PRC REGULATION

Regulations on Company Establishment and Foreign Investment

The establishment, operation and management of corporate entities in China are governed by the Company Law of the PRC (《中華人民共和國公司法》), which was promulgated by the Standing Committee of the National People's Congress, in December 1993 and lately amended in December 2023. A foreign-invested company is also subject to the PRC Company Law unless otherwise provided by the foreign investment laws. Investment activities in the PRC by foreign investors are governed by the Special Administrative Measures for the Access of Foreign Investment (Negative List) (2024 Edition) (《外商投資准入特別管理措施(負面清單)(2024年版)》), or the Negative List, which was promulgated by the Ministry of Commerce of the PRC, or the MOFCOM, and the National Development and Reform Commission, or the NDRC, on 6 September, 2024 and came into effect on 1 November, 2024. The Negative List sets out the restrictive measures in a unified manner, such as the requirements on shareholding percentages. Pursuant to the Negative List, any field not falling under the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment. Foreign Investment Law of the PRC (《中華人民共和國外商投資法》), was promulgated by the National People's Congress on 15 March, 2019 and came into effect on 1 January, 2020. On 30 December, 2019, the MOFCOM and the State Administration for Market Regulation, or the SAMR, promulgated the Measures on Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which came into effect on 1 January, 2020. 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 through the Enterprise Registration System and the National Enterprise Credit Information Publicity System. The China Securities Regulatory Commission, or the CSRC, the State Administration of Foreign Exchange, or the SAFE, the MOFCOM and three other PRC governmental and regulatory authorities promulgated the Rules on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (《關於外國投資者併購境內企業的規定》), or the M&A Rules, on 8 August, 2006, as later amended on 22 June, 2009, governing the mergers and acquisitions of domestic enterprises by foreign investors. The M&A Rules, among other things, require that if a domestic company, a domestic enterprise, or a domestic individual, through an overseas company established or controlled by it/him/her, acquires a domestic company which is affiliated with it/him/her, an approval from the MOFCOM is required.

Regulations on Pharmaceutical Product

Major Regulatory Authorities

Pharmaceutical products in China are monitored and supervised by the National Medical Products Administration, or the NMPA, the predecessor of which is the China Food and Drug Administration, or the CFDA, on national level. According to the Decision of the CFDA on Adjusting the Approval Procedures under the Administrative Approval Items for Certain Drugs (《國家食品藥品監督管理總局關於調整部分藥品行政審批事項審批程序的決定》), which came into effect on 5 May, 2017, the approval of Investigational New Drug Application, or the IND, should be issued by the Center for Drug Evaluation, or the CDE, in the name of the NMPA. The National Health Commission, or the NHC, is responsible for coordinating the formulation of national drug policies, the national essential medicine system and the National Essential Medicines List and drafting the administrative rules for the procurement, distribution and use of national essential medicines.

Drug Regulatory Regime

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》), or the Drug Administration Law, was promulgated by the SCNPC, on 20 September, 1984 and last amended on 26 August, 2019. The Regulations for the Implementation of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》), or the Regulations for the Implementation of the

Drug Administration Law, was promulgated by the State Council on 4 August, 2002 and was last amended on 6 December, 2024. The Drug Administration Law and the Regulations for the Implementation of the Drug Administration Law have jointly established the legal framework for the administration of pharmaceutical products in China.

Regulations on Clinical Trials and Registration of Drugs

Drug Clinical Trial Application

On 22 January, 2020, the SAMR released the amended Administrative Measures for Drug Registration (《藥品註冊管理辦法》), or the Drug Registration Measures, which came into effect on 1 July, 2020. According to the Drug Registration Measures, clinical trials of drugs shall be subject to approval from NMPA, carried out by drug clinical trial organizations and consistent with the Good Clinical Trial Practice for Drugs (《藥物臨床試驗質量管理規範》). Prior to applying for drug clinical trial, the applicant shall complete research work pertaining to pharmacy, pharmacology and toxicology, etc. When applicants submit the application for drug clinical trial, the relevant research materials shall be submitted in accordance with the requirements on declaration materials. Upon form examination, where the declaration materials are found to comply with the requirements, the application shall be accepted. The CDE shall organize pharmacists, medical personnel and other technicians to review the accepted application for drug clinical trials. Within 60 days after the acceptance of the application and the fees paid for the clinical trial applications, the applicant may conduct the clinical trials for the drug in accordance with the clinical trial protocol submitted, if the applicant has not received any negative or questioning opinion from the CDE.

Drug Clinical Trial Registration

The CFDA released the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) on 6 September, 2013, according to which, all clinical trials approved and conducted in China shall publish trial information through the Drug Clinical Trial Information Platform. The applicant shall complete the trial pre-registration within one month after obtaining the clinical trial approval to obtain the trial's unique registration number and complete registration of certain follow-up information before the first subject's enrollment in the trial. If the registration is not completed within one year after the approval of the IND applications, the applicant shall submit an explanation, and if the first submission is not completed within three years, the approval of the IND applications shall automatically expire. The Drug Registration Measures also require that upon obtaining the approval of the IND applications and before conducting a clinical trial, the sponsor shall register the clinical protocol and other information on the Drug Clinical Trial Registration and Information Platform for clinical trials of drugs. During the clinical trial of drugs, the sponsor shall update registration information continuously and register the outcome of the clinical trials upon completion. The registration information shall be published on the platform and the sponsor shall be responsible for the veracity of such information.

