I. REGULATIONS RELATING TO PHARMACEUTICAL PRODUCT

(I) Drug Regulatory Regime

The Drug Administration Law of the People's Republic of China (《中華人民共和國藥品管理法》) (the "**Drug Administration Law**") promulgated by the Standing Committee of the National People's Congress (the "**NPCSC**") in September 1984, latest amended in August 2019 and effective from December 1, 2019, and the Regulations for the Implementation of the Drug Administration Law of the People's Republic of China (《中華人民共和國藥品管理法實施條例》) (the "**Regulations for the Implementation of the Drug Administration Law**") promulgated by the State Council in August 2002, last amended on January 16, 2026 and effective from May 15, 2026 have jointly established the legal framework for drug administration in China. The Drug Administration Law applies to entities and individuals engaged in the research, production, operation, use, and supervision and management of drugs within the territory of the People's Republic of China. It regulates and provides a framework for the management of drug preparations by pharmaceutical manufacturers, drug distributors, and medical institutions, as well as for the development, research, registration, production, operation, pricing, advertising, reserve, and supply of drugs. The Regulations for the Implementation of the Drug Administration Law also set out detailed rules for the implementation of the Drug Administration Law.

(II) Regulations on CAR-T Cell Therapy

China employs distinct regulatory frameworks for 'technology' and 'medicinal products' within the CAR-T cell therapy sector. Clinical research and translational applications of medical technologies fall under the purview of the National Health Commission (the "**NHC**"), whilst medicinal product approvals are overseen by the National Medical Products Administration (the "**NMPA**").

Medical technologies regulated by the NHC

On March 2, 2009, the former Ministry of Health promulgated the Administrative Measures for the Clinical Application of Medical Technologies (《醫療技術臨床應用管理辦法》) (effective on May 1, 2009 and repealed on January 22, 2024), which categorized medical technologies into three classes, with the Ministry responsible for managing the clinical application of Class III medical technologies. On May 1, 2009, the former Ministry of Health promulgated the Catalogue of the First Batch of Class III Medical Technologies Permitted for Clinical Application (《首批允許臨床應用的第三類醫療技術目錄》), authorizing the clinical application of autologous immune cell therapy technologies classified as Class III medical technologies.

Pursuant to the Notice on Cancelling the Approval Process for the Clinical Application of Class III Medical Technologies (《關於取消第三類醫療技術臨床應用准入審批有關工作的通知》) issued by the National Health and Family Planning Commission on June 29, 2015, and its annex Restricted Medical Technologies for Clinical Application (2015 Edition) (《限制臨床應用的醫療技術(2015版)》), the approval requirement for the clinical application of Class III medical technologies has been abolished. Autoimmune cell therapy technologies shall be conducted in accordance with relevant regulations governing clinical research. Pursuant to the Administrative Measures for Clinical Research Projects Conducted by Healthcare Institutions (《醫療衛生機構開展臨床研究項目管理辦法》) issued by the National Medical Products Administration, the National Health Commission, and the National Administration of Traditional Chinese Medicine on October 16, 2014, clinical research shall be subject to a project approval review system within healthcare institutions. Clinical research projects approved by the healthcare institution may only be conducted within that institution. Within 30 days of approving a clinical research project, the healthcare institution shall file the project with the health and family planning administrative department that issued its medical institution practice licence.

The State Council promulgated the Regulations on the Management of Clinical Research and Clinical Translation of New Biomedical Technologies (《生物醫學新技術臨床研究和臨床轉化應用管理條例》) on September 28, 2025, with implementation scheduled for May 1, 2026. Activities involving the manipulation of *ex vivo* cells, tissues, organs, or similar materials for subsequent implantation or administration into the human body to test new biomedical technologies shall comply with these Regulations to assess their safety and efficacy and to define their scope of application, operational procedures, and technical requirements.

New drug approvals regulated by the NMPA

According to the response issued by the NHC on August 26, 2020 to Proposal No. 4371 submitted to the Third Session of the 13th National People's Congress, cell-based preparations such as immune cells possess distinct pharmaceutical attributes. The national drug regulatory authorities have established supporting policies for the approval of such preparations as medicinal products, enabling their rapid and widespread application following authorization.

Pursuant to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the "**Registration Measures**"), which was promulgated on February 28, 2005, latest amended on January 22, 2020 and effective from July 1, 2020, drug registration shall be categorised and administered according to traditional Chinese medicines, chemical drugs, and biological products. Immune cell-related products fall under the category of biological products.

Over the years, NMPA (formerly the China Food and Drug Administration) and the Center for Drug Evaluation ("**CDE**") have issued a series of guidelines to provide direction for the pharmaceutical development, clinical and non-clinical studies of cell therapy products, including Technical Guidance Principles for the Research and Evaluation of Cell Therapy Products (Trial) (《細胞治療產品研究與評價技術指導原則(試行)》), Key Considerations for Pharmaceutical Research and Submission Documentation for Cell Therapy Products Applying for Clinical Trials (《細胞治療產品申請臨床試驗藥學研究和申報資料的考慮要點》), Technical Guidance Principles for Clinical Trials of Immune Cell Therapy Products (Trial Implementation) (《免疫細胞治療產品臨床試驗技術指導原則(試行)》), Technical Guidance on Non-clinical Studies and Evaluation of Gene Therapy Products (Trial Implementation) (《基因治療產品非臨床研究與評價技術指導原則(試行)》), Technical Guidance Principles for Pharmaceutical Research and Evaluation of *In Vitro* Gene Modification Systems (Trial Implementation) (《體外基因修飾系統藥學研究與評價技術指導原則(試行)》) and Guiding Principles for Pharmaceutical Research and Evaluation of Immunological Cell Therapy Products (《免疫細胞治療產品藥學研究與評價技術指導原則》).

