PRC REGULATION

We are subject to a variety of PRC laws, rules and regulations across a number of aspects of our business. This section sets forth a summary of the most significant laws and regulations that are applicable to our current business activities within the territory of the PRC.

REGULATIONS ON PHARMACEUTICAL PRODUCT

Drug Regulatory Regime

The Drug Administration Law of the PRC (the "**Drug Administration Law**") (《中華人民共和國藥品管理法》) promulgated by the Standing Committee of the National People's Congress (the "**SCNPC**") in September 1984, last amended on August 26, 2019, and became effective on December 1, 2019, and the Implementation Regulations of the Drug Administration Law of the PRC (the "**Implementation Regulations**") (《中華人民共和國藥品管理法實施條例》) promulgated by the State Council in August 2002 and last amended on January 16, 2026 and was effective from May 15, 2026, have laid down the legal framework for the establishment and maintenance of pharmaceutical manufacturing and trading enterprises, as well as for the administration of pharmaceutical products including the development and manufacturing of new drugs. According to the Drug Administration Law and the Implementation Regulations, the PRC encourages the research and development of new drugs, and protects the legal rights and interests in the research and development of new drugs.

In 2017, the drug regulatory system entered a new and significant period of reform. The General Office of the State Council and the General Committee of the Communist Party of China jointly issued an Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices (the "**Innovation Opinions**") (《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》) in October 2017. According to the Innovation Opinions, institutions for drug clinical trials should establish an independent ethics committee, and 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 the clinical trial, other member units should recognize the review results of the leader unit and may not conduct repeated reviews. 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.

Research and development of new drugs

Pursuant to the Drug Administration Law, 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.

Pursuant to the Implementation Regulations, 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 in accordance with the Drug Administration Law. 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, and shall file such institution to undertake such clinical trial with the medical products supervisory and administrative department under the State Council and the administrative department of public health under the State Council. Before clinical trials for drugs to be conducted by institutions that will undertake such clinical trials, the subjects or their guardians shall be informed of the facts and their written consents shall be obtained.

On January 22, 2020, State Administration for Market Regulation (the "**SAMR**") issued the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) (the "**Measures for the Administration of Drug Registration**"), which become effective on July 1, 2020. The Measures for the Administration of Drug Registration shall apply to the development, registration, supervision and management activities carried out in the territory of the PRC for marketing of drugs. Pursuant to the Measures for the Administration of Drug Registration, an applicant shall complete relevant research work in terms of pharmacy, pharmacology and toxicology, and drug clinical trials, etc. before applying for drug marketing registration. A drug registration certificate shall be valid for five years. During the validity period, a holder of a drug registration certificate shall continue to ensure the safety, effectiveness and quality controllability of the marketed drug, and apply for re-registration of the drug six months prior to the expiry of the validity period. The Center for Drug Evaluation (the "**CDE**") is responsible for reviewing for accepted drug marketing authorization applications. Where the application is cleared after comprehensive review, the drug shall be approved for marketing and a drug registration certificate shall beissued. An applicant who has obtained a drug registration certificate shall be a drug marketing authorization holder.

Application for Clinical Trial

According to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the China Food and Drug Administration (currently known as the NMPA) on March 17, 2017, the decision on the approval of clinical trials of drugs shall be made by the CDE from May 1, 2017. According to the Measures for the Administration of Drug Registration, 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 a drug clinical trial. The CDE will organize pharmaceutical, medical, and other technicians to review the application and 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 for the clinical trial shall be deemed as approved. In accordance with Measures for the Administration of Drug Registration 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.

Measures for the Administration of Drug Registration further require 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 the 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 in September 2013. 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 the registration and first submission for disclosure of certain follow-up information before the first subject's enrollment in the trial. If the first submission for disclosure is not completed within one year after the approval, the applicant shall submit an explanation, and if the first submission disclosure is not completed within three years, the approval of the clinical trial application shall automatically become void. During the drug clinical trials, the applicant shall update registration information continuously and register information on the outcome of the drug clinical trial upon completion.

Conduct of Clinical Trial

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

Measures for the Administration of Drug Registration further require that 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 a corresponding plan for clinical drug trial, carry out clinical drug trial upon examination and with consent of the ethics committee, and submit a 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.