Phases of Clinical Trials and the Communication with the CDE

According to the Drug Registration Measures, drug clinical trials comprise Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial as well as bioequivalence test. Based on the characteristics of drugs and research objective, the research contents shall include clinical pharmacology research, exploratory clinical trial, confirmatory clinical trial and post-marketing research clinical. According to the Circular 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》) promulgated by the NMPA on 24 July, 2018, where the application for clinical trial of 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 Session to CDE to discuss with CDE the key technical questions including the design of Phase III clinical trial protocol. 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》), which was issued by the CDE on 10 December 2020, stipulates that during the research and development periods and in the registration applications of, among others, the innovative drugs, the applicants may propose to conduct communication meetings with the CDE. 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 meetings convened for the key research and development stages of drugs, which mainly include preclinical trial meetings for new drugs, Phase II clinical trial completion/Pre-phase III clinical trial commencement meetings, pre-marketing authorization meetings of new drugs and Risk assessment and control meetings. Type III meetings refer to meetings not classified as Type I or Type II.

Good Clinical Practices

To improve the quality of clinical trials, the CFDA promulgated the revised Good Clinical Trial Practice for Drugs, or the Revised GCP Rules, promulgated by the NMPA and the NHC on 23 April 2020 and coming into effect on 1 July 2020. The Revised GCP Rules provide comprehensive and substantive requirements on the design and conduct of clinical trials in China. In particular, the Revised GCP Rules enhance the protection for study subjects and tighten the control over bio-samples collected under clinical trials. The Revised GCP Rules also set out the qualifications and requirements, among others, including that the investigators and centers participating in clinical trial shall (i) have professional certification at a clinical trial center, professional knowledge, training experience and capability of clinical trial, and be able to provide the latest resume and relevant qualification documents per request; (ii) be familiar with the trial protocol, investigator's brochure and relevant information of the trial drug provided by the applicant; (iii) be familiar with and comply with the Revised GCP Rules and relevant laws and regulations relating to clinical trials. The preparation, packaging, labeling and coding of the clinical trial products are also provided strictly in the Revised GCP Rules, which requires that, among others, the preparation of the investigational drug shall conform to the relevant requirements for good manufacturing practice of drugs for clinical trial; the packaging labels of the investigational product shall indicate the information on the use only for clinical trial, clinical trial information and information on the drug for clinical trial; the blinded state shall be kept in blind trials. The packaging of the investigational product shall be able to ensure that the drug is not contaminated or deteriorated during the transportation and storage period.

New Drug Application

According to the Drug Registration Measures, an applicant shall, upon completion of pharmacy, pharmacology and toxicology and drug clinical trial, etc. to support registration of marketing of pharmaceuticals, determination of quality standards, verification of commercial scale manufacturing process, and preparation to undergo examination and inspection for pharmaceutical registration, submit an application for pharmaceutical marketing authorization, and submit the relevant research materials in accordance with the requirements for declaration materials. The CDE shall organize pharmacist, medical and other technical personnel to conduct review for accepted pharmaceutical marketing authorization applications in accordance with the requirements. According to the Priority Review and Approval Procedures for Drug Marketing Authorizations (for Trial Implementation) (《藥品上市許可優先審評審批工作程序(試行)》), an applicant for drug marketing authorization may apply for priority review and approval procedures for drugs that have been included in the procedures for breakthrough therapy designation. According to the Announcement on Matters Concerning the Optimization of Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》) jointly issued by the NMPA and the NHC in May 2018 and effective immediately, the CDE will prioritize the allocation of resources for review, inspection, examination and approval of registration applications that have been included in the scope of priority review and approval so as to speed up review and approval.

Marketing Authorization Holder System

Pursuant to the Drug Administration Law, drug marketing authorization holder refers to an enterprise or a drug development institution that has obtained the drug registration certificate. The drug marketing authorization holder shall be responsible for non-clinical research, clinical trials, production and operation, post-marketing research, adverse reaction monitoring, reporting and processing of drugs in accordance with the provisions of the law. Other units and individuals engaged in drug development, production, operation, storage, transportation, use and other activities shall bear corresponding responsibilities pursuant to the law.

Trial Exemptions and Acceptance of Foreign Data

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》) on 6 July, 2018, which provides that overseas clinical data can be submitted for the drug registration applications in China. According to the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data, sponsors may use the data of foreign clinical trials to support drug registration in China, provided that, among others, sponsors must ensure the authenticity, completeness, accuracy and traceability of foreign clinical trial data and such data must be obtained consistent with the relevant requirements under the Good Clinical Trial Practice of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (《人用藥物註冊技術要求國際協調會臨床試驗管理規範》), or the ICH-GCP. Sponsors must also comply with other relevant sections of the Drug Registration Measures when applying for drug registrations in China using foreign clinical trial data.

