PRC REGULATIONS

Laws and Regulations on Drug Research and Development

Regulations on Drug Development

The Drug Administration Law of the People's Republic of China (the "**PRC**") (《中華人民共和國藥品管理法》) (the "**DAL**") which was promulgated by the SCNPC on September 20, 1984, and latest amended on August 26, 2019 and took effect as of December 1, 2019 and 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》) (the "**DAL Implementing Regulation**"), which was latest amended on December 6, 2024 and took effect as of January 20, 2025 provided legal framework for establishment of drug manufacturing enterprises and drug trading enterprises as well as drug administration. The NMPA has its own set of regulations further implementing the DAL; the primary one governing clinical trial applications (referred to individually as a "**CTA**" and collectively as the "**CTAs**"), marketing approval, and post-approval amendment and renewal is known as the Drug Registration Regulation (《藥品註冊管理辦法》) (the "**DRR**"), which was latest amended on January 22, 2020 and effective from July 1, 2020.

The Biosecurity Law of the PRC (《中華人民共和國生物安全法》) (the "**Biosecurity Law**") promulgated by the SCNPC on October 17, 2020 and latest amended on April 26, 2024, establishes a comprehensive legislative framework for the pre-existing regulations in relevant areas. It stipulates that the clinical research of new biomedical technologies shall pass the ethical review and be conducted in the medical institutions with corresponding qualifications and the operation of human clinical research shall be conducted by the professional medical workers with corresponding qualifications.

Regulations on Drug Research

Non-Clinical Research and Animal Testing

The NMPA requires non-clinical data to support registration applications for imported and domestic drugs. According to the DRR, non-clinical safety studies shall be conducted in accordance to the Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) promulgated by the CFDA, which was revised on July 27, 2017 and took effect from September 1, 2017. The NMPA is responsible for the certification of non-clinical safety evaluation and research institutions nationwide and the local provincial drug administrative department is in charge of the daily supervision of non-clinical safety evaluation and research institutions.

Clinical Trials Approval

Clinical trials should be conducted when applying for registration of a new drug. After completing the preclinical studies, the applicant must obtain approval for clinical trials of drugs from the NMPA before the conduction of new clinical drug trials. According to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA on March 17, 2017 and taking effect from May 1, 2017, the decision on the approval of clinical trials of drugs enacted by the CFDA can be made by the CDE from May 1, 2017.

Clinical trials could not proceed until being approved by the NMPA. According to the latest amended DRR, the NMPA now has adopted a system for clinical trials of new drugs where trials can proceed if the applicant has not received any objections from the Center for Drug Evaluation of NMPA (the "**CDE**") within 60 days thereafter. After the issuance of the Announcement of the CFDA on Several Policies on the Appraisal and Approval of Drug Registration (《國家食品藥品監督管理總局關於藥品註冊審評審批若干政策的公告》) (the "**Announcement on Appraisal and Approval of Drug Registration**") on November 11, 2015, as for CTAs for new drugs, the one-time

approval is implemented and the declaration, appraisal and approval at different levels are replaced. The one-time approval mechanism was restated in the Announcement of the NMPA on Adjusting Appraisal and Approval Procedures for Clinical Trials for Drugs (《國家藥品監督管理局關於調整藥物臨床試驗審評審批程序的公告》) (the "**Announcement on Adjusting Appraisal and Approval Procedures**"), which was issued on July 24, 2018 by the NMPA. 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 design. If expanded indications are involved, or the security risks to which subjects are exposed are increased as a result of the alteration to the clinical trials protocols, drastic pharmaceutical changes, or significant security findings for non-clinical research, new applications or supplementary applications of clinical trials might be required, pursuant to the Announcement on Adjusting Appraisal and Approval Procedures.

The DAL further confirms that the drug regulatory department under the State Council shall, within 60 working days from the date on which the application for a clinical trial is accepted, decide on whether to approve it and then notify the clinical trial applicant. In the case of failure to notify the applicant within the prescribed time limit, it shall be deemed as approved. For bioequivalence studies, they shall be filed for record on the website of the CDE as required.

Drug Clinical Trial Registration

Pursuant to the DRR, where a clinical trial is approved, the sponsor shall, prior to conducting subsequent phases of the clinical trial, formulate the clinical trial protocol, carry out the trial upon obtaining approval by the ethics committee, and submit the clinical trial protocol and supporting materials on the CDE website. On September 6, 2013, 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》), providing that all clinical trials approved by the CFDA and conducted in the PRC shall be registered on and trial information shall be published through the Drug Clinical Trial Information Platform under management of the CDE.

Clinical Trial Process

According to the DRR, a clinical development program consists of Phases I, II, III and IV. Phase I refers to the initial clinical pharmacology and safety evaluation studies in humans. Phase II refers to the preliminary evaluation of a drug candidate's therapeutic effectiveness and safety for particular indications in patients, to provide evidence and support for the design of Phase III clinical trials and to settle the administrative dose regimen. Phase III refers to clinical trials undertaken to confirm the therapeutic effectiveness of a drug. Phase III is used to further verify the drug's therapeutic effectiveness and safety on patients with target indications, to evaluate the overall benefit-risk relationships of the drug, and ultimately to provide sufficient evidence for the review of drug registration application. Phase IV refers to a new drug's post-marketing study to assess therapeutic effectiveness and adverse reactions when the drug is widely used, to evaluate the overall benefit-risk relationships of the drug when used among the general population or specific groups and to adjust the administration dose. In accordance with the revised Administrative Measures for Drug Registration, drug clinical trial shall comprise Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial as well as bioequivalence test.

Pursuant to the Circular Concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》) (the "**Several Policies Circular**"), the CDE grants a one-time approval for clinical trial applications for new drugs and does not require separate declarations, reviews or approvals for the subsequent phases of clinical trials. The CDE review focuses on the scientific nature of clinical trial protocols and the control of safety risks to ensure patient safety. Applicants must promptly communicate with the CDE, to resolve problems during clinical trials and make a supplementary report on the latest research materials as the relevant reviewer requires. Upon the completion of Phase I and Phase II clinical trials, the applicant

must submit trial results and the clinical trial protocol for the next phase in a timely manner. Where there is no safety problem, applicants can proceed to Phase III clinical trials after discussion with the CDE. The applicants must report serious adverse events that occur during clinical trials and submit annual research reports. Where clinical trial risks cannot be controlled, the clinical trials must be stopped immediately.

Sampling and Collecting Human Genetic Resources Filing

The MOST promulgated the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) on July 2, 2015, according to which, the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organization of China shall apply for approval of the China Human Genetic Resources Management Office (the "**CHGRMC**").

On May 28, 2019, the State Council of the PRC issued the Administrative Regulations on Human Genetic Resources (《人類遺傳資源管理條例》) (the "**Human Genetic Resource Regulation**"), last amended on March 10, 2024, and took effect from May 1, 2024. The Human Genetic Resource Regulation formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities, under which, a new filing system (as opposed to the advance approval approach originally in place) is put in place for clinical trials utilizing the human genetic resources in mainland China in order to obtain market license at clinical institutions without involving the export of human genetic resources materials outside of mainland China. Foreign organizations, individuals and institutions established or actually controlled by foreign organizations and individuals are not allowed to collect or preserve human genetic resources in mainland China or provide human genetic resources abroad. The Implementation Rules for the Administrative Regulation on Human Genetic Resources (《人類遺傳資源管理條例實施細則》), which was promulgated by the MOST on May 26, 2023, and took effect from July 1, 2023, further clarify the requirements for administrative licensing, record-keeping, and security review in relation to the collection, conservation, utilization, and export of human genetic resources, as well as detailing matters relating to the supervisory review and administrative penalties.

Pathogenic Microorganism Laboratories

The Regulations on Administration of Bio-safety in Pathogenic Microorganism Laboratories (《病原微生物實驗室生物安全管理條例》), which was promulgated by the State Council, effective on November 12, 2004, and latest amended on December 6, 2024, stipulate that pathogenic microorganism laboratories are classified into four levels, namely bio-safety levels 1, 2, 3 and 4 in terms of bio-safety protection levels in accordance with national standards on biosafety of laboratories. Laboratories at bio-safety levels 1 and 2 shall not engage in laboratory activities related to highly pathogenic microorganisms. The construction, alternation or expansion of a laboratory at bio-safety level 1 or 2 shall be filed for record with the local counterparts of the National Health Commission (the "**NHC**").

