PRC LAWS AND REGULATIONS

We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section sets out a summary of the most significant relevant laws, regulations, rules and policies that are applicable to our current business activities in the PRC.

REGULATIONS ON FOREIGN INVESTMENT AND OVERSEAS INVESTMENT

Foreign Investment

Investment activities in the PRC by foreign investors are principally governed by the Catalog of Encouraged Industries for Foreign Investment (2022) (《鼓勵外商投資產業目錄》(2022年版)) (the "**Encouraged Catalog**"), and the Special Administrative Measures (Negative List) for Foreign Investment Access (2024) (《外商投資准入特別管理措施(負面清單)(2024年版)》) (the "**Negative List**"), which are promulgated and amended from time to time by the Ministry of Commerce of the PRC (the "**MOFCOM**") and the NDRC, and together with the Foreign Investment Law of PRC (《中華人民共和國外商投資法》) (the "**FIL**") and its respective implementation rules and ancillary regulations.

On March 15, 2019, the FIL was promulgated by National People's Congress (the "**NPC**") and came into effect on January 1, 2020, which replaced three then existing laws on foreign investments in China, namely, the Chinese-Foreign Equity Joint Ventures Law of PRC (《中華人民共和國中外合資經營企業法》), the Chinese-Foreign Contractual Joint Ventures Law of PRC (《中華人民共和國中外合作經營企業法》) and the Wholly Foreign-owned Enterprise Law of PRC (《中華人民共和國外資企業法》). The FIL, by means of legislation, establishes the basic framework for the access, promotion, protection and administration of foreign investment in view of investment protection and fair competition. According to the FIL, foreign investment shall enjoy pre-establishment national treatment, except for those foreign invested entities that operate in industries deemed to be either "restricted" or "prohibited" in the Negative List, and the State Council shall promulgate or approve a list of special administrative measures for access of foreign investments. To ensure the effective implementation of the FIL, the Regulations on Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》) (the "**Implementation Regulations**"), was promulgated by State Council on December 26, 2019 and came into effect on January 1, 2020, which further clarified that the state encourages and promotes foreign investment, protects the lawful rights and interests of foreign investors, regulates foreign investment administration, continues to optimize foreign investment environment, and advances a higher-level opening.

On December 30, 2019, the MOFCOM and the SAMR promulgated the Measures on Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which came into effect on January 1, 2020. After the Measures on Reporting of Foreign Investment Information came into effect, the Interim Measures for the Administration of Filing for Establishment and Changes in Foreign Investment Enterprises (《外商投資企業設立及變更備案管理暫行辦法》) have been repealed simultaneously. Since January 1, 2020, for foreign investors carrying out investment activities directly or indirectly in China, the foreign investors or foreign-invested enterprises shall submit investment information to the relevant commerce administrative authorities according to the Measure on Reporting of Foreign Investment Information.

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

Overseas Investment

Pursuant to the Measures for the Administration of Overseas Investment (《境外投資管理辦法》) which was issued by the MOFCOM on September 6, 2014 and became effective on October 6, 2014, the MOFCOM and the commerce departments at provincial levels shall subject the overseas investment of enterprises to recordation or confirmation management, depending on the actual circumstances of investment. Overseas investment involving any sensitive country or region, or any sensitive industry shall be subject to confirmation management. Overseas investment under other circumstances shall be subject to recordation management.

Pursuant to the Measures for the Administration of Overseas Investment of Enterprises (《企業境外投資管理辦法》) which was issued by the NDRC on December 26, 2017 and became effective on March 1, 2018, an enterprise in the territory of the PRC (the "**Investor**") shall, in overseas investment, undergo the formalities for the confirmation or recordation, among others, of an overseas investment project (the "**Project**"), report the relevant information, and cooperate in supervisory inspection. Sensitive projects conducted by investors directly or through overseas enterprises controlled by them shall be subject to approval management. Non-sensitive Projects directly conducted by Investors, namely, non-sensitive Projects involving Investors' direct contribution of assets or rights and interests or provision of financing or security, shall be subject to recordation management. The aforementioned sensitive Project means a Project involving a sensitive country or region or a sensitive industry. The NDRC promulgated the Catalogue of Sensitive Sectors for Outbound Investment (2018 Edition) (《境外投資敏感行業目錄(2018年版)》), effective on March 1, 2018, to list the sensitive industries in detail.

REGULATIONS ON DRUG ADMINISTRATION

Drug Regulatory Regime

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the "**Drug Administration Law**") was promulgated by the Standing Committee of the NPC (the "**SCNPC**") on September 20, 1984, latest amended on August 26, 2019 and became effective on December 1, 2019. The Implementation Regulations of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》) (the "**Implementation Regulations**") was promulgated by the State Council on August 4, 2002, and was latest amended on December 6, 2024 and became effective on January 1, 2025. The Drug Administration Law and the Implementation Regulations have jointly established the legal framework for the administration of pharmaceutical products in the PRC, including the research, development and manufacturing of drugs. The Drug Administration Law applies to entities and individuals engaged in the development, production, trade, application, supervision and administration of pharmaceutical products, which regulates and provides a framework for the administration of pharmaceutical manufacturers, pharmaceutical trading companies and medicinal preparations of medical institutions, and the development, research, manufacturing, distribution, packaging, pricing and advertisements of pharmaceutical products. The Implementation Regulations, at the same time, provides the detailed implementation regulations on the Drug Administration Law.

In 2017, the drug regulatory system entered a new and significant period of reform. The General Office of the State Council and the General Committee of China Communist Party jointly issued the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (the "**Innovation Opinions**") on October 8, 2017. According to the Innovation Opinions, institutions for drug clinical trials should establish an independent ethics committee and the clinical trial schemes are subject to examination, approval and signing with approval opinions by the ethics committee before implementation, in order to protect the rights and interests of human subjects in clinical trials. For a multi-center clinical trial conducted in the PRC, after ethical review by the leader unit of clinical trial, other member units should recognize the review results of the leader unit and may not conduct repeated review. In addition, the expedited programs, the record-filing system, the prioritized review mechanism, the acceptance of foreign clinical data under the Innovation Opinions and other recent reforms encourage drug marketing authorization holders to seek marketing approval in China first for the development of drugs in highly prioritized therapeutic areas such as oncology or rare disease areas.