(III) Non-Clinical Research

The non-clinical safety evaluation study for drugs for the purpose of applying for drug registration shall be conducted in accordance with the Good Laboratory Practice for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》), which was promulgated by the former China Food and Drug Administration in August 2003, latest amended in July 2017 and effective from September 1, 2017. In accordance with the Administrative Measures for the Certification of Good Laboratory Practice for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》) issued by the NMPA in January 2023 and effective from July 1, 2023, institutions within the territory of the People's Republic of China intending to conduct non-clinical safety evaluation studies for drug registration applications shall apply for certification of Good Laboratory Practice for Non-clinical Laboratory Studies.

According to the Regulations on the Biosafety Management of Pathogenic Microorganism Laboratories (《病原微生物實驗室生物安全管理條例》) promulgated and implemented on November 12, 2004, latest amended on December 6, 2024 and effective from January 20, 2025, the State implements a classification management system for pathogenic microorganisms and laboratories. Pathogenic microorganism experiments must be conducted in laboratories of the corresponding level. The level of a laboratory conducting such experiments shall not be lower than the level required for that specific activity as specified in the pathogenic microorganism catalog.

(IV) Investigator-initiated Trial

Under Chinese law, healthcare institutions may conduct investigator-initiated clinical trials ("**IIT**"), which are not undertaken for the purpose of product registration, such as for pharmaceuticals or medical devices.

The Administrative Measures for Clinical Research Projects Conducted by Healthcare Institutions (《醫療衛生機構開展臨床研究項目管理辦法》), promulgated on October 16, 2014 by the National Health and Family Planning Commission, the former China Food and Drug Administration, and the State Administration of Traditional Chinese Medicine, stipulates various management matters concerning the organisation, project initiation, finance, implementation, and supervision of clinical research within healthcare institutions.

The NHC, the National Administration of Traditional Chinese Medicine, and the National Centre for Disease Control and Prevention issued the Administrative Measures for Investigator-Initiated Clinical Research in Healthcare Institutions (《醫療衛生機構開展研究者發起的臨床研究管理辦法》) on September 18, 2024. The Measures came into effect on October 1, 2024. They stipulate that during clinical research, healthcare institutions and their investigators must possess the requisite capabilities and necessary financial safeguards, while fully respecting research participants' rights to informed consent and autonomous choice. The Measures further categorize clinical research into observational studies and interventional studies, and elaborate on the fundamental principles and various management requirements for clinical research.

(V) 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 former China Food and Drugs Administration on March 17, 2017 and effective from May 1, 2017, the decision on the approval of clinical trials of drugs can be made by the CDE from May 1, 2017. According to the Registration Measures, 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 completing studies supporting the drug clinical trials, such as pharmaceutical and pharmacological/toxicological research, applicants submitting an application for drug clinical trials shall provide relevant research data in accordance with the requirements for declaration materials. The CDE shall review the application and decide whether or not it agrees to approve the clinical trial application of drugs within 60 days from the date of accepting the application and notify the applicant of the approval results through the website of the CDE. If the CDE fails to do so, the clinical trial application shall be deemed as approved, and the applicant may proceed with the drug clinical trial according to the submitted protocol.

The Registration Measures further stipulate that the applicant shall register information such as the drug clinical trial protocol on the Drug Clinical Trial Information Platform before commencing drug clinical trials. During the clinical trial of drugs, the applicant shall continuously update registration information, and register information on the outcome of the drug clinical trial upon completion of the drug clinical trial.

The NMPA issued the Announcement on Optimizing Matters Related to the Review and Approval of Clinical Trials for Innovative Drugs (《關於優化創新藥臨床試驗審評審批有關事項的公告》) on September 9, 2025. It stipulates that for clinical trial applications of eligible Class 1 innovative drugs of traditional Chinese medicine, chemical drugs, or biological products, the review and approval process shall be completed within 30 working days after acceptance.

(VI) Conducting Clinical Trials

After obtaining clinical trial approval, the applicant shall choose qualified drug clinical trial institutions to conduct clinical trials.

For drugs for which clinical trials were approved to be conducted, if the sponsor intends to add new indications (or major functions) or intends to conduct combination drug therapy with other drugs, the applicant shall submit a new application for drug clinical trial. New drug clinical trials may only be initiated after approval. During drug clinical trials, if safety issues or other risks are identified, the drug clinical trial sponsor shall promptly adjust the clinical trial protocol, suspend or terminate the clinical trial, and report to the CDE. If necessary, the drug regulatory authority may order the adjustment of the clinical trial protocol, or the suspension or termination of the clinical trial.

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》) issued by NMPA in January 2017 provides technical guidelines for applicants and investigators in formulating overall research and development strategy of drugs and separate clinical trial and provides references for pharmaceutical technology assessment.

According to the Announcement on Adjusting the Review and Approval Procedures for Drug Clinical Trials (《關於調整藥物臨床試驗審評審批程序的公告》), if a new drug clinical trial has been approved to be carried out, after the completion of Phase I and Phase II clinical trials and before the implementation of Phase III clinical trials, the applicant shall submit an application for a communication meeting to the CDE to discuss with the CDE on key technical issues including the design of the Phase III clinical trial. The applicant can also apply for communication on key technical issues at different stages of clinical research and development.

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》) issued by the NMPA on and effective from December 10, 2020 and amended in April 2026, during the technical review process of drug research and development and registration applications, the applicant may communicate with the review team of the CDE regarding key technical issues not covered by the current drug research and development and evaluation guidelines. Regarding the clinical development of cell and gene therapy products, the CDE issued the Technical Guidance Principles for Clinical Communication on Cell and Gene Therapy Products (《細胞和基因治療產品臨床相關溝通交流技術指導原則》) on December 28, 2023.