International Multi-Center Clinical Trials

The International Multi-Center Clinical Trial Guidelines (Trial) (《國際多中心藥物臨床試驗指南(試行)》), or the Multi-Center Clinical Trial Guidelines, which was promulgated by the CFDA on 30 January, 2015 and came into effect on 1 March, 2015, provided guidance on the implementation of international Multi-Center Clinical Trials, or the MCCT, in China. According to the Multi-Center Clinical Trial Guidelines, 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 MCCTs in China, the applicants shall comply with relevant laws and regulations, such as the Drug Administration Law, the Regulations for the Implementation of the Drug Administration Law and the Drug Registration Measures, execute the GCP rules, make reference to universal international principles such as the ICH-GCP and comply with the laws and regulations of the countries involved in the international MCCTs. Where the applicants plan to use the data derived from the international multi-center clinical trials for approval of a drug registration in China, 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, Drug Registration Measures and other related laws and regulations. According to the Notice on Technical Guiding Principles for the Acceptance of the Overseas Clinical Trial Data of Drugs (《關於發佈接受藥品境外臨床試驗數據的技術指導原則的通告》) issued by NMPA on 6 July, 2018, if overseas clinical trial data is used in application for drug registration, all (and not some) overseas clinical trial data shall be submitted. If a clinical trial is initially conducted in overseas and subsequent clinical trial will be conducted in China, the applicant of drug registration application is required to evaluate the data from initial clinical trial and to compile a full report. The applicant shall negotiate with the Drug Evaluation Center for acceptance of the initial clinical trial data for subsequent clinical trials.

Approval of Human Genetic Resources

The Regulations on the Administration of Human Genetic Resources of the PRC (《中華人民共和國人類遺傳資源管理條例》), or the HGR Regulation, which was promulgated by the State Council on 28 May, 2019, last amended on 10 March, 2024 and came into effect on 1 May, 2024, further stipulates that, utilization of China's human genetic resources for international cooperation in scientific research shall be subject to the approval of the administrative department for health

under the State Council. In addition, 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 resource to be used shall be filed with the department of health and wellness under the State Council before clinical trials, otherwise, the Department of Health and Wellness under the State Council shall order cooperative parties to stop the illegal acts, confiscate the human genetic resources illegally collected and preserved as well as illegal gains, and impose a fine of not less than RMB500,000 but not more than RMB5,000,000. If the illegal gains reach more than RMB1,000,000, the fine shall be more than five times and less than ten times the illegal gains.

Regulations on Drug Manufacturing

Drug Manufacturing

According to the Drug Administration Law and the Regulations for the Implementation of the Drug Administration Law, all facilities that manufacture drugs in China must obtain a Drug Manufacturing License with an appropriate "scope of manufacturing" from the local drug regulatory authority. This license must be renewed every five years.

Good Manufacturing Practices (GMP)

Pursuant to the Norms on Good Manufacturing Practices (《藥品生產質量管理規範》) last amended on 17 January 2011 and effective from 1 March 2011, sets out the basic standard for the manufacture of pharmaceuticals products, which includes the production facilities, the qualification of the management personnel, production plant and facilities, documentation, material packaging and labelling, inspection, production management, sales and return of products and customers' complaints.

Contract Manufacturing of Drug

The Drug Administration Law specifies that a holder of drug sales approval may produce drugs by itself or may entrust other drug manufacturers. A holder of drug sales approval that intends to manufacture drugs on its own shall obtain a drug manufacturing permit, or if the holder intends to entrust a third-party to manufacture, it shall entrust a qualified drug manufacturer. The holder of drug sales approval and the commissioned manufacturer shall enter into an entrustment agreement and a quality agreement, and strictly perform the obligations pursuant to such agreements. Blood products, anesthetics, psychotropic pharmaceuticals, toxic pharmaceuticals for medical treatment, and pharmaceutical precursor chemicals may not be produced through entrustment, except as otherwise prescribed by the drug administrative department of the State Council.

Monitoring Periods for New Drugs

According to the Regulations for the Implementation of the Drug Administration Law, the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of not more than five years for new drugs approved to be manufactured, commencing from the date of approval, to continually monitor the safety of such new drugs. During the monitoring period of a new drug, no approval shall be granted to any other manufacturer to produce or import the said drug.

Drug Advertisements

According to the Advertising Law of the PRC (《中華人民共和國廣告法》), which was promulgated by the SCNPC in October 1994 and last amended and came effect on 29 April, 2021, certain contents such as statement on cure rate or efficiency shall not be included in the advertisement of drugs. According to the Interim Administrative Measures for the Review of

Advertisements for Drugs, Medical Devices, Health Food, and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) issued by the SAMR on 24 December, 2019 and came into effect on 1 March, 2020, the advertisements for drugs shall not be released without being reviewed and the contents of a drug advertisement shall be based on the drug instructions approved by the drug administration departments.

Medical Insurance Catalog

According to the National Drug Catalog for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄(2024年)》), or the 2024 NRDL, promulgated by the National Healthcare Security Administration and Ministry of Human Resources and Social Security on 27 November, 2024, and later amended on 6 January, 2025, the centralized drug procurement institutions of all provinces, autonomous regions and municipalities directly under the Central Government shall directly link the new added drugs on the provincial centralized drug procurement platform by the end of December 2024. And it is necessary to give full consideration to the continuity of patients' medication and the stability of their treatment, and in principle, they should not be transferred out of the "dual channel" and separate payment scope on the grounds that the negotiated drugs have been transferred to regular catalog management.