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

Application for Clinical Trial

According to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the China Food and Drug Administration (currently known as the NMPA) on March 17, 2017, the decision on the approval of clinical trials of drugs shall be made by the Center for Drug Evaluation ("**CDE**") from May 1, 2017. According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the "**Registration Measures**"), which was promulgated on January 22, 2020 and took effect on July 1, 2020, drug clinical trials shall be divided into Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial, and bioequivalence trial. After the completion of the pharmaceutical, pharmacological and toxicological research of the drug clinical trial, the applicant may submit relevant research materials to CDE for applying for the approval to conduct drug clinical trial. The CDE will organize pharmaceutical, medical and other technicians to review the application and to decide whether to approve the drug clinical trial within 60 days of the date of acceptance of the application. Once the decision is made, the result will be notified to the applicant through the website of the CDE and if no notice of decision is issued within the aforementioned time limit, the application of clinical trial shall be deemed as approval. In accordance with Registration Measures and the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》) issued on July 24, 2018, if a clinical trial applicant does not receive any negative or questioned opinions from the CDE within 60 days after the date when the trial application is accepted and the fees are paid, the applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the CDE.

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

Accelerated Approval for Clinical Trial and Registration

The Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices (《關於改革藥品醫療器械審評審批制度的意見》) issued by the State Council on August 9, 2015, established a reform framework of the evaluation and approval system for drugs and medical devices, and indicated the tasks of enhancing the standards of approval for drug registration, accelerating the evaluation and approval process for innovative drugs, and improving the approval for clinical trials of drugs, etc.

The China Food and Drug Administration (currently known as the NMPA) released the Circular Concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》) on November 11, 2015, which clarified the measures and policies regarding simplifying and accelerating the approval process of clinical trials, including but not limited to an one-time approval procedure allowing the overall approval of all phases of a drug's clinical trials, replacing the phase-by-phase application and approval.

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

According to the Announcement on Matters Concerning the Optimization of Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》) jointly issued by the NMPA and the National Health Commission of the PRC (the "**NHC**") on May 17, 2018, the CDE will prioritize the allocation of resources for review, inspection, examination and approval of registration applications that have been included in the scope of fast track clinical trial approval.

On July 7, 2020, the NMPA issued the Review and Approval Procedures for Conditional Approval of Drug Marketing Applications (Trial Implementation) (《藥品附條件批准上市申請審評審批工作程序(試行)》), pursuant to which and the Registration Measures, an applicant may submit, during the stage of clinical trials, an application for conditional approval, for pharmaceuticals which fall under the following circumstances: (i) drugs for treatment of life-threatening illnesses for which there is no effective treatment, whose clinical trial has data to prove efficacy and to forecast the clinical value thereof; (ii) drugs urgently needed for public health, whose clinical trial has data to prove efficacy and to forecast the clinical value thereof; and (iii) other vaccines urgently needed for major public health emergencies or deemed by the NHC to be urgently needed, which has been concluded upon evaluation that the benefits outweigh the risks. For applications for a conditional approval, the applicant shall communicate with the CDE on the conditional approval criteria for marketing and the post-marketing research work to be continued and completed, and apply for drug marketing authorization upon communication and confirmation. If it is concluded that the conditional approval requirements are complied with, the drug registration certificate shall state the validity period of the drug registration with conditional approval, the post-marketing research

work to be continued and completed and the deadline to complete such work, etc. For the drug which is granted with conditional approval, the holder shall adopt the appropriate risk management measures following marketing of the drug, and complete the drug clinical trial and relevant post-marketing research within the stipulated period, and declare so to the CDE via a supplementary application.

On July 7, 2020, NMPA issued the Priority Review and Approval Procedures for Drug Marketing Authorizations (Trial Implementation) (《藥品上市許可優先審評審批工作程序(試行)》), at the time of application for drug marketing authorization, the following drugs which have obvious clinical value may apply for prioritized review and approval procedures: (i) clinically and urgently needed but insufficient drugs, innovative drugs and improved new drugs for prevention and treatment of major contagious diseases and rare diseases; (ii) new pediatric use pharmaceutical products, dosage form and specifications which comply with pediatric physiological characteristics; (iii) vaccines and innovative vaccines urgently needed for prevention and control of diseases; (iv) drugs included in the procedures for breakthrough therapy designation; (v) drugs which comply with conditional approval criteria; and (vi) other circumstances entitled to prioritized review as stipulated by the NMPA. Upon communication and confirmation with the CDE, when the applicant submits the application for drug marketing authorization, the applicant shall simultaneously submit an application for prioritized review and approval. If an application satisfies one of the foregoing criteria, the CDE shall announce so and admit the application in the prioritized review and approval procedures. The following policy support shall be granted to an application for drug marketing authorization admitted in the prioritized review and approval procedures: (i) the review period shall be limited to no more than 130 days; (ii) for clinically and urgently needed imported drugs for rare diseases which are not yet marketed in the PRC, the review period shall be limited to no more than 70 days; (iii) priority shall be granted to examination, inspection and approval of the commonly used name of drugs (if applicable); and (iv) upon communication and confirmation, supplementary supporting materials may be required.

Conduct of Clinical Trial

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

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

The Announcement on Issuing the Guidelines for General Considerations for Clinical Trials on Drugs (《關於發佈藥物臨床試驗的一般考慮指導原則的通告》) promulgated by the China Food and Drug Administration (currently known as the NMPA) in January 18, 2017 provides technical guidelines for applicants and investigators in formulating overall research and development plan of drugs and separate clinical trial and provides references for evaluation of the technical standards of the drugs.

According to the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》), where the application for clinical trial of new investigational drug has been approved, upon the completion of Phases I and II clinical trials and prior to Phase III clinical trial, the applicant shall submit the application for communication meetings to CDE to discuss with CDE the key technical questions including the design of Phase III clinical trial protocol. According to the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (《藥物研發與技術審評溝通交流管理辦法》), revised by the CDE on December 10, 2020, during the research and development periods and in the registration applications of, among others, the innovative new drugs, the applicants may propose to conduct communication meetings with the CDE. The communication meetings can be classified into three types. Type I meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are held during the key research and development stages of drugs, mainly including meetings before submitting the clinical trial application, meetings upon the completion of Phase II trials and prior to Phase III trials, meetings before submitting the marketing application for a new drug, and meetings for risk evaluation and control. Type III meetings refer to other meetings not classified as Type I or Type II.