Clinical trials shall be conducted in accordance with the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) promulgated by the NMPA and the NHC on April 23, 2020, and effective from July 1, 2020. The Good Clinical Practice for Drug Trials sets forth detailed requirements for the design and conduct of clinical trials, specifying matters such as the responsibilities, composition and operation of ethics committees, the responsibilities of investigators, clinical trial institutions and sponsors, clinical trial protocol design, the preparation of investigator brochures, and the management of essential documents. The Good Clinical Practice for Drug Trials was revised in May 2026, with such revisions taking effect on 1 September 2026.

(VII) New Drug Registration

Pursuant to the Registration Measures, an applicant may file an application for drug marketing authorization, after the completion of pharmaceutical, pharmacological and toxicological studies, clinical trials of drugs and other studies, determination of quality standards, the verification of commercial scale production process, and preparations to receive the check and inspection for drug registration. The NMPA shall subsequently decide whether to approve the application based on applicable laws and regulations. New drugs can only be manufactured and sold in the Chinese market after the applicant obtains marketing authorization. The validity period for a drug registration certificate is five years. During the validity period of the drug registration certificate, the holder shall continuously ensure the safety, efficacy, and quality controllability of the marketed drug and shall apply for drug re-registration within six months prior to the expiration of its validity.

According to the Regulations for the Implementation of the Drug Administration Law, the State shall afford protection to undisclosed test data and other data independently obtained by MAHs of medicinal products containing new chemical entities and other eligible medicinal products. No person may engage in unfair commercial exploitation of such undisclosed test data and other data. The term of protection for such data shall not exceed six (6) years, commencing on the date of registration of the relevant medicinal product. During the protection term, where any other applicant applies for medicinal product registration by relying on such data without the consent of the relevant MAH, such application shall be rejected; provided, however, that this provision shall not apply if such other applicant submits independently-obtained data.

On July 7, 2020, the NMPA promulgated and implemented 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 Preferential Evaluation and Approval Procedures for Drug Marketing Authorization (Trial) (《藥品上市許可優先審評審批工作程序(試行)》), clearly stipulating the applicable working procedures for drugs that meet their respective eligibility criteria.

(VIII) Marketing Authorization Holder System

Pursuant to the Drug Administration Law (《藥品管理法》), the State implements the drug marketing authorization holder system for drug management. A drug marketing authorization holder refers to an enterprise or drug research institution that obtains a drug registration certificate. The drug marketing authorization holder shall, in accordance with the provisions of this Law, bear responsibility for the drug's non-clinical research, clinical trials, production and operation, post-market studies, adverse event monitoring and reporting, and handling.

Except as otherwise provided by laws and regulations, the marketing authorization holder may manufacture drugs themselves or entrust drug manufacturing enterprises with the production. Similarly, the marketing authorization holder may sell drugs themselves or entrust drug distribution enterprises with sales.

(IX) Gathering, Collection and Filing of Human Genetic Resources

On June 10, 1998, the Ministry of Science and Technology ("**MST**") and the former Ministry of Health (now known as NHC) issued and implemented the Interim Measures for the Management of Human Genetic Resources (《人類遺傳資源管理暫行辦法》), which stipulates the requirements that activities such as the gathering, collection, research, development, sale, export, and exit of China's human genetic resources shall comply with. They also specify that any international cooperation project involving China's human genetic resources requires the Chinese collaborating unit to complete the approval procedures.

The Interim Measures for the Management of Human Genetic Resources was replaced by the Regulations on the Management of Human Genetic Resources of the People's Republic of China (《中華人民共和國人類遺傳資源管理條例》) ("**Regulations on the Management of Human Genetic Resources**") promulgated by the State Council in May 2019, most recently revised in March 2024, and effective from May 2024. According to the Regulations on the Management of Human Genetic Resources, international cooperative clinical trials utilizing China's human genetic resources conducted at clinical institutions, which do not involve the exit of human genetic resource materials and aim to obtain marketing authorization for relevant drugs and medical devices in China, do not require approval. However, before commencing the clinical trials, the collaborating parties shall file the types, quantities, and intended uses of the human genetic resources to be used with the competent health authority of the State Council for record. The MST promulgated the Implementation Rules for the Regulations on the Management of Human Genetic Resources (《人類遺傳資源管理條例實施細則》) in May 2023, which became effective on July 1, 2023 and further clarify that human genetic resource information does not include clinical data, imaging data, proteomic data and metabolomic data.

On October 17, 2020, the NPCSC promulgated Biosecurity Law of the People's Republic of China (《中華人民共和國生物安全法》) ("**Biosecurity Law**"), which became effective on April 15, 2021 and was most recently revised on April 26, 2024. As per the Biosecurity Law, engaging in the following activities requires approval from the competent health authority of the State Council: (i) collecting human genetic resources of important genetic families or specific areas in China, or collecting human genetic resources of which the types and quantities are subject to provisions of the competent health department under the State Council, (ii) preserving China's human genetic resources, (iii) using China's human genetic resources to carry out international scientific research cooperation, or (iv) transporting, mailing, and carrying China's human genetic resource materials out of the country.

(X) Product Liability

According to the Product Quality Law of the People's Republic of China (《中華人民共和國產品質量法》) revised by the NPCSC on and effective from December 29, 2018, producers and sellers shall establish and improve internal product quality management systems, strictly implement post quality specifications, quality responsibilities, and corresponding assessment methods. Producers and sellers shall bear product quality responsibilities in accordance with the provisions of this Law.

Pursuant to the Civil Code of the People's Republic of China (《中華人民共和國民法典》) ("**Civil Code**") promulgated by the NPC on May 28, 2020 and effective from January 1, 2021, where a patient suffers damage due to defects in drugs, he may seek compensation from the drug marketing authorization holder, the manufacturer or also from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution, after it has made the compensation, shall have the right to recover the compensation from the liable drug marketing authorization holder or the manufacturer.