Regulations on Intellectual Property Rights

Patents

According to the Patent Law of the PRC (《中華人民共和國專利法》), or the PRC patent law, promulgated by the SCNPC on 12 March, 1984 and further amended on 17 October, 2020 and came into effect on 1 June, 2021 and the Implementing Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), promulgated by the China Patent Bureau Council on 19 January, 1985, and last amended on 11 December, 2023, the term "invention-creations" refers to inventions, utility models and designs. The duration of a patent right shall be 20 years for inventions, 10 years for utility models and 15 years for designs, all commencing from their respective application date. According to the PRC Patent Law, for public health purposes, the patent administrative department under the State Council of the PRC may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which PRC has acceded. In addition, pursuant to the PRC Patent Law, for the purpose of compensating for the time taken to evaluate and get a new drug approved and marketed, the patent administrative department under the State Council would grant compensation for duration of patent rights for invention of a new drug approved to be put on market in China upon request of the patentee. The compensation period shall not exceed five years, and the total validity period of patent rights for a new drug after being approved for market shall not exceed 14 years.

Trademarks

According to the Trademark Law of the People's Republic of China (《中華人民共和國商標法》), or the Trademark Law, revised by the SCNPC on 23 April, 2019 and taking effect on 1 November, 2019, the registered trademark has a validity period of 10 years starting from the registration date. The trademark registrant enjoys the exclusive right to use the trademark.

Domain Names

In accordance with the Measures for the Administration of Internet Domain Names (《互聯網域名管理辦法》) which was issued by the Ministry of Information Industry on 24 August, 2017 and came into effect on 1 November, 2017, domain name registration services shall, in principle, be subject to the principle of "first apply, first register". A domain name registrar shall, in the process of providing domain name registration services, ask the applicant for which the registration is made to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

Regulations on Product Liability

Under current PRC law, manufacturers and vendors of defective products in the PRC may incur liability jointly for loss and injury caused by such products. According to the Civil Code of the PRC (《中華人民共和國民法典》), which was promulgated on 28 May, 2020 and became effective on 1 January, 2021, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury. If a patient suffers damage due to defects in drugs, he may seek compensation from the drug marketing authorization holder 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. The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》), or the Consumer Protection Law, was promulgated on 31 October, 1993 and last amended on 25 October, 2013 to protect consumer rights when they purchase or use goods and services. According to the Consumer Protection Law, all business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the latest amendment, all business operators shall protect the customers' privacy and keep any consumer information they obtain during the business operation strictly confidential. In addition, in extreme situations, pharmaceutical product manufacturers and operators may be subject to criminal liability if their goods or services lead to the death or injuries of customers or other third parties.

Regulation on Information Security and Data Privacy

Pursuant to the Civil Code of the PRC, the personal information of a natural person shall be protected by the law. An information processor shall not disclose or tamper with any personal information collected or stored thereby; and without the consent of the natural person, no personal information shall be illegally provided to any other person, excluding the information through which the specific individual cannot be identified after processing and which cannot be restored. An information processor shall take technical measures and other necessary measures to ensure the security of the personal information collected and stored thereby and prevent information leakage, tampering, and loss. On July 1, 2015, the NPC Standing Committee issued the National Security Law of the PRC (《中華人民共和國國家安全法》) (the "**National Security Law**"), which came into effect on the same day. The National Security Law requires the establishment of national security review and supervision systems to examine foreign investments, critical technologies, internet information technology products and services, and other significant activities that may impact China's national security. On November 7, 2016, the NPC Standing Committee promulgated the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》) (the "**Cybersecurity Law**"), which came into effect on June 1, 2017. According to the Cybersecurity Law, the State implements a cybersecurity multi-level protection system. Network operators shall comply with laws and regulations when conducting business and providing services, and fulfill their obligations to protect cybersecurity. Service providers operating via the network are required to adopt technical measures and other necessary measures, in accordance with laws, administrative regulations, and mandatory national standards, to ensure the safe and stable operation of the network, effectively respond to cybersecurity incidents, prevent illegal criminal activities committed on the network, and maintain the integrity, confidentiality and availability of network data. On October 28, 2025, the Standing Committee of the Fourteenth NPC adopted the Decision on Amending the Cybersecurity Law of the People's Republic of China, pursuant to which the amended Cybersecurity Law became effective on January 1, 2026. This marks the first amendment to the Cybersecurity Law since its implementation in 2017. While maintaining the existing fundamental framework of the cybersecurity regime, the amendment refines and strengthens certain regulatory mechanisms. In particular, it introduces provisions relating to artificial intelligence, which, at the level of a fundamental law, clarify the State's support for the development of artificial intelligence technologies while emphasizing requirements concerning ethical governance, risk assessment and security supervision. In addition, the amendment enhances the liability regime by introducing a tiered penalty system commensurate with the severity of the resulting harm, increasing the penalties