Good Clinical Practices

Clinical trials must be conducted in accordance with the Good Clinical Practice for Drug Trials (《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, including trial protocols, protection of testees' rights and interests, duties of researchers, sponsors and monitors, as well as data management and statistical analysis. According to the GCP Rules, clinical trial means systematical investigation of drugs conducted on human subjects (patients or healthy volunteers) to prove or reveal the clinical, pharmacological and other pharmacodynamic effects, adverse reactions or absorption, distribution, metabolism and excretion of the drug being investigated. In order to ensure the quality of clinical trials and the safety of human subjects, the GCP Rules provides comprehensive and substantive requirements on the design and conduct of clinical trials in the PRC. In particular, the GCP Rules enhances the protection for study subjects and tightens the control over bio-samples collected under clinical trials.

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

The GCP Rules also set out the qualifications and requirements for the investigators and centers participating in clinical trial, including: (i) professional certification at a clinical trial center, professional knowledge, training experience and capability of clinical trial, and being able to provide the latest resume and relevant qualification documents per request; (ii) being familiar with the trial protocol, investigator's brochure and relevant information of the trial drug provided by the applicant; (iii) being familiar with and comply with the GCP Rules and relevant laws and regulations relating to clinical trials; (iv) keeping a copy of the authorization form on work allocation signed by investigators; (v) investigators and clinical trial centers shall accept supervision and inspection organized by the applicant and inspection by the drug regulatory authorities; and (vi) in the case of investigators and clinical trial centers authorizing other individual or institution to undertake certain responsibilities and functions relating to clinical trial, they shall ensure such individual or institution are qualified and establish complete procedures to ensure the responsibilities and functions are fully performed and generate reliable data.

The GCP Rules also summarizes the role of ethic committee in clinical trial process. An ethic committee shall consist of experts working in the medical, pharmaceutical and other fields. The clinical trial protocol may not be executed unless approved by the ethic committee. Pursuant to the Announcement on Issuing the Guidelines for Ethical Review Work of Drug Clinical Trials (《關於印發藥物臨床試驗倫理審查工作指導原則的通知》) promulgated by State Food and Drug Administration (currently known as the NMPA) in November 2010, the ethics committee shall carry out a review on the project of clinical trial on the drug to decide

if it is rational in terms of science and ethics, and shall be subject to guidance and supervision under the drug supervisory and administrative departments. The Regulations for the Administration of Drug Clinical Trial Institutions also stipulates that each clinical trial institution shall maintain an ethic committee responsible for the ethical review of drug clinical trial.

Non-clinical Research

The non-clinical safety evaluation study for drugs for the purpose of applying for drug registration shall be conducted in accordance with the Administrative Measures for Good Laboratories Practice (《藥物非臨床研究質量管理規範》), which was promulgated on August 6, 2003 latest amended on July 27, 2017 by the China Food and Drug Administration (currently known as the NMPA) and effective from September 1, 2017. In April 2007, the China Food and Drug Administration issued the Regulations on the Certification Management of Good Laboratory Practice (《藥物非臨床研究質量管理規範認證管理辦法》), last amended on January 19, 2023 and taking effect on July 1, 2023, which set forth the requirements for an institution to apply for a Certification of Good Laboratory Practice to undertake non-clinical research on drugs.

International Multi-center Clinical Trials

On January 30, 2015, the China Food and Drug Administration (the "CFDA", the predecessor of the NMPA) 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 "**International Multi-Center Clinical Trial Guidelines**"), which took effect as of March 1, 2015, aiming to provide guidance for the regulation of application, implementation and administration of international multi-center clinical trials in China. Pursuant to the International Multi-Center Clinical Trial Guidelines, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Applicant may make use of the data derived from the international multi-center clinical trials for application to the NMPA for approval of an NDA/BLA after satisfying certain requirements under the International Multi-Center Clinical Trial Guidelines. International multi-center clinical trials shall follow internationally prevailing GCP principles and ethics requirements.

Trial Exemptions and Acceptance of Foreign Data

The NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data (《接受藥品境外臨床試驗數據的技術指導原則》) on July 6, 2018, as one of the implementing rules for the Innovation Opinions, which provides that overseas clinical data can be submitted for the drug marketing registration applications in China. Such applications can be in the form of waivers to China-based clinical trials, bridging trials and direct drug marketing registration. According to the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data, sponsors may use the data of foreign clinical trials to support drug marketing registration in China, provided that sponsors must ensure the authenticity, integrity,

accuracy and traceability of foreign clinical trial data and such data must be obtained consistent with the relevant requirements under the Good Clinical Practice of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (the "**ICH**"). Moreover, sponsors shall ensure the scientific design of overseas clinical trials, the compliance of clinical trial quality management system requirements, and the accuracy and integrity of statistical analysis of data. To ensure that the clinical trial design and statistical analysis of the data are scientific and reasonable, for the drugs with simultaneous R&D at home and abroad and forthcoming clinical trials in China, the sponsors may, prior to implementing registrational clinical trials, contact the CDE to ensure the compliance of registrational clinical trials' design with the essential technical requirements for drug registration in China. Sponsors must also comply with other relevant sections of the Registration Measures when applying for drug marketing registrations in China using foreign clinical trial data.

The NMPA now officially permits, and its predecessor agencies have permitted on a case-by-case basis in the past, drugs approved outside of China to be approved in China on a conditional basis without pre-approval clinical trials being conducted in China. Specifically, the NMPA and the NHC released the Procedures for Reviewing and Approval of Clinical Urgently Needed Overseas New Drugs (《關於臨床急需境外新藥審評審批相關事宜的公告》) on October 23, 2018, permitting drugs that have been approved within the last ten years in the United States, the European Union or Japan and that prevent or treat orphan diseases or prevent, or treat serious life-threatening illnesses for which there is either no effective therapy in China, or for which the foreign-approved drug would have clear clinical advantages. Applicants shall establish a risk mitigation plan, timely report the occurrence of adverse reactions, assess the risk situation, propose measures for improvement, and conduct ongoing research on marketed medicines. The NMPA may carry out clinical trial data verification after the drug has been marketed. The CDE has developed a list of qualifying drugs that meet the foregoing criteria.