II. REGULATIONS RELATING TO THE MANUFACTURING, DISTRIBUTION OF DRUGS

(I) Drug Manufacturing Permit

According to the Drug Administration Law and the Regulations for the Implementation of the Drug Administration Law, any entity engaging in drug manufacturing activities shall obtain approval from the drug supervision and administration department under the people's government of the province, autonomous region, or municipality directly under the Central Government at its location, and obtain a Drug Manufacturing Permit. No drug shall be manufactured without a Drug Manufacturing Permit. The validity period of the Drug Manufacturing Permit is 5 years. Upon the expiration of the validity period, if continued production of drugs is required, the permit holder shall apply for the renewal of the Drug Manufacturing Permit within 6 months before the expiration of the permit's validity period, in accordance with the regulations of the drug supervision and administration department of the State Council.

(II) Good Manufacturing Practice

On November 29, 2019, the NMPA issued the Announcement on Issues Pertaining to the Implementation of the Drug Administration Law of the People's Republic of China (《關於貫徹實施<中華人民共和國藥品管理法>有關事項的公告》), confirming that effective from December 1, 2019, Good Manufacturing Practice certificate ("GMP certification") would be canceled, and drug GMP certificates would no longer be issued. However, in accordance with the Drug Administration Law, entities engaged in drug manufacturing activities shall still abide by the Good Manufacturing Practice ("GMP"), establish and improve a drug quality management system, and ensure that the entire process of drug manufacturing continuously meets statutory requirements.

The NMPA issued the Measures for the Administration of Drug Inspection (Trial) (《藥品檢查管理辦法(試行)》) on May 24, 2021, which was revised and implemented on July 19, 2023. It stipulates that if drug manufacturing enterprises apply for a Drug Manufacturing Permit for the first time, on-site inspections shall be conducted in accordance with the relevant contents of GMP. For applications for the reissuance of a Drug Manufacturing Permit, the review shall be conducted based on the principle of risk management, taking into account the enterprise's compliance with drug administration laws and regulations, GMP, and the operation of its quality system. GMP compliance inspections may be conducted when necessary.

Regarding the production and quality management of cell therapy products, the Center for Drug Evaluation of the NMPA issued the Guidelines for the Production Quality Management of Cell Therapy Products (Trial) (《細胞治療產品生產質量管理指南(試行)》) on October 28, 2022, and the Guidelines for the Inspection of Cell Therapy Product Manufacturing (《細胞治療產品生產檢查指南》) on January 13, 2025.

(III) Contract Manufacturing of Drugs

According to the Measures on the Supervision and Administration of the Manufacturing of Drugs (《藥品生產監督管理辦法》), issued by the State Administration for Market Regulation on December 11, 2002, and most recently revised on January 22, 2020, which revision became effective from July 1, 2020, a drug marketing authorization holder may entrust a qualified drug manufacturing enterprise to manufacture drugs.

The Announcement of the National Medical Products Administration on Strengthening the Supervision and Management of Drug Marketing Authorization Holders' Entrusting Production (《國家藥監局關於加強藥品上市許可持有人委託生產監督管理工作的公告》), issued by the NMPA on and effective from October 17, 2023, further implements the primary responsibility of drug marketing authorization holders for quality and safety in drug contract manufacturing, ensuring the quality and safety throughout the entire drug manufacturing lifecycle.

According to the Announcement on Strengthening the Supervision and Administration of Entrusted Drug Production (《關於加強藥品受託生產監督管理工作的公告》) issued by the NMPA on December 30, 2025, where sterile drugs are intended to be manufactured under entrustment, in principle, at least one party (either the marketing authorization holder or the entrusted manufacturer) shall have more than three years of commercial production experience in sterile drugs of the same dosage form.

However, entrustment of sterile drug production may also be carried out if either the holder or the entrusted manufacturer has more than three years of development or production experience in sterile drugs of the same dosage form under any of the following circumstances: 1. The drugs fall into the category of innovative drugs, improved new drugs, national shortage drugs, national clinically necessary and easily shortage drugs, clinically urgent drugs, drugs urgently needed for response to public health emergencies, drugs for rare diseases, as well as overseas-manufactured drugs already marketed in China that are transferred to domestic production; 2. The entrustment of sterile drug production is between enterprises under the same group that implement a unified quality management system; 3. The entrusted manufacturer uses information technology to record data covering the entire process of material management, drug production and testing, and is capable of electronic data exchange with the marketing authorization holder; 4. The entrusted manufacturer has been mainly involved in the development and clinical trial drug production of the sterile drugs to be manufactured under entrustment.

(IV) Drug Circulation Management

The Measures for the Supervision and Administration of Drug Circulation (《藥品流通監督管理辦法》), issued by the former China Food and Drug Administration on January 31, 2007, and effective from May 1, 2007, provide detailed regulations on the procurement, warehousing, transportation, and sale of drugs. The Measures for the Supervision and Administration of Drug Circulation has been superseded by the Measures for Quality Supervision and Administration of Distribution and Use of Medicinal Products (《藥品經營和使用質量監督管理辦法》) promulgated by the State Administration for Market Regulation on September 27, 2023, and effective from January 1, 2024.

According to the Drug Administration Law, the undertaking of drug wholesale is subject to approval of the local drug regulatory department of the people's government of the province, autonomous region, or municipality directly under the central government and requires a Drug Distribution Certificate. The undertaking of drug retail is subject to approval of the drug regulatory department of the local people's government at or above the county level and requires the said certificate. No one may distribute drugs without the certificate. The Measures for Quality Supervision and Administration of Distribution and Use of Medicinal Products further stipulates matters such as the conditions, procedures, changes, and supervision and administration related to the application for a Drug Distribution Certificate.