for conduct that seriously endangers cybersecurity, and further clarifying accountability mechanisms applicable to responsible personnel. On 8 May, 2017, the Supreme People's Court and the Supreme People's Procuratorate jointly released the Interpretations of the Supreme People's Court and the Supreme People's Procuratorate on Several Issues Concerning the Application of Law in the Handling of Criminal Cases Involving Infringement of Citizens' Personal Information (《最高人民法院、最高人民檢察院關於辦理侵犯公民個人信息刑事案件適用法律若干問題的解釋》), or the Interpretation, which came into effect on 1 June, 2017, clarifies several concepts regarding the crime of "infringement of citizens' personal information" stipulated by Article 253A of the Criminal Law of the PRC (《中華人民共和國刑法》), including the "provision of citizens' personal information" and "illegally obtaining any citizen's personal information by other methods". In addition, the Interpretations specify the standards for determining "serious circumstances" and "particularly serious circumstances" of this crime. The Data Security Law of the PRC (《中華人民共和國數據安全法》), which was promulgated by the SCNPC on 10 June, 2021 and took effect on 1 September, 2021, provides that China shall establish a data classification and grading protection system, formulate the important data catalogs to enhance the protection of important data. Processors of important data shall specify the person responsible for data security and management agencies to implement data security protection responsibilities. Relevant authorities will establish the measures for the cross-border transfer of important data. If any company violates the Data Security Law of the PRC to provide important data outside China, such company may be punished by administration sanctions, including penalties, fines, and/or suspension of relevant business or revocation of the business license. 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, was promulgated by the SCNPC on 20 August, 2021 and came into effect on 1 November, 2021. The Personal Information Protection Law reiterates the circumstances under which a personal information processor could process personal information and the requirements for such circumstances, such as when (1) the individual's consent has been obtained; (2) the processing is necessary for the conclusion or performance of a contract to which the individual is a party; (3) the processing is necessary to fulfill statutory duties and statutory obligations; (4) the processing is necessary to respond to public health emergencies or protect natural persons' life, health and property safety under emergency circumstances; (5) the personal information that has been made public is processed within a reasonable scope in accordance with this Law; (6) personal information is processed within a reasonable scope to conduct news reporting, public opinion-based supervision, and other activities in the public interest; or (7) under any other circumstance as provided by any law or regulation. It also stipulates the obligations of a personal information processor. Any violation of the provisions and requirements under the Personal Information Protection Law may subject a personal information processor to rectifications, warnings, fines, suspension of the related business, revocation of licenses, being entered into the relevant credit record or even criminal liabilities. On December 28, 2021, the Cyberspace Administration of China (the "**CAC**"), together with 12 other authorities, jointly promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the "**Measures for Cybersecurity Review**"), which took effect on February 15, 2022. The Measures for Cybersecurity Review stipulate that: (i) a critical information infrastructure operator purchases network products and services or an online platform operator conducts data processing, which affects or may affect national security, a cybersecurity review shall be carried out according to these Measures.; (ii) a key information infrastructure operator purchases network products and services, it shall anticipate the potential national security risks that may arise from the use of such products and services. Those that affect or may affect national security shall be reported to the Cybersecurity Review Office for cybersecurity review (iii) An online platform operator who have more than 1 million users' personal information must report to the Cybersecurity Review Office for cybersecurity review when going public abroad; (iv) If a member entity of the working mechanism for cybersecurity reviews deems that a network product or service or a data processing activity may affect or potentially affect national security, the Cybersecurity Review Office shall submit it to the Central Cyberspace Affairs Commission for approval according to the procedures before conducting a review in accordance with the provisions of these Measures. On July 7, 2022, the CAC promulgated the Measures for the Security Assessment of Outbound Data Transfer (《數據出境安全評估辦法》), which came into effect on September 1, 2022. The Measures for the Security Assessment of Outbound Data Transfer stipulate that data processors, who provide important data

and personal information collected and generated in their operations within the territory of China to recipients overseas, shall conduct a security assessment of outbound data transfers according to these Measures. The Cyberspace Administration of China ("**CAC**") promulgated the Measures for the Standard Contract for the Outbound Transfer of Personal Information (《個人信息出境標準合同辦法》), which came into effect on June 1, 2023. The Measures set forth the specific requirements applicable to personal information processors that provide personal information outside of the PRC by entering into a standard contract with the overseas recipient. On March 22, 2024, the CAC issued the Provisions on Promoting and Regulating Cross-border Data Flows (《促進和規範數據跨境流動規定》) (the "**New Outbound Data Transfer Provisions**"), which took effect on the same date. The New Outbound Data Transfer Provisions stipulate that in case of inconsistencies with the Measures for the Security Assessment of Outbound Data Transfer and Measures for the Standard Contract for the Outbound Transfer of Personal Information, the New Outbound Data Transfer Provisions shall prevail. The New Outbound Data Transfer Provisions clarify specific situations in which certain obligations regarding cross-border data transfers including declaring security assessments for outbound data transfers, entering into standard contracts for outbound personal information, and passing personal information protection certification can be exempted. On September 24, 2024, the State Council issued the Regulations on Network Data Security Management (《網絡數據安全管理條例》), which came into effect on January 1, 2025. The Regulations on Network Data Security Management aim to implement the general requirements for data security management set forth in the Cybersecurity Law, the Data Security Law, and the Personal Information Protection Law. The regulations reiterate the general provisions on data processing activities, personal information protection rules, important data security protection, cross-border network data security management, and the obligations of online platform service providers.