Priority Evaluation and Approval Programs to Encourage Innovation

According to the Opinion on Deepening the Reform of the Evaluation and Approval System to Encourage Innovation in Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (the "**Innovation Opinion**") promulgated by General Office of the Communist Party of China Central Committee and General Office of the State Council on October 8, 2017, for any drugs or medical devices used for the treatment of severe and life-threatening diseases that cannot be treated in an effective manner and those badly needed for public health, if

the early and mid-term indicators in clinical trials show their efficacy and their clinical value are predictable, conditional approval for the marketing of these drugs and medical devices can be granted, and enterprises shall develop the risk control plans to conduct researches according to the requirements.

The Announcement of the NMPA on Promulgating Three Documents Including the Working Procedures for the Evaluation of Breakthrough Therapy Designation Drugs (Trial) (《國家藥監局關於發佈突破性治療藥物審評工作程序(試行)等三個文件的公告》), which was promulgated and implemented by the NMPA on July 7, 2020, refines the requirements and scope of the fast track, and the Opinions on Encouraging the Prioritized Evaluation and Approval for Drug Innovation was repealed simultaneously.

Good Clinical Practices

Clinical trials must be conducted in accordance with the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) (the "**GCP Rules**") promulgated by NMPA and NHC on April 23, 2020 and effective on July 1, 2020, which stipulates the requirements for the procedures of conducting clinical trials. The GCP Rules also set out the qualifications and requirements for the investigators and centers participating in clinical trial.

Acceptance of Foreign Data on Clinical Trials

The NMPA may reduce requirements for clinical trials and data, depending on the drug and the existing data. The NMPA has granted waivers for all or part of trials and has stated that it will accept data generated abroad (even if not part of a global study), including early phase data that meets its requirements. On January 30, 2015, the CFDA promulgated the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial) (《關於發佈國際多中心藥物臨床試驗指南(試行)的通告》) (the "**IMCT Guidelines**"), which took effect on March 1, 2015, to provide guidance for the regulation of application, implementation and administration of international multi-center clinical trials in China. Pursuant to the IMCT Guidelines, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicant plans to make use of the data derived from the international multi-center clinical trials for application to the CFDA for approval of NDA, such international multi-center clinical trials shall satisfy the requirements set forth in the PRC Drug Administration Law (《中華人民共和國藥品管理法》) and its implementation regulations and relevant laws and regulations.

On July 6, 2018, the NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data (《關於發布接受藥品境外臨床試驗數據的技術指導原則的通告》) (the "**Guidance Principles**"). According to the Guidance Principles, sponsors must be attentive to potentially meaningful ethnic differences in the subject population. If drug registration applicants use overseas clinical trials for drug registration applications in mainland China, all overseas clinical trial data shall be provided, rather than selectively. If drug registration applicants plan to carry out follow-up clinical research and development following the early overseas clinical trials, they shall evaluate the early clinical trial data and only after having obtained complete clinical trial data and communicated with the CDE, these data could be used to support the follow-up clinical trials.

Laws and Regulations on Drug Registration and Drug Marketing Authorization Holder

Pursuant to the newly amended DAL the drug marketing authorization holder means an enterprise or a drug research and development institution that has obtained the drug registration certificate, and this pharmaceutical marketing authorization holder shall be responsible for non-clinical laboratory studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of the DAL. Pursuant to the DRR, at the time of application for drug marketing authorization, the applicant and the manufacturing enterprise shall have held the corresponding drug manufacturing permits.

Laws and Regulations on Drug Manufacturing and Distribution, Drug Operation, and Drug Recalls

According to the Measures for Supervision and Administration of Drug Manufacturing (《藥品生產監督管理辦法》) (the "**Drug Manufacturing Measures**"), which was revised by the SAMR on January 22, 2020, and took effect from July 1, 2020, the new drug manufacturer shall be approved and issued with the Drug Manufacturing License by the drug supervision and administration department of the province, autonomous region or municipality directly under the central government where it is domiciled.

The Good Supply Practice ("**GSP**") and Good Manufacturing Practice ("**GMP**") certification for drugs were cancelled, and the application for GSP and GMP certification for drugs were no longer be accepted, since December 1, 2019, pursuant to the Announcement of the NMPA on Implementation of the Drug Administration Law (《國家藥監局關於貫徹實施<中華人民共和國藥品管理法>有關事項的公告》). But the competent regulatory authorities conduct the supervision and regulations through changing from the certification inspection once every five years to the inspection of the implementation of the GMP/GSP from time to time and supervising the compliance of enterprises.

The Administrative Measures for Drug Inspection (Trial) (《藥品檢查管理辦法(試行)》), revised by the NMPA on July 19, 2023, which stipulates that NMPA shall be in charge of the national drug inspection and management work. For the enterprises which apply for the Drug Manufacturing License for the first time, an on-site inspection shall be carried out in accordance with the relevant regulations of GMP. Those which apply for the marketing of drugs shall receive pre-marketing GMP compliance inspections as required in accordance with the provisions of Article 52 of the Drug Manufacturing Measures.

As required by the DAL and the Measures for the Quality Supervision and Administration of the Distribution and Use of Medicinal Products (《藥品經營和使用質量監督管理辦法》) which was promulgated by the SAMR on September 27, 2023, operation of drug business, including drug wholesale and drug retail, is prohibited without a Drug Business Permit. A Drug Business Permit shall state the validity period and the scope of business and be subject to review and reissuance upon expiry of the validity period.

According to the Announcement on Issuing the Measures for the Administration of Medicinal Product Recalls (《關於發佈<藥品召回管理辦法>的公告》) promulgated by NMPA on October 24, 2022 and effective from November 1, 2022, a drug manufacturer should establish and improve its recall system by collecting relevant information about drug safety and conducting investigation and evaluation with respect to the drugs with potential safety hazards. If there are any potential safety hazards that endanger human health and life safety in respect of any drugs sold in the PRC, such manufacturer must start the drug recall procedures.

Laws and Regulations on Coverage and Reimbursement and the Drug Price Regulations in the PRC

Medical Insurance Catalog

According to the Notice Regarding the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》) issued by the PRC Ministry of Labor and Social Security, together with other governmental authorities, the above-mentioned authorities have the power to determine the medicines included in the NRDL, which is divided into two parts, Part A and Part B. Patients purchasing medicines included in Part A of the Medical Insurance Catalog are entitled to reimbursement in accordance with the regulations in respect of basic medical insurance. Patients purchasing medicines included in Part B of the Medical Insurance Catalog are required to pay a certain percentage of the purchase price and the remainder of the purchase price shall be reimbursed in accordance with the regulations in respect of basic medical insurance.

According to the Interim Measures for the Administration of the Use of Drugs Covered by Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) issued by the National Healthcare Security Administration on July 30, 2020 and effective from September 1, 2020, the scope of the use of drugs covered by basic medical insurance is administered through the formulation of the Basic Medical Insurance Drug Catalog. The costs of medicines in line with the Basic Medical Insurance Drug Catalog are paid by the basic medical insurance fund in accordance with national regulations. The State Council's administrative department for medical insurance has established a sound dynamic adjustment mechanism, and in principle adjusts the Basic Medical Insurance Drug Catalog once a year. On the premise of meeting clinical needs, medical insurance designated medical institutions shall give priority to equipping and using drugs in the Basic Medical Insurance Drug Catalog.

According to the Interim Measures for the Administration of the Use of Drugs Covered by Basic Medical Insurance, expenses incurred by insured persons for the use of medicines in the Basic Medical Insurance Drug Catalog can be paid by the basic medical insurance fund if they meet certain conditions. Western medicines and proprietary Chinese medicines in the Basic Medical Insurance Drug Catalog are divided into "Class A drugs" and "Class B drugs". The use of "Class A drugs" is paid for by the insured according to the payment standards and sharing methods stipulated by the basic medical insurance; the use of "Class B drugs" is paid for according to the payment standards stipulated by the basic medical insurance, with a certain percentage paid out of pocket by the insured first, and then paid for according to the sharing methods stipulated by the basic medical insurance. The proportion of out-of-pocket payments for "Class B drugs" is determined by the medical insurance administrative departments in provinces or regions subject to overall planning.