Pursuant to the Opinions on Promoting Drug Price Reform (《推進藥品價格改革的意見》) jointly promulgated by National Development and Reform Commission ("**NDRC**") and other departments on May 4, 2015, from June 1, 2015, except for narcotic drugs and Category I psychotropic drugs, the price of drugs set by the government will be cancelled.

On December 5, 2025, the National Healthcare Security Administration and the Ministry of Human Resources and Social Security issued the Catalog of Innovative Pharmaceuticals for Commercial Health Insurance (2025) (《商業健康保險創新藥品目錄(2025年)》). The catalog includes a variety of anti-tumor cell and gene therapy drugs. Local healthcare security administrations will, in conjunction with relevant departments, actively promote the inclusion of drugs in the commercial health insurance innovative pharmaceutical catalog into the coverage of commercial health insurance.

III. REGULATIONS RELATING TO FOREIGN INVESTMENT

The investment activities of foreign investors in China are primarily regulated by the Catalogue of Encouraged Industries for Foreign Investment (《鼓勵外商投資產業目錄》) and the Special Administrative Measures (Negative List) for the Access of Foreign Investment (《外商投資准入特別管理措施(負面清單)》("**Negative List**"), both issued and from time to time revised by the Ministry of Commerce and the NDRC, as well as the Foreign Investment Law of the People's Republic of China (《中華人民共和國外商投資法》) (the "**Foreign Investment Law**") and its relevant implementation rules and supporting regulations.

The National People's Congress ("**NPC**") promulgated the Foreign Investment Law in March 2019, which came into effect on January 1, 2020. From the perspective of investment protection and fair competition, the Foreign Investment Law has established a basic framework for foreign investment access, promotion, protection, and regulation through legislation. Pursuant to the Foreign Investment Law, the State shall implement the management systems of pre-entry national treatment and negative list for foreign investment. The pre-entry national treatment refers to the treatment accorded to foreign investors and their investments no less favorable than that accorded to domestic investors and their investments at the investment access stage. The State shall accord national treatment to foreign investments outside the Negative List.

To ensure the effective implementation of the Foreign Investment Law, the State Council promulgated the Implementing Rules of the Foreign Investment Law of the People's Republic of China (《中華人民共和國外商投資法實施條例》) (the "**Implementing Rules of the Foreign Investment Law**") in December 2019, with effect from January 1, 2020, which further clarify the State's commitment to encouraging and facilitating foreign investment, protecting the legitimate rights and interests of foreign investors, regulating the administration of foreign investment and continually optimizing the environment of foreign investment environment to advance high-level opening-up.

Under the Negative List, foreign investors are prohibited from investing in human stem cell research, as well as the development and application of gene diagnosis and treatment technologies. However, pursuant to the Notice on Conducting Pilot Programmes for Expanding Opening-up in the Medical Sector (《關於在醫療領域開展擴大開放試點工作的通知》) jointly issued by the Ministry of Commerce ("**MOFCOM**"), the NHC, and the NMPA on September 7, 2024, from September 7, 2024, foreign-invested enterprises within the China (Beijing) Pilot Free Trade Zone, China (Shanghai) Pilot Free Trade Zone, China (Guangdong) Pilot Free Trade Zone, and Hainan Free Trade Port are permitted to engage in the development and application of human stem cell and gene diagnosis and treatment technologies for the purposes of product registration, market launch and production. All products registered for market entry and approved for production may be utilized nationwide. Foreign-invested enterprises intending to participate in the pilot scheme shall comply with relevant Chinese laws, administrative regulations, and other stipulations, including requirements concerning human genetic resource management, clinical trials of medicinal products (including international multi-centre clinical trials), medicinal product registration and market entry, medicinal product production, and ethical review, whilst fulfilling the requisite management procedures.

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 effective from January 18, 2021, any foreign investment that has or possibly has an impact on state security shall be subject to security review in accordance with the provisions hereof.

IV. REGULATIONS ON INFORMATION SECURITY AND DATA PROTECTION

Pursuant to the Civil Code, the personal information of a natural person shall be protected by the law. Any organization or individual shall legally obtain such personal information of others when necessary and ensure the safety of such information, and shall not illegally collect, use, process or transfer personal information of others, or illegally purchase or sell, provide or disclose personal information of others. Besides, the processing of personal information shall comply with the principles of legality, legitimacy and necessity, and excessive processing is strictly prohibited.

On August 20, 2021, the NPCSC promulgated the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) (the "**Personal Information Protection Law**"), which took effect on November 1, 2021. The Personal Information Protection Law further emphasizes the obligations of personal information processors to protect personal information, requiring that the processing of personal information should have a clear and reasonable purpose which should be directly related to the processing purpose, in a method that has the least impact on personal rights and interests, and the collection of personal information should be limited to the minimum scope necessary to achieve the processing purpose to avoid the excessive collection of personal information.

On June 10, 2021, the NPCSC promulgated the Data Security Law of the PRC (《中華人民共和國數據安全法》) (the "**Data Security Law**"), which took effect on September 1, 2021. The Data Security Law has established and improved the fundamental system for national data security management and the obligations of data processors in data security protection.

The Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》) (the "**Cybersecurity Law**") promulgated by the NPCSC on November 7, 2016 and latest amended on October 28, 2025 and effective from January 1, 2026 stipulates that network operators shall fulfill their obligations to safeguard security of the network when conducting business and providing services.

On July 12, 2018, the NHC promulgated the National Healthcare Big Data Standards, Safety and Service Management Measures (for Trial Implementation) (國家健康醫療大數據標準、安全和服務管理辦法(試行)》), with effect from the same day, which specify the guidelines and principles for standard management, security management and service management of the healthcare big data.