On November 15, 2021, the CDE introduced the Guiding Principles for Clinical Research and Development of Anti-tumor Drugs Oriented by Clinical Value (《以臨床價值為導向的抗腫瘤藥物臨床研髮指導原則》), for anti-tumor drugs, which states that the fundamental purpose of the drug market is to address the needs of patients, and emphasizes that drug R&D should be based on patient needs and clinical value.

New drug registration

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

Marketing Authorization Holder Mechanism

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

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

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

Drug Manufacturing

According to the Drug Administration Law and the Implementing Regulations, a drug manufacturing enterprise is required to obtain a Drug Manufacturing Permit from the relevant provincial drug administration authority of the PRC. The grant of such permit is subject to an inspection of the manufacturing facilities, and an inspection to determine whether the sanitary condition, quality assurance systems, management structure and equipment meet the required standards. According to the Measures for the Supervision and Administration of Drug Manufacturing (《藥品生產監督管理辦法》) (the "**Drug Manufacturing Measures**"), last amended on January 22, 2020 and came into effect on July 1, 2020, the Drug Manufacturing Permit is valid for five years and shall be renewed at least six months prior to its expiration date upon a re-examination by the original issuing authority. In addition, the name, unified social credit code, registered address (business premises) and legal representative specified in the drug manufacturing permit shall be the same as that set forth in the business license as approved and issued by the local counterparts of the SAMR. According to the Drug Manufacturing Measures, if the MAH does not manufacture the drug but entrusts others to manufacture the drug, the MAH shall enter into an entrustment agreement and a quality agreement with a qualified drug producer and submit the relevant agreements and the application materials of the actual production site to the competent provincial counterpart of the NMPA where the MAH is located to apply for the Drug Manufacturing Permit.

The Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) (the "**GMP Rules**") was last amended on January 17, 2011 and came into effect on March 1, 2011. The GMP Rules comprise a set of detailed standard guidelines governing the manufacture of drugs, including institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, raw material management, maintenance of sales records and management of customer complaints and AE reports. Under the Drug Manufacturing Measures, a GMP certification is no longer required for drug manufacturing enterprises, but drug manufacturing enterprises shall comply with the GMP Rules in their drug manufacturing activities.

Drug Distribution

According to the Drug Administration Law, the engagement in drug distribution, including drug wholesale and drug retail, is prohibited without a drug distribution license. A drug distribution license shall state the validity period and the scope of business and be subject to review and reissuance upon expiry of the validity period.

The Measures for the Supervision and Management of Drug Distribution and Use Quality (《藥品經營和使用質量監督管理辦法》) promulgated by the SAMR on September 27, 2023 came into effect on January 1, 2024, and the Measures for the Administration of Drug Distribution (《藥品經營許可證管理辦法》) was simultaneously repealed. The Measures for the Supervision and Management of Drug Distribution and Use Quality stipulates the conditions, procedures, changes and supervision and administration of the drug distribution license.

The Good Supply Practice for Pharmaceutical Products (《藥品經營質量管理規範》) (the "**GSP Rules**") was last amended and came into effect on July 13, 2016. The GSP Rules set forth the basic standards in management of distribution quality of drugs and apply to enterprises engaged in drug distribution in the PRC, which require drug distributors to implement strict controls on its distribution of pharmaceutical products, including standards regarding staff qualifications, premises, warehouses, inspection equipment and facilities, management and quality control. Under the Drug Administration Law, the GSP certification is no longer required for drug distributors, but drug distributors are still required to comply with the GSP Rules.

Approval or Filing of Human Genetic Resources

The Ministry of Science and Technology (the "**MST**") promulgated the Service Guide for Administrative Licensing of Human Genetic Resources Gathering, Collection, Trade, Export and Exit Approval (《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 gathering, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organization of China shall apply for approval of the Human Genetic Resources Management Office of the PRC through the online system. The MST and the Human Genetic Resources Management Office of the PRC further respectively

promulgated the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》) on October 26, 2017 and the Circular on Further Optimizing the Administrative Examination and Approval of Human Genetic Resources (《關於進一步優化人類遺傳資源行政審批流程的通知》) on October 19, 2020, which simplify the approval of gathering and collecting human genetic resources for the purpose of listing a drug in the PRC.

The Regulations on the Administration of Human Genetic Resources of the PRC (《中華人民共和國人類遺傳資源管理條例》), promulgated by the State Council on May 28, 2019, latest amended in March 10, 2024 and came into effect on May 1, 2024, further stipulates that in order to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China's human genetic resources at clinical institutions without export of human genetic resource materials. However, the type, quantity and usage of the human genetic resources to be used shall be filed with the administrative department of health under the State Council before clinical trials. On May 26, 2023, the MST issued the Implementation Rules for the Administrative Regulation on Human Genetic Resources (《人類遺傳資源管理條例實施細則》), which came into effect on July 1, 2023, optimizing the scope of administrative licensing and record-keeping, enhancing the operability of the human genetic resources administration system, and implementing the registration and reporting system for the management of human genetic resources.

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

REGULATIONS ON INTELLECTUAL PROPERTY

In terms of international conventions, the PRC has entered into (including but not limited to) the Agreement on Trade-Related Aspects of Intellectual Property Rights (《與貿易有關的知識財產權協定》), the Paris Convention for the Protection of Industrial Property (《保護工業產權巴黎公約》), the Madrid Agreement Concerning the International Registration of Marks (《商標國際註冊馬德里協定》) and the Patent Cooperation Treaty (《專利合作條約》).