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 a new investigational drug has been approved, upon the completion of Phases I and II clinical trials and prior to Phase III clinical trial, the applicant shall submit the application for communication meetings to CDE to discuss with CDE the key technical questions, including the design of 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》) promulgated by the CDE on December 10, 2020, during the research and development periods and in the registration applications of, among others, innovative new drugs, the applicants may propose to conduct communication meetings with the CDE. The communication meetings can be classified into three types. Type I meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are held during the key research and development stages of drugs, mainly including meetings before submitting the clinical trial application, meetings upon the completion of Phase II trials and prior to Phase III trials, meetings before submitting the marketing application for a new drug, and meetings for risk evaluation and control. Type III meetings refer to other meetings not classified as Type I or Type II.

Good Clinical Practices

Clinical trials must be conducted in accordance with the Good Clinical Practice for Drug Trials (the "**GCP Rules**") (《藥物臨床試驗質量管理規範》) promulgated by NMPA and NHC on April 23, 2020, and effective on July 1, 2020, which stipulates the requirements for the procedures of conducting clinical trials, including preclinical 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 provide comprehensive and substantive requirements on the design and conduct of clinical trials in the PRC. In particular, the GCP Rules enhance the protection for study subjects and tighten the control over bio-samples collected under clinical trials.

According to the GCP Rules, a sponsor may entrust part or all of the work and tasks of its clinical trial to a CRO, but the sponsor remains ultimately responsible for the quality and reliability of clinical trial data and shall supervise the work undertaken by the CRO. The CRO shall implement quality assurance and quality control. The sponsor's entrustment of work to a CRO shall be conducted through a contract, and the requirements applicable to sponsors under the GCP Rules shall apply to CROs that undertake relevant work and tasks on behalf of the sponsor. Where a CRO subcontracts any of its tasks, written approval from the sponsor shall be obtained.

Trial Exemptions and Acceptance of Foreign Data

According to the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial) (《關於發佈國際多中心藥物臨床試驗指南(試行)的通告》) (the "**Multi-Center Clinical Trial Guidelines**"), promulgated by the NMPA on January 30, 2015 and effective from March 1, 2015, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicants plan to implement the international multi-center clinical trials in the PRC, the applicants shall comply with relevant laws and regulations, such as the Drug Administration Law, the Implementation Regulations and the Measures for the Administration of Drug Registration, execute the Good Clinical Practice (the "**GCP**"), make reference to universal international principles such as the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (the "**ICH**"), and comply with the laws and regulations of the countries involved in the international multi-center clinical trials. Where the applicants plan to use the data derived from the international multi-center clinical trials for approval of a drug registration in the PRC, it shall involve at least two countries, including China, and shall satisfy the requirements for clinical trials set forth in the Multi-Center Clinical Trial Guidelines and other related laws and regulations.

The PRC joined the ICH in 2017 and has accelerated the alignment of its drug registration regulatory regime with international standards and rapidly enhanced GCP compliance through measures such as revising the GCP Rules, improving the supporting regulatory framework, and strengthening regulatory supervision and inspections since then. The NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data (《接受藥品境外臨床試驗數據的技術指導原則》) in July 2018, as one of the implementing rules for the Innovation Opinions, which provides that overseas clinical data can be submitted for the drug marketing registration applications in China. According to the these guidance principles, sponsors may use the data of foreign clinical trials to support drug marketing registration in China, provided that sponsors must ensure the authenticity, integrity, accuracy and traceability of foreign clinical trial data and such data must be obtained consistent with the relevant requirements under the Good Clinical Practice of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (the "**ICH**"). Moreover, sponsors shall ensure the scientific design of overseas clinical trials, the compliance of clinical trial quality management system requirements, and the accuracy and integrity of statistical analysis of data. To ensure that the clinical trial design and statistical analysis of the data are scientific and reasonable, for the drugs with simultaneous R&D at home and abroad and forthcoming clinical trials in China, the sponsors may, prior to implementing registrational clinical trials, contact the CDE to ensure the compliance of registrational clinical trials' design with the essential technical requirements for drug registration in China. Sponsors must also comply with other relevant sections of Measures for the Administration of Drug Registration when applying for drug marketing registrations in China using foreign clinical trial data.