Medical Insurance Reimbursement Standards

The State Council promulgated the Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents (《關於整合城鄉居民基本醫療保險制度的意見》) in January 2016, which required the integration of the urban resident basic medical insurance and the new rural cooperative medical care system and the establishment of a unified basic medical insurance system, which will cover all urban and rural residents other than rural migrant workers and persons in flexible employment arrangements who participate in the basic medical insurance for urban employees. The General Office of the State Council further released the Guidance on Further Deepening the Reform of the Payment Method of Basic Medical Insurance (《關於進一步深化基本醫療保險支付方式改革的指導意見》) in June 2017. The main objectives are to implement a diversified reimbursement mechanism including diagnosis related groups, per-capita caps, and per-bed-day caps. These new reimbursement methods would replace the current reimbursement method that is based on service category and product price.

Price Regulations

The government exercises regulations over the drugs through establishing a centralized tender process or centralized procurement mechanism, revising the NRDL or provincial medical insurance drug catalogues and strengthening regulation of medical and pricing practices. Also, according to the Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment, enterprises which apply for the registration of new drugs should promise that the prices of their products on the PRC market should not be higher than the comparable market prices in original countries or the surrounding area of the PRC.

Centralized Procurement of Drugs

According to the Certain Regulations on the Trial Implementation of Centralised Tender Procurement of Drugs by Medical Institutions (《醫療機構藥品集中招標採購試點工作若干規定》) promulgated on July 7, 2000 and the Notice of NMPA on Further Improvement on the Implementation of Centralised Tender Procurement of Drugs by Medical Institutions (《國家藥品監督管理局關於進一步做好醫療機構藥品集中招標採購工作的通知》) promulgated on July 23, 2001, not-for-profit medical institutions established by county or higher level government are required to implement centralized tender procurement of drugs.

The Ministry of Health promulgated the Working Regulations of Medical Institutions for Procurement of Drugs by Centralised Tender and Price Negotiations (for Trial Implementation) (《醫療機構藥品集中招標採購和集中議價採購工作規範(試行)》) on March 13, 2002, which provides rules for the tender process and negotiations of the prices of drugs, operational procedures, a code of conduct and standards or measures of evaluating bids and negotiating prices. According to the Notice of the Financial Planning Department of Ministry of Health on Issue of Opinions on Further Regulating Centralised Procurement of Drugs by Medical Institutions (《衛生部財務規劃司關於印發<進一步規範醫療機構藥品集中採購工作的意見>的通知》) promulgated on January 17, 2009, not-for-profit medical institutions owned by the government at the county level or higher or owned by state-owned enterprises (including state-controlled enterprises) shall purchase pharmaceutical products by online centralized procurement. Each provincial government shall formulate its catalog of drugs subject to centralized procurement. Except for drugs in the National List of Essential Drugs (the procurement of which shall comply with the relevant rules on National List of Essential Drugs), certain pharmaceutical products which are under the national government's special control, such as toxic, radioactive and narcotic drugs and traditional Chinese medicines, in principle, all drugs used by not-for-profit medical institutions shall be covered by the catalog of drugs subject to centralized procurement. The Opinions of the General Office of the State Council on Improvement of the Policy of Production, Circulation and Use of Drugs (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》) promulgated on January 24, 2017 by the General Office of the State Council aims to deepen the reform of medicine health system, improve the quality of the drug and regulate the distribution and use of the drug.

The Notice of the General Office of the State Council on Issuing Pilot Plan of Centralised Procurement and Use of the Drug Organised by the State (《國務院辦公廳關於印發國家組織藥品集中採購和使用試點方案的通知》) promulgated on January 1, 2019 aims to improve the pricing mechanism of the drug, which also further regulates the scope and mode of centralized procurement. According to the Implementation Opinions on Expanding the Regional Scope in the Pilot Program of Centralized Drug Procurement and Use Organized by the State (《關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見》) issued by the National Healthcare Security Administration and other departments on September 25, 2019, the regional scope in the pilot program of centralized procurement and use of drugs organized by the State is being expanded and the volume-based procurement model of the pilot program for conducting the centralized procurement and use of drugs organized by the State is being promoted throughout the country.

The Opinions of the General Office of the State Council on Promoting the Centralized Volume-based Procurement of Drugs in a Normalized and Institutionalized Manner (《國務院辦公廳關於推動藥品集中帶量採購工作常態化制度化開展的意見》), which was promulgated by the General Office of the State Council on January 22, 2021, set out the promotion of the normalization and institutionalization of the centralized procurement of drugs. All public medical institutions (including military medical institutions, hereinafter referred to as the same) shall participate in the centralized procurement of drugs, with reference to the requirements of the management of designated social medical institutions and designated pharmacies in accordance with the management of designated agreements for medical insurance. In accordance with the principles of preserving the basics and the clinical care, emphasis shall be placed on including drugs that are listed in the Drug Catalogue of Basic Medical Insurance with large consumption and high procurement price in the procurement scope, and gradually covering various drugs which are clinically necessary and reliable, so as to achieve the procurement of all medicines as much as possible.

On November 18, 2024, the NHSA and the NHC issued and implemented the Notice on Improving the Working Mechanism of Centralized Volume-based Procurement and Implementation of Pharmaceuticals (《關於完善醫藥集中帶量採購和執行工作機制的通知》), proposing the following measures to promote medical institutions and pharmaceutical enterprises to follow and support the Centralized Volume-based Procurement mechanism: (i) ensuring that the selected drugs and consumables are admitted to hospitals; (ii) improve the management level of the use of selected drugs and consumables; (iii) implement the policy of retaining the surplus of centralized procurement; (iv) explore the synergistic linkage of medical service prices, and so on.

Two-invoice System

Pursuant to the 2016 Key Tasks for Deepening the Reform of the Pharmaceutical and Healthcare System (《深化醫藥衛生體制改革2016年重點工作任務》) issued by the General Office of the State Council on April 21, 2016, in order to optimize the order of purchasing and selling pharmaceutical products and reduce circulation steps, the implementation of the "two-invoice system" shall be constructed throughout the pilot provinces for comprehensive healthcare reform and actively encouraged in the public hospitals of the pilot cities therefor.

According to the Circular on Issuing the Implementing Opinions on Carrying out the Two-invoice System for Drug Procurement among Public Medical Institutions (for Trial Implementation) (《印發關於在公立醫療機構藥品採購中推行"兩票制"的實施意見(試行)的通知》), or the Two-Invoice System Notice, which came into effect on December 26, 2016, the two-invoice system means one invoice between the pharmaceutical manufacturer and the pharmaceutical distributor, and one invoice between the pharmaceutical distributor and the medical institution, and thereby only allows a single level of distributor for the sale of pharmaceutical products from the pharmaceutical manufacturer to the medical institution.

According to the Two-Invoice System Notice and the Several Opinions of the General Office of the State Council on Further Reforming and Improving the Policies on Drug Production, Circulation and Use (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》) issued on January 24, 2017, the two-invoice system would be promoted in pilot provinces (or autonomous regions and municipalities directly under the central government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis, and encouraged to be implemented nationwide in 2018.

Laws and Regulations on Environmental Protection and Fire Control

Environment Protection

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), which was promulgated by the SCNPC on December 26, 1989, came into effect on the same day and last amended on April 24, 2014 and came into effect on January 1, 2015, outlines the authorities and duties of various environmental protection regulatory agencies.

According to the Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》) (the "**Construction Environmental Protection Rule**"), which was promulgated by the State Council on November 29, 1998, amended on July 16, 2017 and became effective on October 1, 2017, depending on the impact of the construction project on the environment, a construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form. According to the Environmental Impact Appraisal Law of PRC (《中華人民共和國環境影響評價法》), which was promulgated by the SCNPC on October 28, 2002, amended on July 2, 2016 and December 29, 2018, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the seriousness of effect that may be exerted on the environment.