Trademarks

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) which was promulgated by the SCNPC on August 23, 1982 and latest amended on April 23, 2019 and came into effect on November 1, 2019, and the Implementation Regulations of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》) which was promulgated by the State Council on August 3, 2002, later amended on April 29, 2014, and came into effect on May 1, 2014, the Trademark Office under the State Administration for Industry and Commerce of the PRC (the "**Trademark Office**") shall handle trademark registrations and grant a term of ten years to registered trademarks, which may be renewed for consecutive ten-year period upon request from the trademark owner. The Trademark Law of the PRC has adopted a "first-to-file" principle with respect to trademark registration. Where an application for trademark for which application for registration has been made is identical or similar to another trademark which has already been registered or is under preliminary examination and approval for use on the same kind of or similar commodities or services, the application for registration of such trademark may be rejected. Any person applying for the registration of a trademark may not prejudice the existing right of others, nor may any person register in advance a trademark that has already been used by another party and has already gained a "sufficient degree of reputation" through such party's use. A trademark registrant may, by entering into a trademark licensing contract, license another party to use its registered trademark. Where another party is licensed to use a registered trademark, the licenser shall report the license to the Trademark Office for recordation, and the Trademark Office shall publish it. An unrecorded license may not be used as a defense against a third party in good faith.

Patents

According to the Patent Law of the PRC (《中華人民共和國專利法》), promulgated by the SCNPC on March 12, 1984 and latest amended on October 17, 2020 which became effective on June 1, 2021 and the Implementing Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), promulgated by the State Council on June 15, 2001, and last amended on December 11, 2023 and effective from January 20, 2024, there are three types of patents in the PRC, i.e., invention patents, utility model patents and design patents. The duration of invention patent right, design patent right and utility model patent right shall be 20 years, 15 years and 10 years, respectively, which are all calculated from the date of application. Implementation of a patent without the authorization of the patent holder shall constitute an infringement of patent rights, and shall be held liable for compensation to the patent holder and may be imposed a fine, or even subject to criminal liabilities.

Specifically, for the purpose of compensating for the time taken to evaluate and approve a new drug to be put on market, the patent administrative department under the State Council shall grant compensation for duration of patent rights for invention of a new drug approved to be put on market in the PRC upon request of the patentee. The compensation period shall not exceed five years, and the total validity period of patent rights for a new drug after being approved for marketing shall not exceed 14 years.

Patent Transfer and License

Patent transfer (patent assignment) and patent license are two different ways of transferring or granting rights of a patent. Patent assignment refers to the transfer of ownership of a patent from one party (assignor) to another (assignee). The party who receives the assignment (assignee) becomes the new owner of the patent, has the entire right to enforce it and collect any damages for infringement. In countries like the PRC, patent assignment needs to be recorded with the patent office and announced to public, before it takes effect. On the other hand, patent license grants permission to another party (licensee) to use a patent, but ownership of the patent remains with the original owner (licensor). The licensee is allowed to use the patent subject to the terms of the license agreement, which may specify limitations on territory, field, scope and/or duration of use. In the PRC, the recordal of a patent license agreement is not mandatory.

Trade Secrets

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by the SCNPC on September 2, 1993 and latest amended on April 23, 2019, the term "trade secrets" refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the Anti-Unfair Competition Law of the PRC, business persons are prohibited from infringing others' trade secrets by: (i) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (ii) disclosing, using or permitting others to use the trade secrets obtained illegally under item (i) above; (iii) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (iv) instigating, inducing or assisting others to violate confidentiality obligation or to violate a rights holder's requirements on keeping confidentiality of trade secrets, disclosing, using or permitting others to use the trade secrets of the rights holder. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others' trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties.

Copyrights

According to the Copyright Law of the PRC (《中華人民共和國著作權法》), promulgated by the SCNPC on September 7, 1990 and latest amended on November 11, 2020 which became effective on June 1, 2021, and the Implementation Regulations of the Copyright Law of PRC (《中華人民共和國著作權法實施條例》) promulgated by the State Council on August 2, 2002 and latest amended on January 30, 2013, Chinese citizens, legal persons, or other organizations shall, whether published or not, own copyright in their works, which include, among others, works of literature, art, natural science, social science, engineering technology and computer software. Copyright owners of protected works enjoy personal rights and property rights with respect to publication, authorship, alteration, integrity, reproduction, distribution, lease, exhibition, performance, projection, broadcasting, dissemination via information network, production, adaptation, translation, compilation, and other rights shall be enjoyed by the copyright owners.

Domain Names

According to the Measures on Administration of Internet Domain Names (《互聯網域名管理辦法》), which was promulgated by the Ministry of Industry and Information Technology (the "**MIIT**") on August 24, 2017 and became effective on November 1, 2017, the MIIT is responsible for supervision and administration of domain name services in the PRC. Communication administrative bureaus at provincial levels shall conduct supervision and administration of the domain name services within their respective administrative jurisdictions. Domain name registration services shall, in principle, be subject to the principle of "first apply, first register". A domain name registrar shall, in the process of providing domain name registration services, ask the applicant for which the registration is made to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

REGULATIONS ON INFORMATION SECURITY AND DATA PROTECTION

Personal Information Protection

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

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

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》) (the "**Interpretations**") were 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.

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

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. The Data Security Law mainly sets forth specific provisions regarding establishing basic systems for data security management, including data classification and hierarchical protection system, risk assessment system, monitoring and early warning system and emergency disposal system. In addition, it clarifies the data security protection obligations of organizations and individuals carrying out data activities and implementing data security protection responsibility. The Data Security Law stipulates the measures to support and promote data security and development, to establish and optimize the national data security management system and to clarify organizations' and individuals' responsibilities in data security.