The NMPA now officially permits, and its predecessor agencies have permitted on a case-by-case basis in the past, drugs approved outside of China to be approved in China on a conditional basis without pre-approval clinical trials being conducted in China. Specifically, the NMPA and the NHC released the Procedures for Reviewing and Approval of Clinical Urgently Needed Overseas New Drugs (《臨床急需境外新藥審評審批工作程序》) in October 2018, which provide an expedited review and approval pathway drugs that have been approved within the last ten years in the United States, the European Union or Japan and that prevent or treat orphan diseases or prevent, or treat serious life-threatening illnesses for which there is

either no effective therapy in China, or for which the foreign-approved drug would have clear clinical advantages. Applicants will be required to establish a risk mitigation plan and may be required to complete trials in China after the drug has been marketed. The CDE has developed a list of qualifying drugs that meet the foregoing criteria.

The NMPA promulgated the Announcement on the Application of the ICH Guideline E6(R3): Good Clinical Practice (《關於適用<E6(R3)：藥物臨床試驗品質管制規範技術指導原則>國際人用藥品註冊技術協調會指導原則的公告》) (the "**E6(R3) Announcement**") on December 22, 2025, which became effective on March 31, 2026, and pursuant to which all drug clinical trials initiated on or after such date will be required to comply with the ICH E6(R3) principles. The CDE shall be responsible for providing technical guidance in connection with the implementation of this Announcement. Key changes that the E6(R3) Announcement may directly affect the execution and oversight of clinical development projects include, among others: (i) the establishment of a "quality by design" approach, under which sponsors are expected to identify and manage critical-to-quality factors early in the planning process, shifting the focus from retrospective inspection to proactive prevention; (ii) implementation of a risk-proportionate quality management principle, which requires that monitoring and oversight activities be tailored to the nature and level of risks to trial integrity and participant protection; (iii) enhanced data governance requirements and lifecycle-based management of computerized systems, which obligate responsible parties to ensure data traceability, data reliability, and appropriate validation of trial systems throughout their lifecycle; and (iv) clearer articulation of the sponsor's ultimate oversight responsibilities, with an emphasis on comprehensive evaluation and supervision of outsourced activities and third-party partners, including contract research organizations, that contribute to trial conduct or data generation.

New drug registration

Pursuant to the Measures for the Administration of Drug Registration, the measures shall apply to those engaging in drug development and registration as well as the supervision and management thereof for the purpose of the marketing of drugs within the territory of the PRC. Drug registration refers to an activity where an applicant for drug registration submits an application for drug clinical trial, marketing authorization and re-registration, among others, as well as supplementary application as per legal procedures and in line with relevant requirements, and the medical products administration conducts examinations in terms of safety, efficacy and quality controllability, etc. based on laws, regulations and existing scientific cognition to decide whether to approve the application. Drug registration shall be subject to classified registration administration in terms of traditional Chinese medicines, chemical drugs and biological products, etc.

In the process of drug registration, the drug supervisory and administrative department shall carry out on-site inspections and complaint-driven inspections on non-clinical research and clinical trials and production site inspection before granting the drug marketing approval to ensure the authenticity, accuracy and integrity of application materials.

The drug regulatory department may request the applicant or the drug research institution undertaking the drug experiments to repeat the experiments regarding the project, methods and data based on the application data. It may also entrust a drug testing institution or other drug research institutions to repeat the experiment or conduct methodological verification.

If an applicant entrusts another institution with drug researches or single experiment, testing or pilot manufacture of drug samples, it shall execute a contract with the entrusted party, and state such entrustment in the registration application. The applicant shall be responsible for the authenticity of the research data stated in the application materials.

Pursuant to the Announcement on Several Policies Pertaining to the Review and Approval of Drug Registration (《關於藥品註冊審評審批若干政策的公告》) (effective on November 11, 2015), in order to improve the quality and efficiency for the review and approval of drugs, the drug supervisory and administrative department adopts drug registration, review and approval policies, such as improving the approval standards for generic drugs, standardizing the review and approval of improved new drugs and optimizing the review and approval of clinical trial applications.

Marketing Authorization Holder Mechanism

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

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

The MAH shall establish a drug quality assurance system and be equipped with special personnel to take charge of quality management on drugs independently. The drug MAH 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 MAH is an overseas enterprise, its designated domestic enterprise shall perform the obligations of the MAH and jointly assume responsibilities of the MAH with the overseas enterprise.

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 Human Genetic Resources Management Office of the PRC further promulgated 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, promulgated by the State Council in May 2019, latest amended in March 2024 and came into effect in May 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 (the "**Biosecurity Law**") (《中華人民共和國生物安全法》) which became effective on April 15, 2021 and latest amended 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.