Drainage and Sewage Disposal and Pollutant Discharges

Enterprises that engage in the activities of industry, construction, catering, and medical treatment, etc. that discharges sewage into urban drainage facilities shall apply to the relevant competent urban drainage department for the permit for discharging sewage into drainage pipelines under relevant laws and regulations, including the Regulations on Urban Drainage and Sewage Disposal (《城鎮排水與污水處理條例》), which was promulgated on October 2, 2013 and came into force on January 1, 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 last amended on December 1, 2022 and took effect on February 1, 2023. The drainage entity that has not obtained the drainage license shall not discharge sewage into urban drainage facilities.

Pursuant to the provisions of the Regulation on the Administration of Permitting of Pollutant Discharges (《排污許可管理條例》) promulgated on January 24, 2021 and effective on March 1, 2021, and the Measures for Pollutant Discharge Permitting Administration (《排污許可管理辦法》) promulgated on April 1, 2024 and became effective on July 1, 2024, the PRC implements the classified pollutant discharge permit management (i.e., key management, simplified management and registration management) on pollutant discharges of enterprises based on factors such as the volume of pollutants generated, the amount of pollutant discharged and the degree of impact on the environment. Enterprises and other producers that are included in the Classification Administration List of Pollutant Discharge Permits for Fixed Pollution Sources (《固定污染源排污許可分類管理名錄》) 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. 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》), entities generating hazardous waste shall store, utilize and dispose hazardous waste according to the relevant requirements of the state and environmental protection standards, and shall not dump or pile up hazardous waste without authorization.

Fire Control

Fire control pursuant to the Fire Control Law of the PRC (《中華人民共和國消防法》) last amended on April 29, 2021 and effective therefrom, if the design of fire control of a construction project has not been examined pursuant to the relevant laws or failed to pass the examination, the construction of such project is not allowed. If a completed construction project has not gone through the fire safety inspection or failed to satisfy the requirements of fire safety upon inspection, such project is not allowed to be put to use or business. According to the Interim Regulations on Administration of Examination and Acceptance of Fire Control Design of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) issued by the Ministry of Housing and Urban-Rural Development on April 1, 2020 and latest amended on 21 August, 2023, an examination system for fire control design and acceptance only applies to special construction projects, and for other projects, a record-filing and spot check system would be applied.

Laws and Regulations on Intellectual Property Protection

The Trademark Law of the PRC (《中華人民共和國商標法》) was promulgated by the SCNPC on August 23, 1982, implemented on March 1, 1983, and most recently revised on April 23, 2019, with implementation from November 1, 2019. The Regulations for the Implementation of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》) were issued by the State Council on August 3, 2002, implemented on September 15, 2002, and most recently revised on April 29, 2014, with implementation from May 1, 2014. According to these laws and regulations, the validity period of a registered trademark is 10 years from the date of approval. To continue using a trademark upon the expiry of its validity, renewal procedures must be completed in accordance with the provisions within the 12 months preceding expiration. If renewal procedures are not completed within this period, a six-month extension is allowed. Each renewal extends the validity period for 10 years, starting from the day following the expiration of the last validity period.

The Patent Law of the PRC (《中華人民共和國專利法》) was enacted by the SCNPC on March 12, 1984, implemented on April 1, 1985, and most recently revised on October 17, 2020, with implementation from June 1, 2021. 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》) were issued by the State Council on June 15, 2001, implemented on July 1, 2001, and most recently revised on December 11, 2023, with implementation from January 20, 2024. According to these laws, regulations and detailed rules, patents in China are categorized into three types: invention patents, utility model patents and design patents. The term of an invention patent right is 20 years, the term of a utility model patent is 10 years, and the term of a design patent is 15 years, all of which are calculated from the filing date. Any entity or individual that exploits another's patent must conclude a licensing agreement with the patent holder and pay royalties. Exploiting a patent without the permission of the patent holder constitutes an infringement of their patent rights.

On July 4, 2021, the NMPA and the National Intellectual Property Administration jointly issued the Implementation Measures for Early Resolution Mechanism of Pharmaceutical Patent Disputes (for Trial Implementation) (《藥品專利糾紛早期解決機制實施辦法(試行)》), which establishes an early resolution mechanism of pharmaceutical patent disputes. Provided there are disputes from the patentee or interested party considering the patent declaration, the pharmaceutical marketing authorization holder may, within 45 days from the disclosure date of the drug marketing authorization application by drug evaluation institutions in the PRC, initiate legal proceedings in the People's Court or apply for an administrative ruling to the patent administration department of the State Council on whether the relevant technical solution of the drug under application falls within the scope of protection of the relevant patent right.

The Administrative Measures for the Internet Domain Name (《互聯網域名管理辦法》) were issued by the Ministry of Industry and Information Technology (the "**MIIT**") on August 24, 2017, and implemented on November 1, 2017. According to these management measures, the MIIT is the primary regulatory authority for the management of Internet domain names in China. Domain name registration is processed through domain name root servers and their operating institutions, domain name registration management institutions and domain name registration service institutions established in accordance with the relevant regulations.

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by the NPCSC on September 2, 1993 and last amended on June 27, 2025 and became effective on October 15, 2025, business operators are prohibited from infringing others' trade secrets by, including but not limited to (i) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion or any other illicit means; (ii) disclosing, using or allowing other person to use a trade secret acquired from the right holder by any means as specified in the preceding subparagraph. If a third party knows or should have known the above mentioned illegal conducts but nevertheless acquires, uses or allows other persons to use such trade secrets, the third party shall be deemed to have infringed others' trade secrets.

Laws and Regulations on Labor Protection

The Labor Law of the PRC (《中華人民共和國勞動法》) was promulgated by the SCNPC on July 5, 1994, implemented on January 1, 1995, and most recently revised and implemented on December 29, 2018. The Labor Law of the PRC stipulates matters related to promoting employment, labor contracts, working hours, rest and leave, wages, labor safety and hygiene, special protection for female and minor workers, vocational training, social insurance and welfare, labor disputes, supervision and inspection, as well as legal liabilities. The Labor Contract Law of the PRC (《中華人民共和國勞動合同法》) was issued by the SCNPC on June 29, 2007, implemented on January 1, 2008, and most recently revised on December 28, 2012, with the revision taking effect on July 1, 2013. The Implementation Regulation of the Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》) were issued and implemented by the State Council on September 18, 2008. According to the aforementioned law and regulation, a written labor contract shall be established when forming a labor relationship. Employers shall not force employees to work overtime and must pay overtime wages according to national regulations if overtime is arranged. Wages must not be lower than the local minimum wage standard and must be paid to employees promptly.

The PRC Social Insurance Law (《中華人民共和國社會保險法》) (the "**Social Insurance Law**") issued by the SCNPC in 2010 and latest amended on December 29, 2018, has established social insurance systems of basic pension insurance, basic medical insurance, work-related injury insurance, unemployment insurance and maternity insurance and has elaborated in detail the legal obligations and liabilities of employers who fail to comply with relevant laws and regulations on social insurance. According to the Social Insurance Law and the Provisional Regulations on Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) promulgated by the State Council on January 22, 1999 and most recently amended on March 24, 2019 and effective from the same date, enterprises shall register social insurance with local social insurance and pay or withhold relevant social insurance for or on behalf of its employees. Any

employer that fails to make social insurance contributions may be ordered to rectify the non-compliance and pay the required contributions within a prescribed time limit and be subject to a late fee. If the employer still fails to rectify the failure to make the relevant contributions within the prescribed time, it may be subject to a fine ranging from one to three times the amount overdue.

On July 31, 2025, the Supreme People's Court of the PRC has issued the Interpretation II by the Supreme People's Court of the PRC on Legal Issues 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)》) (the "**Interpretation II**"), which took effect from September 1, 2025. Pursuant to the Interpretation II, it is a statutory obligation on both the employers and employees to participate in the social insurance. Any arrangement not to participate in social insurance, either by unilateral undertaking or mutual agreement, is invalid. Further, the Interpretation II specifies that if the employee terminates the labor contract on the grounds that the employer has failed to make social insurance contributions as required by law, and claims economic compensation from the employer, the People's Court of the PRC shall uphold the claim.