Regulations on Environment Protection

Pursuant to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), or the Environmental Protection Law, promulgated by the SCNPC, in December 1989, amended in April 2014 and effective in January 2015, any entity which discharges or will discharge pollutants during its course of operations or other activities must implement effective environmental protection safeguards and procedures to control and properly treat waste gas, waste water, waste residue, dust, malodorous gases, radioactive substances, noise vibrations, electromagnetic radiation and other hazards produced during such activities. According to the Measures for Pollutant Discharge Permitting Administration (《排污許可管理辦法》), promulgated by the Ministry of Ecology and Environment in 2024, enterprises, institutions and other producers and operators, or the pollutant discharge enterprises, that have been included in the Classification Management List for Fixed Source Pollution Permits (2019 Edition) (《固定污染源排污許可分類管理名錄(2019年版)》) shall apply for and obtain a discharge permit in accordance with the prescribed time limit. According to the Classification Management List for Fixed Source Pollution Permits (2019 Edition), the manufacturing of biological drugs and products falls into the classification management scope for fixed source pollution permits. The pollutant discharge license is valid for 5 years and the discharging units should apply for renewal 60 days before the expiry for the continuous pollutant discharge. Pursuant to the Regulations on Urban Drainage and Sewage Disposal (《城鎮排水與污水處理條例》), which was promulgated in October 2013 and came into effect in January 2014, and the Measures for the Administration of Permits for the Discharge of Urban Sewage into the Drainage Network (《城鎮污水排入排水管網許可管理辦法》), which was promulgated in January 2015 and further amended in December 2022, drainage entities covered by urban drainage facilities shall discharge sewage into urban drainage facilities in accordance with the relevant provisions of the PRC. Where a drainage entity needs to discharge sewage into urban drainage facilities, it shall apply for a drainage license in accordance with the provisions of these Measures.

Regulations on Fire Prevention

The Fire Prevention Law of the PRC (《中華人民共和國消防法》), or the Fire Prevention Law, which was promulgated on 29 April, 1998 and most recently amended on 29 April, 2021, provides that fire control design and construction of a construction project shall comply with the PRC's fire control technical standards for construction projects. Developers, designers, builders, project supervisors, etc. shall be responsible for the quality of the fire control design and construction of the construction project pursuant to the law. The development project fire safety design examination and acceptance system shall be implemented for development projects which are required to have fire safety design in accordance with the national fire protection technical standards for project construction.

Regulations on Foreign Exchange and Dividend Distribution

Foreign Exchange Control

According to the PRC Regulation for the Foreign Exchange (《中華人民共和國外匯管理條例》) promulgated by the State Council on 29 January, 1996, which was amended on 14 January, 1997 and 5 August, 2008, payments of current account items, such as trade and service-related foreign exchange transactions, may be made in foreign currencies without prior approval from SAFE by complying with certain procedural requirements. By contrast, approval from or registration with appropriate government authorities is required where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses. According to the Circular on Further Improving and Adjusting the Foreign Exchange Policies on Direct Investment (《關於進一步改進和調整直接投資外匯管理政策的通知》) promulgated by the SAFE on 13 February, 2015 and came into effective on 1 June, 2015, the opening of and payment into foreign exchange accounts under direct investment accounts are no longer subject to approval by the SAFE. Later, the SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》) on 13 February, 2015, which was further amended on 30 December, 2019 and prescribed that the bank instead of the SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while the SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank. The Provisions on the Administration of Foreign Exchange in Foreign Direct Investments by Foreign Investors (《外國投資者境內直接投資外匯管理規定》), which were promulgated by the SAFE on 11 May, 2013 and further amended on 30 December, 2019, regulate and clarify the administration over foreign exchange administration in foreign direct investments. According to the Circular on the Reform of the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises (關於改革外商投資企業外匯資本金結匯管理方式的通知》) promulgated by the SAFE on 30 March, 2015, which was amended in December 2019 and March 2023, and the Circular on the Reform and Standardization of the Management Policy of the Settlement of Capital Projects (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) promulgated by the SAFE in June 2016, which was further amended in December 2023, the settlement of foreign exchange by foreign-invested enterprises shall be governed by the policy of foreign exchange settlement on a discretionary basis.

Regulations on Labor

Labor Law and Labor Contract Law

According to the PRC Labor Law (《中華人民共和國勞動法》), which was promulgated by the SCNPC on 5 July 1994 and lately amended on 29 December, 2018, the PRC Labor Contract Law (《中華人民共和國勞動合同法》), which was promulgated by the SCNPC on 29 June, 2007 and amended on 28 December, 2012, and the Implementing Regulations of the Employment Contracts 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 18 September, 2008, labor contracts in written form shall be executed to establish labor relationships between employers and employees. In addition, wages of employees cannot be lower than the local minimum wage.