REGULATIONS ON FOREIGN INVESTMENT

The Company Law of the PRC (《中華人民共和國公司法》) (the "**Company Law**"), which was last amended on December 29, 2023 and became effective on July 1, 2024, regulates the establishment, operation and management of corporate entities in China and classifies companies into limited liability companies and limited companies by shares. The latest revisions mainly focus on including but not limited to refining the systems for the establishment and withdrawal of companies, optimizing the organizational structure of companies, modifying the capital system of companies, strengthening the responsibilities of controlling shareholders and the management level, strengthening the social responsibilities of companies. The Company Law applies to foreign-invested companies unless relevant laws provide otherwise.

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

In March 2019, the FIL was promulgated by National People's Congress (the "**NPC**") and came into effect on January 1, 2020. 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 "negative list", and the State Council shall promulgate or approve a list of special administrative measures for access of foreign investments. To ensure the effective implementation of the FIL, the Regulations on Implementing the Foreign Investment Law of the PRC (the "**Implementation Regulations**") (《中華人民共和國外商投資法實施條例》), was promulgated by the 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 SAMR promulgated the Measures on Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which came into effect in January 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 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 Measure on Reporting of Foreign Investment Information.

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

On September 6, 2024, the NDRC and the MOFCOM promulgated Negative List (2024 Edition), effective on November 1, 2024. The Negative List sets forth in a unified manner all special regulatory measures applicable to foreign investment access, including requirements relating to equity ratios and senior management personnel qualifications. It covers 11 industry sectors. For sectors not included in the Negative List, the principle of equal treatment between domestic and foreign investments shall apply in regulatory practice.

In December 2025, the NDRC and the MOFCOM promulgated Encouraged Catalog (2025 Edition), effective on February 1, 2026. Encouraged Catalog guides more foreign investment toward advanced manufacturing, modern services, high-tech industries, energy conservation and environmental protection, as well as central, western, and northeastern regions. The Encouraged Catalog comprises the Nationwide Catalogue of Industries for Encouraged Foreign Investment (including pharmaceutical outsourcing services (Contract Research Organization) and the Catalogue of Advantageous Industries for Foreign Investment in Central-Western, Northeastern Regions and Hainan Province, offering preferential policies for foreign investment within designated industries.

Our PRC legal advisors are of the view that we are principally engaged in clinical CRO services, which do not fall within any prohibited or restricted industries listed in the Special Administrative Measures for Foreign Investment Access (Negative List) (2024 Edition).

REGULATIONS ON OVERSEAS INVESTMENT

Pursuant to the Measures for the Administration of Overseas Investment (《境外投資管理辦法》) promulgated by MOFCOM and effective on October 6, 2014, MOFCOM and the commerce departments of provinces 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》), an enterprise in the territory of the People's Republic of China (the "investor") shall, in overseas investment, undergo the formalities for the confirmation or recordation, among others, of an overseas investment project (the "project"), report the relevant information, and cooperate in supervisory inspection. Sensitive projects conducted by investors directly or through overseas enterprises controlled by them shall be subject to 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), effective on March 1, 2018 to list the sensitive industries in detail.

REGULATIONS ON INFORMATION SECURITY AND DATA PROTECTION

According to the PRC Civil Code (《中華人民共和國民法典》), the personal information of an individual shall be protected by the law. Any organization or individual that needs to obtain personal information of others shall obtain such information legally and ensure the safety of such information, and shall not illegally collect, use, process or transmit personal information of others, or illegally purchase or sell, provide or make public personal information of others. In addition, the processing of personal information shall follow the principles of lawfulness, legitimacy and necessity.

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

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

On November 7, 2016, the SCNPC promulgated the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》), which became effective on June 1, 2017, last amended on October 28, 2025, and became effective on January 1, 2026, according to which, network operators shall fulfill their obligations to safeguard the security of the network when conducting business and providing services. Those who build, operate or provide services through networks shall take technical measures and other necessary measures according to laws, regulations and compulsory national standards to safeguard the safe and stable operation of the networks, respond to network security incidents effectively, prevent illegal and criminal activities, and maintain the integrity, confidentiality and usability of network data. The network operator shall not collect personal information irrelevant to the services it provides or collect or use the personal information in violation of the provisions of laws and regulations or agreements concluded with its users.