Pursuant to the Regulations on Administration of Housing Provident Fund (《住房公積金管理條例》), which was promulgated on April 3, 1999 and last revised on March 24, 2019, employers in mainland China shall provide their employees with housing provident fund. Employers who fail to contribute to the above housing provident funds may be ordered to make full payment within a prescribed time period by the housing provident fund management center. If an employer fails to make the payment towards the housing provident funds within a prescribed time limit, an application may be made to a people's court for enforcement.

Laws and Regulations on Taxation

Enterprise Income Tax

Pursuant to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得税法》) (the "**EIT Law**") latest amended by the SCNPC and came into effect on December 29, 2018 and the Regulations on the Implementation of the EIT Law (《中華人民共和國企業所得税法實施條例》) latest amended by the State Council on December 6, 2024 and came into effect on January 20, 2025, a domestic enterprise which is established within mainland China in accordance with the laws or established in accordance with any laws of foreign countries (regions) but with an actual management entity within mainland China shall be regarded as a resident enterprise. A resident enterprise shall be subject to a tax rate of 25% of any income generated within or outside mainland China. A preferential tax rate shall be applicable to any key industry or project which is supported or encouraged by the State.

According to the Announcement on Several Issues concerning the Enterprise Income Tax on Income from the Indirect Transfer of Assets by Non-Resident Enterprises (《關於非居民企業間接轉讓財產企業所得税若干問題的公告》) (the "**Tax Circular 7**") which was promulgated by the STA on February 3, 2015 and came into effect on the same day, where a non-resident enterprise indirectly transfers equities and other assets of a mainland China resident enterprise to avoid the tax payment obligation by making an arrangement with no reasonable business purpose, such indirect transfer shall be redefined and recognized as a direct transfer in accordance with the provisions of the EIT Law. Where the tax on the income from the indirect transfer of real estate or equities shall be paid in accordance with the provisions of the Tax Circular 7, the entity or individual that directly assumes the obligation to make relevant payments to the transfer or according to the provisions of the relevant laws or as agreed upon in the contract shall be the withholding agent.

In 2017, the STA issued the Announcement on Issues Relating to Withholding at Source of Income Tax of Non-resident Enterprises (《國家税務總局關於非居民企業所得税源泉扣繳有關問題的公告》) (the "**Tax Circular 37**"), most recently amended in 2018, which further elaborates the relevant implemental rules regarding the calculation, reporting and payment obligations of the withholding tax by the non-resident enterprises. Tax Circular 37 may be determined by the tax authorities to be applicable to our offshore transactions or sale of our shares or those of our offshore subsidiaries where non-resident enterprises, being the transferors, were involved.

Value-Added Tax

On December 25, 2024, the SCNPC issued the Value-Added Tax Law of the PRC (《中華人民共和國增值稅法》) (the "**VAT Law**"), which became effective from January 1, 2026. According to the VAT Law, any entities and individuals (including individual businesses) engaged in the sale of goods, services, intangible assets and immovables and importation of goods within the territory of the PRC are VAT payers and shall pay VAT in accordance with the VAT Law. Except for taxpayers' export of goods, the sale of services or intangible assets within the scope as prescribed by the State Council by domestic entities and individuals across national borders and other circumstances specified for by the State Council, the rate of VAT for sale of goods, labor services of processing, repair or replacement, or tangible movable property leasing services or import of goods is 13% unless otherwise specified, such as the rate of VAT for sale of agricultural products is 9%, and the rate of VAT for sale of transportation, postal, basic telecommunications, construction, or immovable leasing services, sale of immovables, or transfer of the rights to use land is 9%. In addition to the above circumstances, the rate of VAT for sale of services or intangible assets is 6%.

Laws and Regulations on Foreign Exchange

Foreign Exchange

The SAFE issued the Circular on Reforming of the Management Method of the Settlement of Foreign Currency Capital of Foreign-Invested Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》) (the "**SAFE Circular 19**") on March 30, 2015, and it became effective on June 1, 2015, which was partially repealed on December 30, 2019, and latest amended on March 23, 2023. The SAFE Circular 19 expands pilot reform of the administration of the settlement of the foreign exchange capitals of foreign-invested enterprises nationwide. On June 9, 2016, SAFE further promulgated the Circular on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《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》) (the "**SAFE Circular 16**"), which, among other things, amends certain provisions of SAFE Circular 19 and was partially amended on December 4, 2023. Pursuant to SAFE Circular 19 and SAFE Circular 16, the flow and use of the Renminbi capital converted from foreign currency denominated registered capital of a foreign-invested company is regulated such that Renminbi capital may not be used for business beyond its business scope or to provide loans to persons other than affiliates unless otherwise permitted under its business scope.

According to the SAFE Circular on Further Promoting Cross-border Trade and Investment Facilitation (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》) which was promulgated on October 23, 2019 and amended on December 4, 2023, foreign-invested enterprises engaged in non-investment business are permitted to settle foreign exchange capital in RMB and make domestic equity investments with such RMB funds according to law on the condition that the current Negative List are not violated and the relevant domestic investment projects are genuine and in compliance with laws. According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《國家外匯管理局關於優化外匯管理支持涉外業務發展的通知》) (the "**SAFE Circular 8**"), issued by SAFE on April 10, 2020, under the prerequisite of ensuring true and compliant use of funds and compliance with the prevailing administrative provisions on use of income under the capital account, eligible enterprises are allowed to make domestic payments by using their capital funds, foreign credits and the income under capital accounts of overseas listing, without prior provision of the evidentiary materials concerning authenticity to the bank for each transaction. The handling banks shall conduct spot checks afterwards in accordance with the relevant requirements.

Foreign Exchange Registration of Overseas Investment by PRC Resident

In July 2014, SAFE promulgated the Circular 37 and its implementation guidelines, pursuant to which, residents of mainland China (including institutions and individuals of mainland China) must register with local branches of SAFE in connection with their direct or indirect offshore investment in an overseas special purpose vehicle, or SPV, directly established or indirectly controlled by the residents of mainland China or the purposes of offshore investment and financing

with their legally owned assets or interests in domestic enterprises, or their legally owned offshore assets or interests. The SAFE Circular 13 amends the SAFE Circular 37 by requiring residents of mainland China or entities to register with qualified banks rather than the SAFE or its local branch in connection with their establishment or control of an offshore entity established for the purpose of overseas investment or financing.

Employee Stock Incentive Plan

On February 15, 2012, the SAFE promulgated the Notice of on Issues concerning the Foreign Exchange Administration of Domestic Individuals' Participation in Equity Incentive Plans of Overseas [**REDACTED**] Companies (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》) (the "**SAFE Circular 7**"). In accordance with the SAFE Circular 7 and relevant rules and regulations, the citizens of mainland China or non-PRC citizens residing in mainland China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas [**REDACTED**] company, subject to a few exceptions, are required to register with the SAFE through a domestic qualified agent, which could be a mainland China subsidiary of such [**REDACTED**] company, and complete certain procedures. We and our employees who are citizens of mainland China or who reside in mainland China for a continuous period of not less than one year and who participate in our stock incentive plan will be subject to such regulation.

Laws and Regulations on Company Establishment and Foreign Investment

Regulations Relating to Corporation

The establishment, operation and management of corporate entities in the PRC is governed by the Company Law of the PRC (《中華人民共和國公司法》) (the "**Company Law**"), which was promulgated by the SCNPC on December 29, 1993 and came into effect on July 1, 1994, and was last amended on December 29, 2023 and became effect on July 1, 2024. The Company Law of the PRC generally governs two types of companies, namely limited liability companies and joint stock limited companies. Both types of companies have the status of legal persons, and the liability of shareholders of a limited liability company or a joint stock limited company is limited to the amount of registered capital they have contributed. The Company Law of the PRC shall also apply to foreign invested companies in form of limited liability company or joint stock limited company. Where laws on foreign investment have other stipulations, such stipulations shall prevail.