On December 28, 2021, the Cyberspace Administration of China (the "**CAC**") and other authorities jointly promulgated the amended Measures for Cybersecurity Review (《網絡安全審查辦法》), which became effective on February 15, 2022. According to the Measures for Cybersecurity Review, an cybersecurity review shall be made if (I) critical information infrastructure operators purchase network products and services and network platform operators carry out data processing activities, which affect or may affect national security; (II) network platform operators possessing more than one million users' personal information seek to list abroad; and (III) network products, services and data processing activities are deemed to affect or may affect national security by the member units of the cybersecurity review working mechanism and shall be reported by the Cybersecurity Review Office to the Central Cyberspace Affairs Commission for approval in accordance with the procedures.

The State Council promulgated the Regulations on Network Data Security Management (《網絡數據安全管理條例》) (the "**Data Security Regulations**") in September, 2024, which came into effect on January 1, 2025. The Data Security Regulations reiterate and refine general provisions for network data processing activities, rules for the protection of personal information, important data security protection, the management of cross-border transfer of network data, and the obligations of network platform service providers.

The CAC promulgated and implemented the Provisions on Promoting and Regulating Cross-border Data Flow (《促進和規範數據跨境流動規定》) on March 22, 2024, which explicitly state that a data processor is not required to apply for a security assessment of outbound data transfer for data treated as important data if the relevant authority or region does not notify the data processor that the data is treated as important data or does not publicly release the data as important data.

V. REGULATIONS RELATING TO INTELLECTUAL PROPERTY RIGHTS

(I) Patent

Pursuant to the Patent Law of the PRC (《中華人民共和國專利法》) promulgated by the NPCSC, last amended in October 2020 and effective from June 1, 2021 and the Detailed Rules for the Implementation of the Patent Law of the PRC (《中華人民共和國專利法實施細則》) promulgated by the State Council, last amended on December 11, 2023 and effective from January 20, 2024, patents are divided into three types, namely, invention patent, design patent and utility patent. Invention patents are valid for 20 years, while design patents and utility patents are valid for 15 years and 10 years, respectively, starting from the date of application. Any exploitation of a patent without the patentee's consent is considered patent infringement, for which the infringer shall bear liability for damages to the patentee. In cases such as counterfeit patents, the infringer may be subject to fines or even criminal prosecution.

In particular, to compensate for the time taken for the review and approval process before the marketing of a new drug, with respect to the patent for invention related to a new drug which has been approved for marketing in China, the patent administration department under the State Council shall, at the request of the patentee, award a compensation on the term of the patent. The compensation term shall not be more than five years, and the total effective term of the patent right shall not be more than 14 years from the date of marketing approval for the new drug.

The NMPA and the China National Intellectual Property Administration jointly issued and implemented the Measures for the Implementation of the Early Resolution Mechanism for Drug Patent Disputes (for Trial Implementation) (《藥品專利糾紛早期解決機制實施辦法(試行)》) on July 4, 2021, establishing an early resolution mechanism for drug patent disputes.

(II) Trade Secret

According to the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》) (the "**Anti-Unfair Competition Law**"), promulgated by the NPCSC on September 2, 1993, and last amended on June 27, 2025 and effective from October 15, 2025, the term "trade secrets" refers to technical and operational business information that is unknown to the public, has business interests, and is maintained as a secret with security measures taken by its right holder. According to the Anti-Unfair Competition Law, business operators are prohibited from infringing upon others' trade secrets. Natural persons, legal persons, and unincorporated organizations other than business operators that commit the relevant illegal acts shall be deemed to have infringed upon others' trade secrets. If a third party knows or should have known that an employee or former employee of the right holder of the trade secrets, or any other entity or individual has committed the relevant illegal acts but nevertheless acquires, discloses, uses or allows another person to use such trade secrets, the third party shall be deemed to have infringed upon others' trade secrets. The parties whose trade secrets are infringed upon may apply for administrative corrections, and the regulatory authorities shall order to stop any illegal activities and impose fine penalties on the infringing parties.

(III) Trademark

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) currently in effect and last amended by NPCSC on June, 2026 which shall come into force on January 1, 2027 and the Implementation Regulations of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》) promulgated by the State Council on August 3, 2002, last amended on April 29, 2014 and effective from May 1, 2014, the period of validity for a registered trademark is 10 years, commencing from the date of approval of registration. If, upon expiry of the period of validity, the registrant needs to continue to use the trademark, it or he/she shall go through the formalities for renewal as required within 12 months prior to the date of expiry. Where the registrant fails to do so within the specified period, a grace period of six months may be granted. The period of validity for each renewal of registration is 10 years, commencing from the day after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be canceled. Pursuant to the Trademark Law of the PRC amended on June, 2026, the departments responsible for trademark enforcement actions shall have the power to investigate and penalize acts infringing upon the exclusive right to use registered trademarks in accordance with the law; where any such infringement constitutes a suspected criminal offence, the said departments shall promptly transfer the case to the public security organs for legal handling.

(IV) Copyright

According to the Copyright Law of the PRC (《中華人民共和國著作權法》) promulgated by the NPCSC on September 7, 1990, last amended in November 2020 and effective from June 1, 2021 and the relevant implementation regulations, works of Chinese citizens, legal persons or unincorporated organizations, namely ingenious intellectual achievements in the fields of literature, art and science that can be presented in a certain form, whether published or not, shall enjoy copyright. A copyright owner of the protected work enjoys personal 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 that shall be enjoyed by the copyright owners.