On December 28, 2021, the Cyberspace Administration of China (the "**CAC**"), jointly with 12 other administrative authorities, promulgated the revised Measures for Cybersecurity Review (《網絡安全審查辦法》) (the "**MCR**"), which became effective on February 15, 2022. According to the MCR, (i) CIIO that the purchase of cyber products and services or network platform operators that engage in data processing activities that affects or may affect national security shall be subject to the cybersecurity review by the Cybersecurity Review Office, the department which is responsible for the implementation of cybersecurity review under the CAC; (ii) network platform operators with personal information of more than one million users that seek for listing in a foreign country are obliged to apply for a cybersecurity review by the Cybersecurity Review Office; and (iii) the relevant regulatory authorities may initiate cybersecurity review if such regulatory authorities determine that the issuer's network products or services, or data processing activities affect or may affect national security. On September 24, 2024, the State Council promulgated the Administration Regulations on Cyber Data Security (the "**Data Security Regulations**") (《網絡數據安全管理條例》), which came into effect on January 1, 2025. The Data Security Regulations reiterate and refine the general regulations for cyber data processing activities, rules of personal information protection, important data security protection, cyber data cross-border transfer management, and the responsibilities of online platform service providers.

On July 7, 2022, the CAC promulgated the Measures for the Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》) (the "**Security Assessment Measures**"), which became effective on September 1, 2022. The Security Assessment Measures provide four circumstances, under any of which data processors shall, through the local cyberspace administration at the provincial-level, apply to the national cyberspace administration for security assessment of cross-border data transfer. These circumstances include: (i) where the important data are transferred to an overseas recipient; (ii) where the personal information is transferred to an overseas recipient by a CIIO or a data processor that has processed personal information of more than one million individuals; (iii) where a data processor provides personal information to an overseas recipient if such data processor has already provided overseas the personal information of 100,000 individuals or sensitive personal information of 10,000 individuals in total since January 1 of the preceding year; or (iv) other circumstances under which security assessment of outbound data transfer is required as prescribed by the national cyberspace administration. In addition, on February 22, 2023, the Measures for the Administration of Standard Contractual Clauses for the Cross-Border Transfer of Personal Information (《個人信息出境標準合同辦法》), or the SCC Measures, were promulgated by the CAC, which took effect on June 1, 2023. The SCC Measures attach the

prescribed template for the standard contract on the outbound transfer of personal information that could be used as an available option to satisfy the condition for cross-border transfer of personal information under Article 38 of the Personal Information Protection Law.

On March 22, 2024, the CAC promulgated the Provisions on Promoting and Regulating Cross-Border Data Flows (《促進和規範數據跨境流動規定》), effective on the date of promulgation. The provisions provide several exemptions from undergoing data security assessment, obtaining personal information protection certification or entering into standard contract for outbound transfer of personal information for businesses. 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.

REGULATIONS ON INTELLECTUAL PROPERTY

In terms of international conventions, the PRC has entered into (including but not limited to) the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Paris Convention for the Protection of Industrial Property, the Madrid Agreement Concerning the International Registration of Marks, and the Patent Cooperation Treaty.

Patent

In accordance with the Patent Law of the PRC (《中華人民共和國專利法》), promulgated by the SCNPC, which was last amended in October 2020 and became effective 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》), which were promulgated by the State Council on June 15, 2001 and last amended on December 11, 2023 and became effective on January 20, 2024, patents are divided into three categories: invention patents, design patents, and utility model patents. An invention or utility model for which a patent is to be granted shall be novel, inventive and practically applicable. The China National Intellectual Property Administration shall be responsible for accepting, examining and approving applications for patents. The duration of invention patent rights, design patent rights, and utility model patent rights shall be 20 years, 15 years, and 10 years, respectively, all calculated from the date of application. Implementation of a patent without the authorization of the patent holder shall constitute an infringement of patent rights, and the infringer shall be held liable for compensation to the patent holder and may be subject to fines or even criminal liabilities.

Trade Secrets

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) (the "**Anti-Unfair Competition Law**"), as last amended on June 27, 2025, and became effective on October 15, 2025, the term "trade secrets" refers to technical, operational or other commercial information that is unknown to the public and of commercial value and for which the right holder has taken corresponding confidentiality measures. Under the Anti-Unfair Competition Law, business persons are prohibited from infringing others' trade secrets by: (i) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (ii) disclosing, using, or permitting others to use the trade secrets obtained illegally under item (i) above; (iii) disclosing, using, or allowing another person to use a trade secret in its possession, in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; or (iv) abetting, inducing or aiding another person to

acquire, disclose, use, or allow another person to use the trade secret of the right holder in violation of his or her confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known of the aforementioned illegal conduct but nevertheless obtains, uses, or allows another person to use the trade secret of others, the third party may be deemed to have committed a misappropriation of the others' trade secrets. Regulatory authorities may stop any illegal activities and fine infringing parties.