Regulations Relating to Foreign Investment

On January 1, 2020, the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the "**FIL**") and the Regulations on the Implementation of the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》) became effective. On December 30, 2019, the MOFCOM and the SAMR jointly promulgated the Measures for Reporting of Information on Foreign Investment (《外商投資信息報告辦法》), which came into effect on January 1, 2020 and pursuant to which, foreign investors shall submit an initial or change report through the Enterprise Registration System when establishing foreign-invested enterprises or acquiring equity in non-foreign-invested enterprises and for any subsequent changes.

Pursuant to the FIL, the PRC has adopted a system of national treatment which includes a negative list with respect to foreign investment administration. The Special Administrative Measures (Negative List) for the Access of Foreign Investment (2024 Version) (《外商投資准入特別管理措施(負面清單)(2024年版)》) (the "**Negative List**"), which were promulgated by the NDRC and the MOFCOM on September 6, 2024 and became effective on November 1, 2024 and the Catalog of Industries for Encouraging Foreign Investment (2025 Version) (《鼓勵外商投資產業目錄(2025年版)》) (the "**Encouraging Catalog**"), which was promulgated by the NDRC and the MOFCOM on December 15, 2025 and became effective on February 1, 2026, listed the categories of encouraged, restricted, and prohibited industries. Any industry not included in the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment.

According to the Measures for the Administration of Overseas Investment of Enterprises (《企業境外投資管理辦法》) promulgated by the NDRC on December 26, 2017 and implemented on March 1, 2018, investors engaging in overseas investment are required to complete formalities for the confirmation or recordation, among others, of an overseas investment project, report the relevant information, and cooperate in supervisory inspection. Pursuant to the Measures for the Administration of Overseas Investment (《境外投資管理辦法》) promulgated by the MOFCOM on March 16, 2009, lastly amended on September 6, 2014 and implemented on October 6, 2014, the MOFCOM and the provincial counterparts promulgate regulations providing that overseas investment of enterprises to be subject to recordation or confirmation management, depending on the actual circumstances of investment.

Laws and Regulations on Overseas [REDACTED]

On February 17, 2023, the CSRC promulgated the Trial Administrative Measures of the Overseas Securities [**REDACTED**] and [**REDACTED**] by Domestic Enterprises (《境內企業境外發行證券和上市管理試行辦法》) and relevant five guidelines (the "**Overseas [REDACTED] Trial Measures**"), which came into effect on March 31, 2023. According to the Overseas [**REDACTED**] Trial Measures, PRC domestic enterprises that seek to [**REDACTED**] and [**REDACTED**] securities in overseas markets, either in direct or indirect means (the "**Overseas [REDACTED] and [REDACTED]**"), are required to fulfill the filing procedure with the CSRC and submit filing reports, legal opinions, and other relevant documents with the CSRC within three working days after the relevant application is submitted overseas.

On February 24, 2023, the CSRC together with the MOF and National Administration of State Secrets Protection and National Archives Administration of China have promulgated the Provisions on Strengthening the Confidentiality and Archives Administration Concerning the Overseas Securities [**REDACTED**] and [**REDACTED**] 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》). If domestic enterprises provide or publicly disclose to relevant securities companies, securities service institutions, overseas regulatory agencies and other parties, or provide or publicly disclose documents and materials involving state secrets or state organ work secrets through the issuer, they shall report the matters to the competent authorities for examination and approval, and file them with the department for the administration and management of state secrets at the same level for the record.

Laws and Regulations on Information Security and Data Protection

Personal Information Protection

According to the Civil Code, personal information of an individual shall be protected by the law. Any organization or individual that needs to obtain personal information of others shall obtain such information legally and ensure the safety of such information, and shall not illegally collect, use, process or transmit personal information of others, or illegally purchase or sell, provide or publish personal information of others. In addition, the processing of personal information shall follow the principles of lawfulness, appropriateness and necessity.

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 was promulgated by the SCNPC on August 20, 2021 and became effective on November 1, 2021 requires that the processing of personal information should have a clear and reasonable purpose and should be limited to the minimum scope necessary to achieve the processing purpose, adopt a method that has the least impact on personal rights and interests, and shall not process personal information that is not related to the processing purpose.

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》) was promulgated on May 8, 2017 and became

effective on June 1, 2017. The Interpretations clarify 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 "citizens' personal information", "violation of relevant national provisions", "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 "extraordinary serious circumstances" of this crime.

Privacy Data Security and Data Export

On June 10, 2021, the SCNPC 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 became effective on September 1, 2021. On December 28, 2021, the Cyberspace Administration of China (the "**CAC**"), jointly with 12 other administrative authorities, promulgated the revised Measures for Cybersecurity Review (《網絡安全審查辦法》) (the "**MCR**"), which became effective on February 15, 2022. According to the MCR; (i) that the purchase of cyber products and services by the Critical Information Infrastructure Operator (the "**CIIO**"), and the data processing activities carries out online platform operators which affects or may affect national security, shall be subject to the cybersecurity review by the Cybersecurity Review Office, the department which is responsible for the implementation of cybersecurity review under the CAC; (ii) network platform operators with personal information of more than one million users that seek for [**REDACTED**] in a foreign country are obliged to apply for a cybersecurity review by the Cybersecurity Review Office; and (iii) the relevant regulatory authorities may initiate cybersecurity review if such regulatory authorities determine that the issuer's network products or services, or data processing activities affect or may affect national security. On September 24, 2024, the State Council promulgated the Administration Regulations on Cyber Data Security (《網絡數據安全管理條例》) (the "**Data Security Regulations**"), which came into effect on January 1, 2025. In addition, the officially promulgated Data Security Regulations do not specifically include the requirement that cyber data processing entities seeking a [**REDACTED**] in Hong Kong that affects or may affect national security should apply for a cybersecurity review, as the requirement originally set forth in the draft regulations published on November 14, 2021. Instead, the officially promulgated regulations generally provide that cyber data processors whose cyber data processing activities affect or may affect national security shall be subject to national security review in accordance with the relevant regulations.

On July 7, 2022, the CAC promulgated the Measures for the Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》) (the "**Security Assessment Measures**"), which became effective on September 1, 2022. The Security Assessment Measures provides four circumstances, under any of which data processors shall, through the local cyberspace administration at the provincial-level, apply to the national cyberspace administration for security assessment of cross-border data transfer.

The Measures on the Standard Contract for the Cross-Border Transfer of Personal Information (《個人信息出境標準合同辦法》) (the "**SCC Measures**") were promulgated by the CAC on February 22, 2023 and took effect on June 1, 2023. The SCC Measures attach the prescribed template for the standard contract on the cross-border transfer of personal information that could be used as an available option to satisfy the condition for cross-border transfer of personal information under Article 38 of the Personal Information Protection Law.

On March 22, 2024, the CAC promulgated the Provisions on Promoting and Regulating Cross-Border Data Flows (《促進和規範數據跨境流動規定》), effective on the date of promulgation. The provisions provide several exemptions from undergoing data security assessment, obtaining personal information protection certification or entering into standard contract for outbound transfer of personal information for businesses. The provisions also explicitly state that data processors are not required to conduct data security assessments for cross-border transfer of important data if the data has not been notified or published as important data by relevant departments or regions.

OVERVIEW OF LAWS AND REGULATIONS IN THE UNITED STATES

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

Laws and Regulations in Relation to New Drug

U.S. Government Regulation of Drug and Biological Products

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations, and biologics under the FDCA and the Public Health Service Act and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative actions or judicial sanctions. These actions and sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, the market acceptance of our products and our reputation.

The process of obtaining regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations requires 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.

Once a product candidate is identified for development, it enters preclinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Preclinical testing is conducted in accordance with FDA's Good Laboratory Practice regulations. A sponsor of an IND must submit the results of the preclinical tests, manufacturing information, analytical data, the clinical trial protocol, and any available clinical data or literature to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions and places the trial on a clinical hold within that 30-day period. FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance. Any such concerns or holds must be adequately addressed by the drug sponsor for the study to proceed.

All clinical trials, which involve the administration of the investigational product to humans, must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practice regulations, including the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board (the "**IRB**"), must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to subjects.