(V) Domain Name

According to the Administrative Measures for Internet Domain Names (《互聯網域名管理辦法》), promulgated by the Ministry of Industry and Information Technology on August 24, 2017 and effective from November 1, 2017, the "first to file, first to register" principle is adopted for domain name registration services. A domain name registrar shall, in the process of providing domain name registration services, ask the applicant for the registration of a domain name to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

VI. REGULATIONS RELATING TO FIRE CONTROL AND ENVIRONMENTAL PROTECTION

(I) Fire Control

Pursuant to the Fire Control Law of the PRC (《中華人民共和國消防法》) promulgated by the NPCSC on April 29, 1998, and last amended on and effective from April 29, 2021, the department of emergency management of the State Council shall monitor and administer the nationwide fire control work. The departments of emergency management of local people's governments above county level shall monitor and administer the fire control work within their administrative region, and the fire control and rescue institutions of the people's government at the same level shall be responsible for the implementation. The design and construction of fire control of the construction projects must comply with the national technical standards of fire control.

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, last amended on August 21, 2023 and effective from October 30, 2023, an examination system for fire control design and fire protection acceptance shall apply to special construction projects, and for other projects, a record-filing and spot check system shall be implemented.

(II) Environmental Protection

The NPCSC promulgated the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) (the "**Environmental Protection Law**") on December 26, 1989, which was last amended on April 24, 2014 and became effective on January 1, 2015. 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, safeguarding public health, advancing ecological civilization, and promoting sustainable economic and social development.

The NPCSC promulgated the Law of People's Republic of China on Environmental Impact Appraisal (《中華人民共和國環境影響評價法》) (the "**Law on Environmental Impact Appraisal**") on October 28, 2002, which was last amended and became effective on December 29, 2018. According to the Law on Environmental Impact Appraisal, the state practices classified management over the appraisals of the environmental impacts of construction projects according to the seriousness of the impacts.

According to 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)》) promulgated by the Ministry of Ecology and Environment of the PRC on November 30, 2020 and effective from January 1, 2021, the construction entities shall work out the report of environmental impacts, the report form of environmental impacts or the registration form of environmental impacts in accordance with the provisions of the catalogue.

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 from November 20, 2017 and the Regulations on the Administration of Construction Project Environmental Protection (《建設項目環境保護管理條例》), which was revised on July 16, 2017 and became effective on October 1, 2017, after the completion of a construction project for which a report of environmental impacts or a report form of environmental impacts 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 a report of environmental impacts or a report form of environmental impacts is required shall not be put into production or use until the environmental protection completion acceptance check has been passed.

According to the Regulations on the Administration of Permitting of Pollutant Discharges (《排汙許可管理條例》) promulgated on January 24, 2021 and effective from March 1, 2021 and the Measures for Pollutant Discharge Permitting Administration (《排汙許可管理辦法》) promulgated on April 1, 2024 and effective from July 1, 2024, a pollutant discharge entity shall be subject to the classified administration of permitting of pollutant discharges according to the factors including the volume of pollutants generated, the volume of discharge, and the impact on the environment (namely key administration, simplified administration and registration management for pollutant discharge). Enterprises, institutions and other producers and operators that have been included in the Classified Administration List of Pollutant Discharge Permitting for Stationary Environmental Pollution Sources (《固定污染源排汙許可分類管理名錄》) shall apply for and obtain a pollutant discharge permit or fill in a pollutant discharge registration form within the prescribed time limit, and shall not discharge pollutants without a pollutant discharge permit or filling in a pollutant discharge registration form.

According to the Regulations on Urban Drainage and Sewage Treatment (《城鎮排水與污水處理條例》) promulgated on October 2, 2013, and effective from January 1, 2014, and the Measures for the Administration of Permits for Discharging Urban Sewage into Drainage Network (《城鎮污水排入排水管網許可管理辦法》) revised on December 1, 2022, and effective from February 1, 2023, enterprises, institutions, and individual businesses engaged in industrial, construction, catering, medical, and other activities shall apply to the competent urban drainage authority for a permit to discharge sewage into the drainage network and discharge sewage in accordance with the requirements of the permit.

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》), promulgated by the NPCSC on October 30, 1995, last amended on April 29, 2020 and effective from September 1, 2020, entities generating hazardous waste shall store, utilize and dispose of 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 provide or entrust hazardous waste to unlicensed entities or other business operators for collection, storage, utilisation, or disposal activities, 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 with approval authority.

The Environmental Code of the PRC was promulgated by the NPC in March 2026 and officially came into force on August 15, 2026. This Code systematically consolidates and revises relevant laws and regulations governing ecological and environmental matters. Upon its effective date, relevant laws (including the Environmental Protection Law, Law on Environmental Impact Appraisal and the Law on the Prevention and Control of Environmental Pollution Caused by Solid Waste of the PRC) were concurrently repealed.

VII. REGULATIONS RELATING TO LABOR AND PRODUCTION SAFETY

(I) Labor Relations

According to the Labor Law of the PRC (《中華人民共和國勞動法》) promulgated by the NPCSC on July 5, 1994 and last amended on and effective from December 29, 2018, the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), which was promulgated by the NPCSC on June 29, 2007, was amended on December 28, 2012, and came into effect on July 1, 2013, and the Regulations on Implementation of the Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》) which was promulgated by the State Council on September 18, 2008 and came into effect on the same day, labor contracts in written form shall be executed to establish labor relationships between employers and employees. Wages to be paid to employees by the employers shall not be lower than the local standards of minimum wages. The employers must establish a system for labor safety and sanitation, strictly comply with national rules and standards, provide education regarding labor safety and sanitation to their employees, provide employees with labor safety and sanitation conditions and necessary labor protection articles in compliance with national rules, and carry out regular health examinations for employees engaged in work involving occupational hazards.