On 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 listing in a foreign country are obliged to apply for a cybersecurity review by the Cybersecurity Review Office; and (iii) the relevant regulatory authorities may initiate cybersecurity review if such regulatory authorities determine that the issuer's network products or services, or data processing activities affect or may affect national security. On November 14, 2021, the CAC published the Administration Regulations on Cyber Data Security (Draft for Comments) (《網絡數據安全管理條例(徵求意見稿)》), which stipulated that data processing entities should apply for cybersecurity review in the event that, among others, its listing in Hong Kong affects 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. The Data Security Regulations reiterate and refine the general regulations for cyber data processing activities, rules of personal information protection, important data security protection, cyber data cross-border transfer management, and the responsibilities of online platform service providers. In addition, the officially promulgated Data Security Regulations do not specifically include the requirement that cyber data processing entities seeking a listing 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. These circumstances include: (i) where the important data are transferred to an overseas recipient; (ii) where the personal information is transferred to an overseas recipient by a CIIO or a data processor that has processed personal information of more than one million individuals; (iii) where a data processor provides personal information to an overseas recipient if such data processor has already provided overseas the personal information of 100,000 individuals or sensitive personal information of 10,000 individuals in total since January 1 of the preceding year; or (iv) other circumstances under which security assessment of outbound data transfer is required as prescribed by the national cyberspace administration.

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. These exemptions include, among others, the scenario where a data processor, other than a CIIO, has cumulatively transferred overseas personal information, excluding sensitive personal information, of fewer than 100,000 individuals since January 1 of the current year. A data processor, other than a CIIO, shall enter into a standard contract with overseas recipients for the cross-border transfer of personal information or obtain certification for personal information protection if since January 1 of the current year, the data processor has cumulatively transferred to overseas recipients (a) personal information of more than 100,000 but less than 1,000,000 individuals, excluding sensitive personal information, or (b) sensitive personal information of less than 10,000 individuals. The provisions also explicitly state that data processors are not required to conduct data security assessment for cross-border transfer of important data if the data has not been notified or published as important data by relevant departments or regions.

REGULATIONS ON LEASING

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

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

According to the Interpretation of the Supreme People's Court on Several Issues concerning the Application of Law in the Trial of Cases about Disputes Over Lease Contracts on Urban Buildings (2020 version) (《最高人民法院關於審理城鎮房屋租賃合同糾紛案件具體應用法律若干問題的解釋(2020修正)》), which took effect on January 1, 2021, if the ownership of the leased premises changes during lessee's possession in accordance with the terms of the lease contract, and the lessee requests the assignee to continue to perform the original lease contract, the PRC court shall support it, except that the mortgage right has been established before the lease of the leased premises and the ownership changes due to the mortgagee's realization of the mortgage right.

REGULATIONS ON FIRE PROTECTION AND ENVIRONMENTAL PROTECTION

Fire Control

Pursuant to the Fire Control Law of the PRC (《中華人民共和國消防法》) promulgated by the SCNPC on April 29, 1998, and last amended on April 29, 2021 and effective therefrom, the Department of Emergency Management under the State Council and the local people's governments at or above county level shall supervise and administer the matters of fire protection, while the fire control and rescue institutions of such people's governments shall be responsible for implementation. The design of fire control of the construction projects must comply with the national technical standards of fire control. If the design of fire control of a construction project has not been examined pursuant to the relevant laws or failed to pass the examination, the construction of such project is not allowed. If a completed construction project has not gone through the fire safety inspection or failed to satisfy the requirements of fire safety upon inspection, such project is not allowed to be put to use or business. According to 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.

Environmental Protection

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

Environment Impact Assessment

On October 28, 2002, the SCNPC promulgated the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》), which was latest amended on December 29, 2018. The State Council implemented the environmental impact assessment to classify construction projects according to the impact of the construction projects on the environment. The Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》) was promulgated by the State Council on November 29, 1998, amended on July 16, 2017 and became effective on October 1, 2017. According to the Environmental Impact Assessment Law and the Administration Rules on Environmental Protection of Construction Projects, depending on the impact of the construction project on the environment, the construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form.

On November 30, 2020, Ministry of Ecology and Environment of the PRC promulgated the Classified Administration Catalogue of Environmental Impact Assessments for Construction Project (2021 version) (《建設項目環境影響評價分類管理名錄(2021年版)》), which became effective on 1 January 2021, setting forth the environmental impact assessment category of construction projects.

According to the Environmental Impact Assessment Law, where a construction entity commenced construction prior to submission of the environmental impact report and environmental impact statement of the construction project or prior to resubmission of the environmental impact report and environmental impact statement, the ecological environment authorities at the county level or above shall order it to stop the construction, impose a fine of not less than 1% but not more than 5% of the overall investment amount for such construction project according to the seriousness and consequences of such violations, and order it to restore to the original status; and the person-in-charge and responsible personnel of the construction project shall be liable to administrative sanctions in accordance with laws.

Pursuant to the Interim Measures for Environmental Protection Acceptance of Completed Construction Projects (《建設項目竣工環境保護驗收暫行辦法》) effective as of November 20, 2017 and the Regulations on the Administration Construction Project Environmental Protection (《建設項目環境保護管理條例》), which was promulgated on November 29, 1998, latest amended on 16 July 2017 and implemented on October 1, 2017, after the completion of a construction project for which an environmental impact report or an environmental impact report form is required, the construction entity shall, according to standards and procedures prescribed by the environmental protection administrative authorities, conduct environmental protection completion acceptance check and compile an acceptance check report. A construction project for which an environmental impact report or an environmental impact report form is required shall not be put into production or use until the environmental protection completion acceptance check has been passed.

Pollutant Discharges Permitting Administration

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.

For any violation of the Regulation on the Administration of Permitting of Pollutant Discharges and the Measures for Pollutant Discharge Permitting Administration, in accordance with the Environmental Protection Law of the PRC, the Atmospheric Pollution Prevention and Control Law of the PRC (《中華人民共和國大氣污染防治法》), the Water Pollution Prevention and Control Law of the PRC (《中華人民共和國水污染防治法》) and other laws and regulations, the environmental protection authorities have the right to order to make corrections, restrict production, suspend production for rectification, and suspend business and close down, and impose a fine. If a violation of the public security provisions is constituted, it shall be punished for public security violation in accordance with the law. If a crime is constituted, it shall be investigated for criminal liabilities in accordance with the law.

Disposal of Hazardous Waste

Pursuant to the Law on the Prevention and Control of Environmental Pollution Caused by Solid Waste of the PRC (《中華人民共和國固體廢物污染環境防治法》), which was promulgated by the SCNPC on October 30, 1995 and was latest amended on 29 April 2020 and became effective on September 1, 2020, entities generating hazardous waste shall store, utilise 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 authorisation. Furthermore, it is forbidden to entrust hazardous waste to entities without a permit for disposal, or else the competent ecological and environmental authorities shall order it to make rectification, impose fines, confiscate illegal gains, and in serious circumstances, order it to suspend business or close down upon the approval of the government authorities.