Clinical trials generally are conducted in three sequential phases, known as phase I, phase II and phase III, and may overlap.

- Phase I clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. Typically, the primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.

- Phase II clinical trials involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is typically collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is generally conducted.

- Phase III clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Specifically for oncology drugs and biologics, FDA has and may continue to publish guidance documents describing clinical trial design and conduct considerations for, ad impacting, regulated industry. For example, in August 2018, the FDA introduced a draft guidance document titled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics Guidance for Industry", which was finalized in March 2022. This guidance paper acknowledges a new clinical trial design, which the FDA calls the first-in-human multiple expansion cohort trial. These are trial designs that have a single protocol with an initial dose escalation phase for the initial determination of a tolerated dose and multiple concurrently accruing expansion cohorts with assessments that are more typical of phase II trials (i.e., to assess anti-tumor activity). The new trial design is intended to efficiently expedite the clinical development of oncology drugs, including biological products, through multiple expansion cohort trial designs. The guidance document describes several factors, considerations, and risks of employing such trial designs, some of which may be applicable to our development programs.

A number of other requirements also apply to FDA regulated clinical trials. For instance, FDA seeks to ensure that clinical trial data is meaningful for and applicable to a U.S. population and medical practice, which may impact FDA's acceptance of data from foreign clinical studies. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than 7 calendar days after the sponsor's initial receipt of the information. 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.

If a clinical trial involves the use of an investigational device, including an in vitro diagnostic device or delivery device, the sponsor may also need to comply with FDA's investigational device regulations and obtain an investigational device exemption from the FDA. Drugs and biologics that require the use of a medical device may also be considered combination products. In such cases, the use of the two products together must be shown to be safe and effective for the proposed intended use and the labeling of the two products must reflect their combined use. In some cases, the device component may require a separate premarket submission. Once approved or cleared, the sponsor of the device component submission (or the combination product submission, if both components are covered by one premarket submission) would need to comply with FDA's post-market device requirements.

A sponsor may choose, but is not required, to conduct a clinical trial at sites outside the United States under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. When a foreign clinical trial is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval or licensing. In particular, such studies must be conducted in accordance with GCP, including review and approval by an IRB or independent ethics committee, or IEC, and informed consent from volunteers. The FDA must be able to validate the data through an onsite inspection or remote regulatory assessment, if deemed necessary by the FDA.

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 cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase IV studies may be made a condition to approval of the NDA/BLA. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA or a BLA. Unless deferred or waived, NDAs or BLAs, or supplements must contain data adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Further, for product candidates intended for the treatment of adult cancer which are directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer, with the application, sponsors must submit reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, gathered using appropriate formulations for each applicable age group, to inform potential pediatric labeling. The submission of an NDA or a BLA is subject to the payment of a substantial user fee and an annual prescription drug product program fee, unless a waiver applies.

Within 60 days of its receipt, the FDA reviews the NDA/BLA to ensure that it is sufficiently complete for substantive review before it accepts the NDA/BLA for filing. After accepting the NDA/BLA filing, the FDA begins an in-depth substantive review to determine, among other things, whether a product is safe and effective for its intended use. The FDA also evaluates whether the product's manufacturing is cGMP-compliant to assure the product's identity, strength, quality and purity. Before approving the NDA/BLA, the FDA typically will inspect whether the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA/BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities

are not acceptable, it may request additional testing or information. The FDA may refer the NDA/BLA to an advisory committee, a panel of experts, for review whether the application should be approved and under what conditions and considers such recommendations when making decisions.

The FDA may refuse to approve the NDA/BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. The FDA will issue a complete response ("**CR**") letter describing all of the specific deficiencies that the FDA identified in the NDA/BLA that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the CR letter may include recommended actions that the applicant might take to place the application in a condition for approval. The applicant may either resubmit the NDA/BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

The regulatory approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including phase IV clinical trials, to further assess a product's safety and effectiveness after NDA/BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In the United States, products composed of components that would normally be regulated by different centers at the FDA are known as combination products. Typically, the FDA's Office of Combination Products assigns a combination product to a specific Agency Center as the lead reviewer. The FDA determines which Center will lead a product's review based upon the product's primary mode of action. Depending on the type of combination product, its approval, clearance or licensure may usually be obtained through the submission of a single marketing application. However, the FDA sometimes will require separate marketing applications for individual constituent parts of the combination product which may require additional time, effort, and information. Even when a single marketing application is required for a combination product, the relevant Centers may participate in the review. An applicant will also need to discuss with the Agency how to apply certain premarket requirements and post-marketing regulatory requirements, including conduct of clinical trials, adverse event reporting and good manufacturing practices, to their combination product.

Expedited Development and Review Programs

The FDA has various programs that are intended to expedite or streamline the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures. The programs include fast track designation, breakthrough therapy designation, accelerated approval, priority review and orphan drug designation, among others.

Fast Track Designation

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a drug is intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and demonstrates the potential to address an unmet medical need for the disease or condition. Under the fast-track program, the sponsor of a drug candidate may request FDA to designate the product for a specific indication as a fast-track product concurrent with or after the filing of the IND for the drug candidate. The FDA must make a fast-track designation determination within 60 days after receipt of the sponsor's request.

In addition to other benefits, such as the ability to have more interactions with FDA, FDA may initiate review of sections of a fast-track product's NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing a fast-track application does not begin until the last section of the NDA is submitted. In addition, the fast-track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Breakthrough Therapy Designation

Another program available for sponsors is the breakthrough therapy designation. A drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request that a product be designated as a breakthrough therapy concurrently with, or at any time after, the submission of an IND, and the FDA must determine if the candidate qualifies for such designation within 60 days of receipt of the request. If so designated, the FDA will act to expedite the development and review of the product's marketing application, including by meeting with the sponsor throughout the product's development, providing timely advice to the sponsor to ensure that the development program to gather preclinical and clinical data is as efficient as practicable.

Accelerated Approval

Under FDA's accelerated approval regulations, the FDA may approve a drug or biologic candidate for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("**IMM**"), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. A product candidate approved on this basis is subject to additional post-marketing compliance requirements, including the completion of post-approval clinical trial to confirm the effect on the clinical endpoint. By the date of approval of an accelerated approval product, FDA must specify the conditions for the required post approval studies, including enrollment targets, the study protocol, milestones, and target completion dates. FDA may also, and frequently does, require that the confirmatory Phase IV studies be commenced prior to FDA granting a product accelerated approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Priority Review

The FDA may give a priority review designation to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months after the filing date, rather than the standard review of ten months under the Prescription Drug User Fee Act guidelines.

Orphan Drug Designation

Under The Orphan Drug Act of 1983, the FDA may grant orphan drug designation to drugs or biologic candidates intended to treat a rare disease or condition generally affecting fewer than 200,000 individuals in the U.S. or for which a manufacturer has no reasonable expectation of recovering drug treatment research and development costs. Sponsors must also provide a medically plausible basis for the use of the drug for the rare disease or condition. The first applicant to receive FDA approval for the disease or indication for which it has orphan drug designation is entitled to a seven year exclusive marketing period. During the exclusivity period, the FDA may not approve any other applications to market the same product for the same disease or condition except in limited circumstances. After the FDA grants the orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

Post-Marketing Requirements

Following the approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers are typically restricted from marketing or promoting such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require the development of additional data, preclinical studies, or clinical trials. 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. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

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 and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA/BLA, including recall.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval of the product if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug or biologic reaches the market. Corrective action could delay drug or biologic distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug or biologic, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug or biologic, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug or biologic approvals; drug or biologic seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

Patent Term Restoration

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.

Recently Passed Law by the U.S. Government: The BIOSECURE Act

On January 25, 2024, Representative Mike Gallagher (R-WI) introduced the BIOSECURE Act (H.R. 7085) (the "**Act**") to the U.S. House of Representatives. A goal of the Act is to safeguard the United States biotechnology supply chain amid concerns over potential national security threats perceived by those introducing the legislation to be associated with the PRC. The proposed legislation was referred to the House Committee on Oversight and Accountability, and passed by a vote of 306-81 in the House. The proposed legislation was referred to the U.S. Senate, and specifically the U.S. Senate Committees on Homeland Security and Governmental Affairs. On September 9, 2024, the U.S. House of Representatives voted in favor of its version of the Act. The U.S. Senate did not vote on either its version or the House-passed version and the legislation died at the conclusion of the 118th Congress in January 2025.