(II) Social Insurance

Pursuant to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) (the "**Social Insurance Law**") promulgated by the NPCSC on October 28, 2010 and last amended on and effective from December 29, 2018, the PRC established social insurance systems such as basic pension insurance, basic medical insurance, work-related injury insurance, unemployment insurance and maternity 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 last amended on and effective from March 24, 2019, any premium paying entity shall carry out social insurance registration at the local social insurance agency and pay and withhold social insurance premiums in accordance with regulations. Where the premium paying entity fails to pay social insurance premiums on time and in full amount, it will be ordered to make such payment or replenish the deficiency within a fixed period. Moreover, an overdue fine may be demanded. If the premium paying entity still fails to make social insurance contributions within the stipulated deadline, it may be subject to a fine ranging from one to three times the amount overdue.

According to the Interpretation (II) of the Supreme People's Court on 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)》) promulgated on July 31, 2025, and effective from September 1, 2025, where an employer and an employee agree or the employee promises the employer that no social insurance contributions are required, the people's court shall deem such agreement or promise invalid. Where an employer fails to pay social insurance contributions as required by law, and an employee requests termination of the labor contract and payment of economic compensation by the employer pursuant to Article 38(3) of the Labor Contract Law, the people's court shall support such request in accordance with the law. Where an employer subsequently makes up for the unpaid social insurance contributions in accordance with the law and requests the employee to return the previously paid social insurance contribution compensation, the people's court shall support such request in accordance with the law.

(III) Housing Provident Fund

Pursuant to the Regulations on Management of Housing Provident Fund (《住房公積金管理條例》) promulgated by the State Council on April 3, 1999 and last amended on and effective from March 24, 2019, a unit shall go to the housing provident fund management center to undertake registration of payment and deposit of the housing provident fund and go through the formalities of opening housing provident fund accounts on behalf of its staff and workers. A unit and its staff

and workers are also required to pay and deposit housing provident funds in full and in a timely manner. Where a unit is overdue in the payment and deposit of, or underpays, the housing provident fund, the housing provident fund management center shall order it to make the payment and deposit within a prescribed time limit; where the payment and deposit has not been made after the expiration of the time limit, an application may be made to a people's court for compulsory enforcement.

(IV) Production Safety

Pursuant to the Production Safety Law of the PRC (《中華人民共和國安全生產法》) (the "**Production Safety Law**") promulgated by the NPCSC on June 29, 2002, last amended on June 10, 2021 and effective from September 1, 2021, a production and operation enterprise shall comply with the Production Safety Law and other relevant production safety laws and regulations, enhance production safety management, establish a sound production safety accountability system and production safety rules, improve production safety conditions, strengthen the construction of safety production standardization and elevate safety production levels to ensure production safety. The person-in-charge of a production and operation enterprise shall be fully responsible for the production safety of the enterprise.

VIII. REGULATIONS RELATING TO FOREIGN EXCHANGE AND TAXES

See Appendix III of this document for details on regulations relating to foreign exchange and taxes.

IX. RELEVANT REGULATIONS ON OVERSEAS LISTING

(I) Filing Requirements of the China Securities Regulatory Commission ("CSRC") for Overseas Offerings and Listings

On February 17, 2023, the CSRC issued several regulations concerning the filing-based administration of overseas offerings and listings by domestic companies, including the Trial Administrative Measures for the Overseas Issuance and Listing of Securities by Domestic Enterprises (《境內企業境外發行證券和上市管理試行辦法》) (the "**Overseas Listing Trial Measures**") and related supporting guidelines. According to these provisions, a domestic enterprise in the PRC seeking to issue and list securities on an overseas market, whether directly or indirectly, shall file a record with the CSRC within three working days after submitting its overseas listing application documents.

Domestic enterprises conducting overseas issuance and listing activities must strictly comply with national security laws, administrative regulations, and relevant provisions — including those related to foreign investment, cybersecurity, and data security — and shall faithfully fulfill their obligations to safeguard national security.

(II) Confidentiality and Archives Management in Relation to Overseas Listings

On February 24, 2023, the CSRC, in conjunction with other relevant government departments, jointly promulgated the Provisions on Strengthening Confidentiality and Archives Management Work Related to Overseas Securities Issuance 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 "**Confidentiality Provisions**"). According to the Confidentiality Provisions, domestic enterprises, as well as securities companies and securities service institutions providing the relevant services, shall take necessary measures to fulfill their confidentiality and archive management responsibilities. They shall not disclose any state secrets or work secrets of state organs, nor shall they prejudice national and public interests.

(III) H Share Full Circulation

"Full Circulation" refers to the listing and trading of domestic non-listed shares of H-share companies (including non-listed domestic shares held by domestic shareholders prior to overseas listing, non-listed domestic shares issued domestically after overseas listing, and non-listed shares held by foreign shareholders) on the Hong Kong Stock Exchange. On November 14, 2019, the CSRC promulgated the Guidelines on the Application for "Full Circulation" Business of Domestic Non-listed Shares of H-share Companies (《H股公司境內未上市股份申請"全流通"業務指引》) (the "**Full Circulation Guidelines**"), which were partially amended on August 10, 2023, in accordance with the Decision of the China Securities Regulatory Commission on Amending and Repealing Certain Securities and Futures Regulatory Documents (《中國證券監督管理委員會關於修改、廢止部分證券期貨制度文件的決定》).

Under the Full Circulation Guidelines, provided that relevant laws and regulations as well as policies on state asset management, foreign investment, and industry supervision are complied with, shareholders of domestic non-listed shares may independently negotiate and determine the quantity and proportion of shares to be circulated, and authorize the H-share company to submit the application for Full Circulation. To apply for Full Circulation, the H-share company shall submit an application to the CSRC in accordance with the necessary administrative filing procedures under the Overseas Listing Trial Measures.