be subject to environmental impact assessment.

Environment Impact Assessment

On October 28, 2002, the SCNPC promulgated the *Environmental Impact Assessment Law of PRC* (《中華人民共和國環境影響評價法》), which was latest amended on December 29, 2018. According to the *Environmental Impact Assessment Law*, the State Council implemented the

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environmental impact assessment to classify construction projects according to the impact of the construction projects on the environment. Pursuant to the *Interim Measures for Environmental Protection Acceptance of Completed Construction Projects* (《建設項目竣工環境保護驗收暫行辦法》) effective as of November 20, 2017 and the *Regulations on the Administration Construction Project Environmental Protection* (《建設項目環境保護管理條例》), which was revised on July 16, 2017 and implemented on October 1, 2017, after the completion of a construction project for which an environmental impact report or an environmental impact report form is required, the construction entity shall, according to standards and procedures prescribed by the environmental protection administrative authorities, conduct environmental protection completion acceptance check and compile an acceptance check report. A construction project for which an environmental impact report or an environmental impact report form is required shall not be put into production or use until the environmental protection completion acceptance check has been passed.

On November 30, 2020, Ministry of Ecology and Environment of the PRC (中華人民共和國生態環境部) promulgated the *Classified Administration Catalogue of Environmental Impact Assessments for Construction Project (2021 version)* (《建設項目環境影響評價分類管理名錄(2021年版)》), which became effective on January 1, 2021. According to the *Environmental Impact Assessment Law*, where a construction entity commenced construction prior to submission of the environmental impact report and environmental impact statement of the construction project or prior to resubmission of the environmental impact report and environmental impact statement, the ecological environment authorities at the county level or above shall order it to stop the construction, impose a fine of not less than 1% but not more than 5% of the overall investment amount for such construction project according to the seriousness and consequences of such violations, and order it to restore to the original status; and the person-in-charge and responsible personnel of the construction project shall be liable to administrative sanctions in accordance with laws.

Disposal of Hazardous Waste

Pursuant to the *Law on the Prevention and Control of Environmental Pollution Caused by Solid Waste of the PRC* (《中華人民共和國固體廢物污染環境防治法》), which was promulgated by the SCNPC in 1995 and was latest amended on April 29, 2020, entities generating hazardous waste shall store, utilize and dispose hazardous waste according to the relevant requirements of the state and environmental protection standards, and shall not dump or pile up hazardous waste without authorization. Furthermore, it is forbidden to entrust hazardous waste to entities without a permit for disposal, or else the competent ecological and environmental authorities shall order it to make rectification, impose fines, confiscate illegal gains, and in serious circumstance, order it to suspend business or close down upon the approval of the government authorities.

REGULATIONS ON EMPLOYMENT AND SOCIAL WELFARE

According to the *Labor Law of the PRC* (《中華人民共和國勞動法》) promulgated by the SCNPC on July 5, 1994 and 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》) promulgated by the SCNPC on June 29, 2007 and amended on December 28, 2012, and the *Implementing Regulations of the Labor Contract Law of the PRC* (《中華人民共和國勞動合同法實施條例》) promulgated by the State Council on September 18, 2008 and came into effect on the same day, employers must enter into written labor contracts with full-time employees. All employers shall comply with local minimum wage standards. Employers must establish a system for labor safety and sanitation, strictly comply with national standards, and provide relevant education to their employees. Violations of the *Labor Contract Law* and the *Labor Law* may result in fines, and in serious cases, other administrative and criminal liabilities may be incurred.

In accordance with the *Labor Contract Law* and the *Interim Provisions on Labor Dispatching* (《勞務派遣暫行規定》) promulgated by the Ministry of Human Resources and Social Security of the PRC (中華人民共和國人力資源和社會保障部) on January 24, 2014 and became effective on

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March 1, 2014, it specified the scope and proportion of the usage of the laborer, execution and performance of labor dispatch agreements and legal liability. An employer shall strictly control the number of dispatched laborers which shall not exceed 10% of the total number of its workers. An employer that is in violation thereof shall be ordered to make correction by the labor administrative department. Where no correction is made by the prescribed deadline, the employer shall be subject to a fine ranging from RMB5,000 to RMB10,000 for each dispatched worker.