At the time, the Act, as proposed, generally would prohibit U.S. executive branch agencies from:

1. procuring or obtaining any biotechnology equipment or service produced or provided by a "biotechnology company of concern";

2. entering into or renewing a contract with an entity that uses such biotechnology equipment or enters into a contract requiring the use of such biotechnology equipment after the applicable effective date of the prohibition; or

3. providing loan or grant funds to perform either of these functions.

The Act proposed defining "biotechnology company of concern" ("**BCC**") to mean five named entities, namely BGI, MGI, Complete Genomics, WuXi AppTec, and WuXi Biologics, and any subsidiary, parent or successor of the foregoing.

On October 9, 2025, the U.S. Senate passed a revised version of the BIOSECURE Act as an amendment to the NDAA for the year of 2026. The final version of the NDAA containing this legislative language was passed by the Senate and House of Representatives and signed into law by President Trump on December 18, 2025. This version of the Act materially mitigates potential impacts, specifically, the Act eliminates the prior, explicit designation of "BCC" (which had included Wuxi AppTec) and instead adopts a dynamic identification framework tied to the U.S. Department of Defense's annual List of Chinese Military Companies, also known as the 1260H List, and the U.S. Government also has the ability to designate entities as BCCs through a separate designation process. At present, that list includes BGI and MGI, but does not include Wuxi Apptec or its affiliates. In addition, the legislation narrows the definition of restricted "biotechnology equipment or services," expressly excluding specific references to specific references to certain core technologies, including mass spectrometry and PCR instruments.

Specifically, the Act prohibits the U.S. Government from procuring or obtaining biotechnology equipment or services produced or provided by a "BCC"; entering into, extending, or renewing government contracts with an entity that directly or indirectly (e.g., via a subcontractor) uses biotechnology equipment or services from a BCC in performance of that federal contract; and/or issuing grants or loans to purchase, obtain, or use biotechnology equipment or services produced by a BCC. The Act also prohibits U.S. government loan and grant recipients from using federal loan or grant money to enter into contracts with entities that use equipment from BCCs in the performance of any federal prime contract or subcontract.

Now in the implementation phase, U.S. agencies will further define compliance obligations under the Act through the U.S. regulation approval process known as notice and comment rulemaking or through other procedures. The President of the United States may also issue executive orders with respect to the content of the Act.

Laws and Regulations in Relation to Outbound Investment

On October 28, 2024, the U.S. Department of the Treasury issued final regulations (the "**Final Rule**") to implement Executive Order 14105, "Addressing United States Investments in Certain National Security Technologies and Products in Countries of Concern" (August 9, 2023). The Final, which Rule, which took effect on January 2, 2025, prohibits or requires notification of certain investments by "U.S. persons" or their foreign subsidiaries in "covered foreign persons," which are defined as certain individuals or entities associated with a country of concern that are engaged in, or associated with parties engaged in, activities involving semiconductors and microelectronics, quantum information technologies, or artificial intelligence. The Final Rule applies if the covered foreign person or a related party is working with specified technologies in one of these fields.

The Comprehensive Outbound Investment National Security ("**COINS**") Act of 2025, signed into law on December 18, 2025, as part of the 2026 NDAA, expands the list of targeted technologies for the Final Rule by adding hypersonic systems and high-performance computing. The legislation also authorizes Treasury to designate additional technologies in the future. The COINS Act requires Treasury to issue regulations implementing these changes within 450 days of its enactment (i.e., March 2027). We will continue to monitor the status of these and future changes to the Final Rule and assess relevant risks.

LAWS AND REGULATIONS OF AUSTRALIA

Laws and Regulations of Clinical Development

Clinical trials conducted in Australia are regulated by the Therapeutic Goods Administration ("**TGA**"). Clinical trials must comply with a number of laws and regulations in Australia at the Commonwealth and State/Territory levels, including the *Therapeutic Goods Act 1989 (Cth) and the Therapeutic Goods Regulations 1990 (Cth)*. Clinical trials must also comply with: the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guidelines for Good Clinical Practice, as adopted and annotated by the TGA (the "**ICH GCP Guidelines**"); and the National Statement on Ethical Conduct in Human Research (the "**National Statement**").

There are two schemes for the approval of clinical trials in Australia: the Clinical Trial Notification ("**CTN**") scheme; and the Clinical Trial Approval ("**CTA**") scheme. The CTN scheme involves the TGA being notified of the clinical trial, but not undertaking any evaluation of the clinical trial. The CTA scheme involves the TGA not only being notified of the clinical trial, but also conducting an evaluation and assessment of the clinical trial prior to its commencement. The CTN scheme is generally used for earlier phase studies when there is adequate preclinical information about the product, particularly in relation to safety. The CTA scheme is generally used for high-risk or novel treatments, where there is little known or no knowledge about the safety of the goods. The decision regarding which scheme to follow is generally up to the sponsor of the trial and the applicable Human Research Ethics Committee ("**HREC**"), although the CTA scheme is mandatory for certain types of biological medicines. Clinical trials in Australia require the approval of the research institute that is conducting the trial, following a review by its HREC before the trial commences. HRECs are also responsible for overseeing clinical trials.

Clinical trials conducted in Australia must have a trial sponsor that is an Australian company. It is permissible for a foreign corporation to engage an Australian company to act as the sponsor of a clinical trial in Australia, often referred to as the Local Sponsor. In this situation, the foreign corporation does not, itself, need to obtain any licenses or authorizations in respect of the clinical trial. The Australian trial sponsor is responsible for the initiation, management and financing (or arranging the financing) for the clinical trial and is legally responsible for the conduct of the clinical trial, including obtaining the requisite licenses or authorizations. The trial sponsor does not need to be the manufacturer of the product being trialed. The product manufacturer may rely on the results the trial when seeking to have the product registered on the Australian Register of Therapeutic Goods.

Clinical trials in Australia must follow the ICH GCP Guidelines as annotated by the TGA. The TGA's annotations provide additional guidance regarding compliance with the National Statement, obtaining informed consent in special cases, responsibility for the conduct of the trial (including management, data handling and record keeping), the manufacturing, packaging, labelling and coding of investigational products, and reporting for adverse drug reactions. The approval of a clinical trial in Australia is conditional upon compliance with the ICH GCP Guidelines as annotated by the TGA.

Clinical trials in Australia must also comply with the National Statement. The National Statement sets out the Australian ethical standards against which all research involving humans, including clinical trials, are reviewed. The approval of a clinical trial in Australia is conditional upon compliance with the National Statement.

In relation to safety reporting requirements, clinical trials conducted in Australia must follow: the Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95), as annotated by the TGA; and the National Health and Medical Research Council ("**NHMRC**") Guidance: Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods.

Additionally, per the ICH GCP Guidelines as annotated by the TGA, products used in clinical trial must comply with the applicable good manufacturing practices ("**GMP**"). For investigational products manufactured in Australia, the relevant manufacturing standards are set out in the *Therapeutic Goods (Manufacturing Principles) Determination 2020 (Cth)*. Generally, therapeutic goods (other than blood, blood components, haematopoietic progenitor cells and biologicals that do not comprise or contain live animal cells, tissues or organs) must be manufactured in accordance with the Guide to Good Manufacturing Practice of Medicinal Products (PE 009-15, 1 May 2021) published by PIC/S.

Under both the CTN and CTA schemes, the clinical trial sponsor for a trial involving medicines or biological products must provide to the TGA information about the proposed dosage form, route of administration, formulation, dosage, and frequency of administration of the product (amongst other information), prior to the commencement of the clinical trial. If a change to the dosage is proposed to be made following the completion of a phase I clinical trial, then that change must be either notified to the TGA (if the clinical trial falls under the CTN scheme), or approved by the TGA (if the clinical trial falls under the CTA scheme). The change would also require review and approval by the HREC overseeing the trial.