Trademark

According to the Trademark Law of the PRC (《中華人民共和國商標法》) most recently amended on April 23, 2019, and effective from November 1, 2019, and the Implementation Regulation of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》), most recently amended on April 29, 2014, and effective from May 1, 2014, registered trademarks are granted a term of ten years which may be renewed for consecutive ten-year periods upon request by the trademark owner. Trademark license agreements must be filed with the Trademark Office for record, and the Trademark Law of the PRC has adopted a "first-to-file" principle with respect to trademark registration. Conducts that shall constitute an infringement of the exclusive right to use a registered trademark include but are not limited to using a trademark that is identical with or similar to a registered trademark on the same or similar goods without the permission of the trademark registrant. The infringing party will be ordered to stop the infringement act immediately and may be imposed a fine. The infringing party may also be held liable for the right holder's damages, which will be equal to gains obtained by the infringing party or the losses suffered by the right holder as a result of the infringement, including reasonable expenses incurred by the right holder for stopping the infringement. Trademark license agreements must be filed with the Trademark Office. The licensor shall supervise the quality of the commodities on which the trademark is used, and the licensee shall guarantee the quality of such commodities.

Copyright

According to the Copyright Law of the PRC (《中華人民共和國著作權法》), promulgated by the SCNPC, which was last amended in November 2020, and its related Implementing Regulations, Chinese citizens, legal persons, or other organizations shall, whether published or not, own copyright in their works, which include, among others, works of literature, art, natural science, social science, engineering technology, and computer software. Copyright owners of protected works enjoy personal rights and property rights with respect to publication, authorship, alteration, integrity, reproduction, distribution, lease, exhibition, performance, projection, broadcasting, dissemination via information network, production, adaptation, translation, compilation, and other rights shall be enjoyed by the copyright owners.

Domain Names

The Measures on Administration of Internet Domain Names (《互聯網域名管理辦法》) was promulgated by the MIIT in 2017, which adopts a "first to file" rule to allocate domain names to applicants, and provides that the MIIT shall supervise the domain name services nationwide and publicize the PRC domain name system. After completion of the registration procedures, the applicant will become the holder of the relevant domain name.

REGULATIONS ON LEASING

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

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

REGULATIONS ON EMPLOYMENT AND SOCIAL WELFARE

Employment

Pursuant 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 latest amended on December 29, 2018 and 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 latest amended on December 28, 2012 and came into effect on July 1, 2013, employers shall execute written labor contracts with full-time employees. All employers shall comply with local minimum wage standards. Employers shall establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, working location, occupational hazards, and status of safe production as well as remuneration and other conditions.

Social Insurance

The Social Insurance Law of the PRC (the "**Social Insurance Law**") (《中華人民共和國社會保險法》) 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 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. Pursuant to the Interpretation II of the Supreme People's Court of Issues Concerning the Application of Law in the Trial of Labor Dispute Cases (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)》) enacted by the Supreme People's Court on July 31, 2025 and implemented on September 1, 2025, any agreement between an employer and an employee or any commitment made by an employee to the employer stating that social insurance premiums need not be paid shall be deemed invalid by the people's court. If an employer fails to pay social insurance premiums in accordance with the law, and the employee requests to terminate the labor contract and claims economic compensation pursuant to Article 38 Paragraph 3 of the Labor Contract Law, the people's court shall support such claims in accordance with the law. In the circumstances described in the preceding paragraph, if the employer subsequently pays the social insurance premiums in accordance with the law and requests the employee to return the compensation already paid for the social insurance premiums, the people's court shall support such requests in accordance with the law.

Housing Provident Fund

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 latest amended on March 24, 2019, employers are required to make contribution to housing provident funds for their employees. Where an employer fails to pay up housing provident funds, the housing provident fund administration center may order it to make payment within a prescribed time limit. If the employer still fails to do so, the housing provident fund administration center may apply to the court for compulsory enforcement of the unpaid amount.