The *Social Insurance Law of the PRC* (《中華人民共和國社會保險法》) (the “**Social Insurance Law**”) issued by the SCNPC in 2010 and latest amended on December 29, 2018, has established social insurance systems of basic pension insurance, basic medical insurance, work-related injury insurance, unemployment insurance and maternity insurance and has elaborated in detail the legal obligations and liabilities of employers who fail to comply with relevant laws and regulations on social insurance. According to the *Social Insurance Law and the Provisional Regulations on Collection and Payment of Social Insurance Premiums* (《社會保險費徵繳暫行條例》) promulgated by the State Council on January 22, 1999 and most recently amended on March 24, 2019 and became effective from the same date, enterprises shall register social insurance with local social insurance and pay or withhold relevant social insurance for or on behalf of its employees. Any employer that fails to make social insurance contributions may be ordered to rectify the non-compliance and pay the required contributions within a prescribed time limit and be subject to a late fee. If the employer still fails to rectify the failure to make the relevant contributions within the prescribed time, it may be subject to a fine ranging from one to three times the amount overdue.

In accordance with the *Regulations on the Administration of Housing Provident Funds* (《住房公積金管理條例》) promulgated by the State Council on April 3, 1999, and amended on March 24, 2002, and March 24, 2019, enterprises must register at the designated administrative centers and open bank accounts for depositing employees’ housing provident funds. Employers and employees are also required to pay and deposit housing provident funds, with an amount no less than 5% of the monthly average salary of the employee in the preceding year in full and on time. In case of overdue payment or underpayment by employers, orders for payment within a specified period will be made by the housing fund management center. Where employers fail to make payment within such period, enforcement by the people’s court will be applied. In case of failure to register and open accounts for depositing employees’ housing provident funds, the housing fund management center shall order employers to go through the formalities within a specified period, where employers fail to do such formalities within the prescribed time, a fine of not less than RMB10,000 nor more than RMB50,000 shall be imposed.

REGULATIONS ON TAXATION AND FOREIGN EXCHANGE

For more details, please refer to “Appendix III — Taxation and Foreign Exchange” in this document.

REGULATIONS ON OVERSEAS LISTINGS

Pursuant 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》) promulgated by the China Securities Regulatory Commission (中國證券監督管理委員會) (the “**CSRC**”) on February 17, 2023, which became effective on March 31, 2023, it regulates the overseas securities offering and listing activities of domestic companies, whether directly or indirectly: (1) where a PRC company carries out securities offering and listing in an overseas market, it shall go through the filing procedures with the CSRC and submit relevant information, and shall submit the initial filing materials within three working days of submitting the initial public offering and listing application documents; and (2) PRC companies that are directly or indirectly listing in overseas markets and intend to conduct subsequent offerings in the same overseas markets shall go through the filing procedures with the CSRC and report relevant information; they shall also submit the filing within three working days of the completion date of the subsequent offering. In addition, no overseas offering and listing shall be conducted under any of the following circumstances: (1) it is prohibited by the PRC laws, administrative regulations or relevant rules of the state to conduct overseas

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offering and listing; (2) overseas offering and listing may endanger national security as reviewed and determined by the relevant competent department of the State Council in accordance with the laws; (3) a domestic enterprise or its controlling shareholder or actual controller has committed a criminal crime in the last three years; (4) a domestic enterprise is under investigation according to the laws for being suspected of crimes or major violations of laws and regulations and no conclusion has yet been made thereof; or (5) there is a major dispute over ownership of the equity interests held by the controlling shareholder or the shareholder controlled by the controlling shareholder or the actual controller.

According to the *Provisions on Strengthening the Confidentiality and Archives Management of 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》) (the “**Archives Provisions**”) promulgated by the CSRC, the MOF, the State Secrets Bureau (中華人民共和國國家保密局) and the State Archives Administration of the PRC (中華人民共和國國家檔案局) on February 24, 2023 and implemented from March 31, 2023, domestic enterprises, securities companies and securities service institutions providing corresponding services shall strictly comply with the relevant requirements for confidentiality and archives management, establish and improve confidentiality and file management systems, and take the necessary measures to implement confidentiality and archives management responsibilities, in the direct or indirect overseas securities offering or listing activities by domestic enterprises. According to the Archives Provisions, during the process of domestic enterprises conducting offering and listing overseas, if documents or data involving state secrets or adversely affecting national security or the public interest need to be provided or publicly disclosed to relevant securities companies, securities service agencies, overseas regulatory authorities and other units and individuals, the relevant approval/filing and other regulatory procedures shall be completed.