Social Insurance and Housing Provident Funds

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which issued by the SCNPC on 28 October, 2010 and was newly revised on 29 December, 2018, enterprises and institutions in China shall provide their employees with welfare schemes covering basic pension insurance, unemployment insurance, maternity insurance, work-related injury insurance and basic medical insurance. The employer shall, within 30 days from the date of employment, apply to the social insurance agency for social insurance registration for the employee. Any employer who violates the regulations above shall be ordered to make correction within a prescribed time limit; if the employer fails to rectify within the time limit, the employer and its directly liable person will be fined. If the employer fails to pay social insurance contributions on time and in full, the social insurance agency shall place an order with the employer demanding full payment within a prescribed period, and an overdue payment fine at the rate of 0.5‰ shall be levied as of the date of indebtedness. When the payment is not made at the expiry of the prescribed period, a fine above the overdue amount but less than its triple shall be demanded by the authoritative administrative department. According 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' Court on July 31, 2025 and implemented on September 1, 2025. Where an employer and an employee enter into a written or verbal agreement that social insurance premiums need not be paid by both parties, the people's court shall not support this arrangement and shall determine that the agreement is invalid. Accordingly, when an employer fails to pay social insurance premiums even as previously agreed between the employer and an employee, upon the employee's termination of the employment contract, the employer shall make up the unpaid social insurance premiums and pay economic compensation to the employee in accordance with the provisions of the Labor Law. According to Regulations on Management of Housing Provident Fund (《住房公積金管理條例》) issued by the State Council on 3 April, 1999 and revised and implemented on 24 March, 2019, the enterprises shall fully pay the housing provident fund contribution for the employees on time, with the contribution ratio no less than 5% of the average monthly salary of the relevant employee in the previous year. The housing provident fund contribution paid by the employees and the employers shall be owned by the employees.

Regulations on Taxation

Enterprise Income Tax

According to the Enterprise Income Tax Law (《中華人民共和國企業所得稅法》) promulgated by the NPC on 16 March, 2007 and amended by the SCNPC on 24 February, 2017 and 29 December, 2018, and the Implementation Rules of the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》) promulgated by the State Council on 6 December, 2007 and lately amended on 6 December, 2024, other than a few exceptions, the income tax rate for both domestic enterprises and foreign-invested enterprises is 25%. Enterprises are classified as either "resident enterprises" or "non-resident enterprises." Besides enterprises established within China, enterprises established outside China whose "de facto management bodies" are located in China are considered "resident enterprises" and subject to the uniform 25% enterprise income tax rate for their global income. A non-resident enterprise refers to an entity established under foreign law whose "de facto management bodies" are not within China but have an establishment or place of business in the PRC, or who do not have an establishment or place of business in China but have income sourced within China. An income tax rate of 10% will normally be applicable to dividends declared to non-PRC resident enterprise investors that do not have an establishment or place of business in China or that have such establishment or place of business, but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends are derived from sources within China.

Value Added Tax ("VAT")

According to the Value-Added Tax Law of the PRC (《中華人民共和國增值税法》) promulgated by the SCNPC on 25 December, 2024 and came into effect on 1 January, 2026, except stipulated otherwise, taxpayers who sell goods, labor services or tangible personal property leasing services or import goods shall be subject to a 17% tax rate; taxpayers who sell transport services, postal services, basic telecommunications services, construction services, or real property leasing services, sell real property, transfer the land use right shall be subject to an 11% tax rate, and taxpayers who sell services or intangible assets, unless otherwise provided, shall be subject to a 6% tax rate.

Regulations on Securities Offering and Listing Outside of the PRC

On 6 July, 2021, the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council jointly promulgated the Opinions on Strictly Combating Illegal Securities Activities in accordance with the Law (《關於依法從嚴打擊證券違法活動的意見》), or the Opinions on Securities Activities. The Opinions on Securities Activities emphasize the need to strengthen the management of securities activities and the supervision of overseas listing of listed companies, both domestic and foreign, and propose effective measures, such as the promotion of the construction of a phase-by-phase supervisory system, to deal with the risks and events faced by listed companies in the PRC outside the PRC. On 17 February, 2023, the CSRC promulgated the Trial Measures for the Administration of Offshore 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》), or the Trial Measures for Administration, which became effective on 31 March, 2023, and five related guidelines. Pursuant to the Trial Measures for Administration, a domestic enterprise that directly or indirectly issues and lists securities overseas shall file a record with the CSRC and report the relevant information. On 24 February, 2023, the CSRC jointly with other authorities, promulgated the Provisions on Strengthening Confidentiality and File Management Related to Overseas Issuance and Listing of Securities by Domestic Enterprises or the Confidentiality Provisions (《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》), which came into effect on 31 March, 2023. Pursuant to the Confidentiality Provisions, domestic joint stock companies that directly issue shares to be listed overseas and domestic operating organizations of enterprises listed overseas through indirect share issuance shall submit for approval and comply with other regulations, before filing prior to publicly disclosing or providing to securities companies, securities service providers, overseas regulatory bodies and other entities and individuals any documents or information that involves state secrets, the working secrets of state organs, or documents and information that, if divulged, would jeopardize national security or public interests.

OVERVIEW OF U.S. LAWS AND REGULATIONS

This section summarizes the principal laws and regulations in the U.S. that are relevant to our business.