REGULATIONS ON FOREIGN EXCHANGE

Regulations relating to Foreign Currency Exchange

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

The SAFE issued the Circular on Reforming of the Management Method of the Settlement of Foreign Currency Capital of Foreign-Invested Enterprises (the "**SAFE Circular 19**") (《關於改革外商投資企業外匯資本金結匯管理方式的通知》) on March 30, 2015, and latest amended on March 23, 2023. The SAFE Circular 19 expands a pilot reform of the administration of the settlement of the foreign exchange capitals of foreign-invested enterprises nationwide. In June 2016, SAFE further promulgated the Circular on the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange

Settlement Management Policy of Capital Account (the "**SAFE Circular 16**") (《關於改革和規範資本項目結匯管理政策的通知》), which was partially amended on December 4, 2023, and among other things, amends certain provisions of SAFE Circular 19. Pursuant to SAFE Circular 19 and SAFE Circular 16, the flow and use of the Renminbi capital converted from foreign currency-denominated registered capital of a foreign-invested company is regulated such that Renminbi capital may not be used for business beyond its business scope or to provide loans to persons other than affiliates unless otherwise permitted under its business scope.

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

Regulations relating to Stock Incentive Plans

Pursuant to the Circular on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly Listed Company (the "**SAFE Circular 7**") (《關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》), promulgated by SAFE in February 2012, employees, directors, supervisors, and other senior management participating in any share incentive plan of an overseas publicly-listed company who are PRC citizens or who are non-PRC citizens residing in China for a continuous period of not less than one year, subject to a few exceptions, are required to register with SAFE through a domestic agency. Moreover, an overseas-entrusted institution must be retained to handle matters in connection with the exercise or sale of stock options and the purchase or sale of shares and interests.

REGULATIONS ON TAXATION

Enterprise Income Tax

According to the EIT Law of the PRC (《中華人民共和國企業所得稅法》), which was promulgated by the SCNPC and was latest amended on December 29, 2018, and the Regulation on the Implementation of the EIT Law of the PRC (《中華人民共和國企業所得稅法實施條例》), which was promulgated by the State Council and was latest amended in December 2024 and effective from January 2025, a uniform 25% enterprise income tax rate is imposed on both foreign invested enterprises and domestic enterprises, except where tax incentives are granted to special industries and projects. The enterprise income tax rate is reduced to 20% for qualifying small low-profit enterprises. Key high-tech enterprises that are supported by the PRC's government may enjoy a reduced tax rate of 15% for enterprise income tax.

Value-added Tax

Pursuant to the Value-Added Tax Law of the PRC (《中華人民共和國增值税法》), which was promulgated by the SCNPC on December 25, 2024, came into effect on January 1, 2026 and repealed the Provisional Regulations on Value-added Tax of the PRC (《中華人民共和國增值税暫行條例》) simultaneously, all entities and individuals (including privately or individually-owned business) that sell goods, services, intangible assets, immovables, and import goods in the PRC shall be taxpayers of value-added tax and shall pay value-added tax. Unless otherwise provided, the import tax rate for the sales of goods, processing, repair and maintenance services, and leasing services of tangible movables is 13%; the tax rate for the sales of transportation, postal, basic telecommunications, construction, immovables leasing services, sales of immovables, transfer of land use rights, and sales or imports of goods prescribed by law is 9%; the tax rate for the sales of services and intangible assets is 6%.

REGULATIONS ON OVERSEAS LISTINGS

Overseas Listings

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 (the **"Overseas Listing Trial Measures"**), where a domestic company seeks overseas securities issuance and listing, the issuer shall file with the CSRC in accordance with the Overseas Listing Trial Measures. If an issuer procures an overseas initial public offering or listing, it shall file with the CSRC within three (3) business days after submitting application documents for overseas securities issuance and listing. According to the Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) jointly issued by the CSRC and other departments on February 24, 2023 and effective on March 31, 2023, in the overseas offering and listing activities of domestic enterprises, domestic enterprises, and securities companies and securities service institutions that provide corresponding services shall strictly comply with the applicable laws and regulations of the PRC and satisfy the requirements of these Provisions, enhance the legal awareness of safeguarding state secrets and strengthening archives administration, establish and improve the confidentiality and archives work system, and take necessary measures to fulfill the confidentiality and archives administration obligations, and shall not divulge state secrets or work secrets of state organs, or harm the interests of the state or the public.

Our PRC legal advisors are of the view that we comply with the filing requirements stipulated in the Trial Measures for the Administration of Overseas Issuance and Listing of Securities by Domestic Enterprises and the supporting regulatory guidelines. There are no circumstances that would prohibit our overseas issuance and listing.