REGULATIONS ON EMPLOYMENT AND SOCIAL WELFARE

Employment

The major PRC laws and regulations that govern employment relationship are the Labor Law of the PRC (《中華人民共和國勞動法》), (the "**Labor Law**"), which was promulgated by the SCNPC on July 5, 1994, last amended and came into effect on December 29, 2018), the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), (the "**Labor Contract Law**"), which was promulgated by the SCNPC on June 29, 2007 and became effective on January 1, 2008, and then amended on December 28, 2012 and became effective on July 1, 2013, and the Implementation Rules of the Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》), (the "Implementation Rules of the Labor Contract Law"), promulgated by the State Council on September 18, 2008 and came into effect on the same day. According to the aforementioned laws and regulations, labor relationships between employers and employees must be executed in written form. The laws and regulations above impose stringent requirements on the employers in relation to entering into fixed-term employment contracts, hiring of temporary employees and dismissal of employees. As prescribed under the laws and regulations, employers shall ensure their employees have the right to rest and the right to receive wages no lower than the local minimum wages. Employers must establish a system for labor safety and sanitation that strictly abides by state standards and provide relevant education to its employees. Violations of the Labor Contract Law and the Labor Law may result in the imposition of fines and other administrative liabilities and/or incur criminal liabilities in the case of serious violations.

Social Insurance

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which was promulgated by the SCNPC on October 28, 2010 and latest amended on December 29, 2018, enterprises and institutions in the PRC shall provide their employees with welfare schemes covering basic pension insurance, basic medical insurance, unemployment insurance, maternity insurance, work-related injury insurance and other welfare plans. The employer shall apply to the local social insurance agency for social insurance registration within 30 days from the date of its formation. And it shall, within 30 days from the date of employment, apply to the social insurance agency for social insurance registration for the employee. Any employer who violates the regulations above shall be ordered to rectify within a prescribed time limit; if the employer fails to rectify within the time limit, the employer and its directly liable person will be fined. Meanwhile, the Interim Regulation on the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》), which was promulgated by the State Council on January 22, 1992 and came into effect on the same day, and latest amended and became effective on March 24, 2019, prescribes the details concerning the social insurance.

According to Interpretation (II) of the Supreme People's Court on Issues Concerning the Application of Law in the trial of Labor Dispute Cases (the "**New Judicial Interpretation**"), promulgated on July 31, 2025, and effective as of September 1, 2025, if an employer and an employee agree or the employee undertakes that social insurance contributions are not required to be paid, the People's Court shall deem such agreement or undertaking invalid. Furthermore, where an employer fails to pay social insurance contributions in accordance with the law, and the employee seeks to terminate the labor contract and claims economic compensation from the employer pursuant to Item (3) of Article 38 of the PRC Labor Contract Law, the People's Court shall support such claims, in which case, the employer remains liable for paying economic compensation to the employee. Under the circumstances specified in the preceding paragraph, if the employer has paid the social insurance contributions retroactively in accordance with the law and then claims that the employee shall return the compensation for social insurance contributions already paid, the People's Court shall support such claim in accordance with the law.

Housing Provident Fund

According to the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), which was promulgated by the State Council on April 3, 1999 and came into effect on the same day, and latest amended on March 24, 2019, any newly established entity shall make deposit registration at the designated administrative centers and open bank accounts for depositing employees' housing provident funds. Employers and employees are also required to pay and deposit housing provident funds, with an amount no less than 5% of the monthly average salary of the employee in the preceding year in full and on time. Any entity that fails to make payment of housing provident funds within the time limit or has a shortfall in payment of housing provident funds will be ordered to make the payment or make up the shortfall within a prescribed time limit, otherwise, the housing provident management center is entitled to apply for compulsory enforcement with the People's Court.

In case of failure to register and open accounts for depositing employees' housing provident funds, the housing fund management center shall order employers to complete the relevant procedures within a prescribed time limit, where employers fail to complete the relevant procedure within the time limit, a fine of not less than RMB10,000 nor more than RMB50,000 shall be imposed.

REGULATIONS ON FOREIGN EXCHANGE

Regulations relating to Foreign Currency Exchange

The principal regulations governing foreign currency exchange in China are the Foreign Exchange Administration Regulations of the PRC (《中華人民共和國外匯管理條例》), most recently amended in August 5, 2008. Under the PRC foreign exchange regulations, payments of current account items, such as profit distributions, interest payments and trade and service related foreign exchange transactions, can be made in foreign currencies without prior approval from the SAFE, by complying with certain procedural requirements. By contrast, approval from or registration with appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital account items, such as direct investments, repayment of foreign currency-denominated loans, repatriation of investments and investments in securities outside of China.

The SAFE issued the Circular on Reforming of the Management Method of the Settlement of Foreign Currency Capital of Foreign-Invested Enterprises (《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 a 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 the State Administration of Foreign Exchange 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.

On October 23, 2019, SAFE issued the Circular on Further Facilitating Cross-border Trade and Investment (《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》) (the "**SAFE Circular 28**"), which cancels the restrictions on domestic equity investments by capital fund of non-investment foreign invested enterprises and allows non-investment foreign invested enterprises to use their capital funds to lawfully make equity investments in China, provided that such investments do not violate the Negative List and the target investment projects are genuine and in compliance with laws. According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《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 Offshore Investment by PRC Residents

The SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles (《國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) (the "**SAFE Circular 37**") on July 4, 2014. The SAFE Circular 37 requires PRC residents (including PRC institutions and individuals) must register with local branches of SAFE in connection with their direct or indirect offshore investment in an overseas special purpose vehicle (the "**SPV**") directly established or indirectly controlled by PRC residents for 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. Such PRC residents are also required to amend their registrations with SAFE when there is a change to the basic information of the SPV, such as changes of a PRC resident individual shareholder, the name or operating period of the SPV, or when there is a significant change to the SPV, such as changes of the PRC individual resident's increase or decrease of its capital contribution in the SPV, or any share transfer or exchange, merger, division of the SPV.