U.S. Government Regulation of Drug and Biological Products

In the U.S., the FDA regulates drugs under the FDCA and biologics under the FDCA and PHSA. Obtaining regulatory approvals and maintaining compliance requires substantial time and financial resources. Failure to comply may result in administrative or judicial sanctions, including refusal to approve applications, approval withdrawal, clinical holds, warning letters, product recalls or seizures, suspension of production, injunctions, or civil or criminal penalties. Before clinical testing, product candidates undergo pre-clinical testing including laboratory evaluations and animal studies conducted under Good Laboratory Practice regulations. Sponsors must submit pre-clinical results, manufacturing information, and clinical trial protocols to the FDA. The IND becomes effective 30 days after FDA receipt unless the FDA places a clinical hold due to concerns or non-compliance. All clinical trials must be conducted under qualified investigators in accordance with Good Clinical Practice regulations, with written informed consent from all subjects. An

Institutional Review Board ("**IRB**") must review and approve clinical trial plans before commencement and reapprove at least annually. IRBs can suspend or terminate trials not conducted in accordance with requirements or associated with unexpected serious harm. Clinical trials generally are conducted in three sequential phases, known as Phase I, Phase II and Phase III, and may overlap. Phase I trials assess metabolism, pharmacologic action, tolerability, and safety in small numbers of subjects; Phase II trials evaluate proof of concept, dosing, and preliminary efficacy in disease-affected patients; and Phase III trials involve large multi-site studies to demonstrate effectiveness, safety, and overall benefit/risk for product labeling. Progress reports must be submitted annually to the FDA. Safety reports must be submitted within 15 calendar days, and unexpected fatal or life-threatening adverse reactions must be reported within 7 calendar days. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, which is publicly available at **www.clinicaltrials.gov**. Concurrent with clinical trials, companies usually complete additional animal studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions.

U.S. Review and Approval Processes

Product development, pre-clinical and clinical trial results, manufacturing processes, and proposed labeling are submitted to the FDA as an NDA or BLA, subject to user fees. The FDA reviews within 60 days to determine if the application is complete, then conducts substantive review for safety, effectiveness, and GMP compliance, typically including facility inspections. The FDA may refuse approval or issue a complete response letter identifying deficiencies requiring additional data or changes. Approval may be limited to specific indications or dosages, and may require labeling precautions or post-approval studies including Phase IV trials. Combination products composed of components normally regulated by different FDA centers are assigned a lead reviewer based on primary mode of action and may require single or separate marketing applications.

Post-Marketing Requirements

Following approval, manufacturers remain subject to FDA regulation including monitoring, record-keeping, adverse experience reporting, and promotion and advertising requirements. Manufacturers cannot promote off-label uses, and violations may result in significant liability and investigation. Promotional materials must be submitted to FDA with first use. Modifications to the drug, including changes in indications, labeling, or manufacturing, may require approval of a new or supplemental NDA/BLA with additional data or studies. The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy ("**REMS**"), to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA/BLA must submit a proposed REMS. The FDA will not approve the NDA/BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation, and the obligation to investigate and correct any deviations from cGMP. Manufacturers must register with FDA and state agencies and are subject to unannounced inspections for cGMP compliance. Violative conditions could result in enforcement actions, and post-approval problems may result in product restrictions or recall. The FDA may withdraw approval if compliance is not maintained or problems occur post-market. Discovery of previously unknown problems may result in labeling revisions, post-market studies, or distribution restrictions. Other consequences include marketing or manufacturing restrictions, product withdrawal, fines, warning letters, refusal to approve applications, product seizure, or civil or criminal penalties.

Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product development and FDA review of an NDA or a BLA if approval of the application is the first permitted commercial marketing or use of a biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product's testing phase, which is the time between IND and NDA/BLA submission, and all of the review phase, which is the time between NDA/BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration, only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended, and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug candidate for which an NDA or a BLA has not been submitted.

BIOSECURE Act

On December 20, 2023, the U.S. Senate introduced a legislation that would prohibit U.S. federal government contracts, grants or loans to entities that use biotechnology equipment or services provided by certain Chinese biotechnology companies. On September 9, 2024, the U.S. House of Representatives voted in favor of a similar version of such legislation titled the BIOSECURE Act (the "**BIOSECURE Act**"). On October 9, 2025, the U.S. Senate introduced an amended version of the BIOSECURE Act ("**October 2025 Senate Amendment**") into the FY2026 National Defense Authorization Act ("**FY2026 NDAA"**). The final reconciled version of the FY2026 NDAA was released on December 7, 2025, incorporating a revised version of the BIOSECURE Act based on the October 2025 Senate Amendment, which was signed by President Trump on December 18, 2025. The core provisions of the enacted BIOSECURE Act remain consistent with the October 2025 Senate Amendment: federal agencies are prohibited from contracting with or funding companies that are designated "biotechnology companies of concern." The BIOSECURE Act's final definition of "biotechnology companies of concern" includes (A) entities on the Department of Defense's section 1260H list of Chinese military companies operating in the United States (known as the "**1260H List**"), and (B) entities that will be named through a process headed by the Office of Management and Budget ("**OMB**"), who must supplement the list of biotechnology companies of concern within one year of enactment. Prohibitions in the BIOSECURE Act will not take effect until the OMB issues implementing guidance and relevant federal regulations are finalized. The OMB must publish the initial list of "biotechnology companies of concern" within one year of the FY2026 NDAA's enactment (i.e., by December 2026). Within 180 days of publishing this list, OMB must issue implementation guidance for the BIOSECURE Act's requirements. The Federal Acquisition Regulation ("**FAR**") Council must then update the FAR within one year. Prohibitions for 1260H List entities take effect 60 days after the FAR revision, while prohibitions for companies newly named by the OMB take effect 90 days after the FAR revision. A grandfathering period applies for up to five years after the FAR revision, where the prohibitions do not apply to biotechnology equipment or services produced or provided under contracts or agreements (including previously negotiated contract options) entered into before the applicable effective date.