Failure to comply with the registration procedures set forth in the SAFE Circular 37 may result in restrictions being imposed on the foreign exchange activities of the relevant onshore company, including the payment of dividends and other distributions to its offshore parent or affiliate, the capital inflow from the offshore entities and settlement of foreign exchange capital, and may also subject relevant onshore company or PRC residents to penalties under PRC foreign exchange administration regulations.

Regulations relating to Stock Incentive Plans

Pursuant to the Circular on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly Listed Company (《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"), promulgated by SAFE on February 15, 2012, employees, directors, supervisors, and other senior management participating in any share incentive plan of an overseas publicly-listed company who are PRC citizens or who are non-PRC citizens residing in China for a continuous period of not less than one year, subject to a few exceptions, are required to register with SAFE through a domestic agency. Moreover, an overseas-entrusted institution must be retained to handle matters in connection with the exercise or sale of stock options and the purchase or sale of shares and interests.

The income of foreign exchange PRC residents by selling out the shares according to the equity incentive plan and the dividend distributed by the overseas-listed company shall be distributed to the PRC residents after being remitted to the bank account in China opened by the domestic institutions.

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》) 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 the PRC in accordance with the laws or established in accordance with any laws of foreign countries (regions) but with an actual management entity within the PRC shall be regarded as a resident enterprise. A resident enterprise shall be subject to a EIT of 25% of any income generated within or outside the PRC. A preferential EIT rate shall be applicable to any key industry or project which is supported or encouraged by the State. High and new technology enterprises which are supported by the State may enjoy a reduced EIT rate of 15%.

The PRC and the government of Hong Kong entered into the Arrangement between the Mainland of the PRC and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《內地和香港特別行政區關於對所得税避免雙重徵税和防止偷漏税的安排》) (the "**Arrangement**") on August 21, 2006 and came into effect on December 8, 2006. According to the Arrangement, if a Hong Kong resident company owns at least 25% equity interests in a PRC company and is the beneficial owner of the dividends paid by the PRC company, the PRC withholding tax on the dividends shall not exceed 5% of the gross amount of the dividends.

Pursuant to the Circular of the State Administration of Taxation on Relevant Issues relating to the Implementation of Dividend Clauses in Tax Agreements (《國家税務總局關於執行税收協定股息條款有關問題的通知》) which was promulgated by the State Administration of Taxation (the "**SAT**") and became effective on February 20, 2009, all of the following requirements shall be satisfied before a fiscal resident of the other party to a tax agreement can be entitled to such tax agreement treatment as being taxed at a tax rate specified in the tax agreement for the dividends paid to it by a PRC resident company: (i) such a fiscal resident who obtains dividends should be a company as provided in the tax agreement; (ii) the equity interests and voting shares of the PRC resident company directly owned by such a fiscal resident reaches a specified percentage; and (iii) the equity interests of the PRC resident company directly owned by such a fiscal resident, at any time during the twelve months prior to receipt of the dividends, reach a percentage specified in the tax agreement.

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稅若干問題的公告》) (the "**Tax Circular 7**") which was promulgated by the SAT 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 PRC resident enterprise to avoid the EIT 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 EIT 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.

Value-Added Tax

Pursuant to the Interim Regulations on Value-added Tax of the PRC (《中華人民共和國增值稅暫行條例》), which was promulgated on December 13, 1993 by the State Council, came into effect on January 1, 1994, and latest amended on November 19, 2017, as well as the Implementation Rules for the Interim Regulations on Value-Added Tax of the PRC (《中華人民共和國增值稅暫行條例實施細則》), which was promulgated on December 25, 1993 by the Ministry of Finance of the PRC (the "**MOF**"), came into effect on the same day and latest amended on October 28, 2011, any entities and individuals engaged in the sale of goods, supply of processing, repair and replacement services, or import of goods within the territory of the PRC are taxpayers of Value-added tax (the "**VAT**") and shall pay the VAT in accordance with the law and regulation. The rate of VAT for sale of goods is 17% unless otherwise specified, such as the rate of VAT for sale of transportation is 11%. With the VAT reforms in the PRC, the rate of VAT has been changed several times. The MOF and the STA issued the Notice on Adjusting VAT Rates (《關於調整增值稅稅率的通知》) on April 4, 2018 to adjust the tax rates of 17% and 11% applicable to any taxpayer's VAT taxable sale or import of goods to 16% and 10%, respectively, and these adjustments became effect on May 1, 2018. Subsequently, the MOF, the STA and the General Administration of Customs jointly issued the Announcement on Relevant Policies for Deepening the VAT Reform (《關於深化增值稅改革有關政策的公告》) on March 20, 2019 to make a further adjustment, which came into effect on April 1, 2019. The tax rate of 16% applicable to the VAT taxable sale or import of goods shall be adjusted to 13%, and the tax rate of 10% applicable thereto shall be adjusted to 9%.

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》), or the VAT Law, which shall become 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%.

REGULATIONS ON OVERSEAS LISTING

CSRC Filing

Pursuant to the Measures for the Administration on Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) together with 5 supporting guidelines (together with the Measures for the Administration on Overseas Securities Offering and Listing by Domestic Companies, collectively referred to as the "**Overseas Listing Regulations**"), promulgated by the China Securities Regulatory Commission (the "**CSRC**") on 17 February 2023, which became effective on 31 March 2023, where a PRC domestic company seeks to directly or indirectly offer and list securities in overseas markets, the issuer or the designated entity shall file the required documents with the CSRC within three business days after its application for initial public offering is submitted. Any overseas offering and listing made by an issuer that meets both the following conditions will be determined as indirect: (1) 50% or more of the issuer's operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent accounting year is accounted for by domestic companies; and (2) the main parts of the issuer's business activities are conducted in the Chinese Mainland, or its main places of business are located in the Chinese Mainland, or the senior managers in charge of its business operation and management are mostly Chinese citizens or domiciled in the Chinese Mainland. The determination of the indirect overseas offering and listing of PRC domestic companies shall follow the principle of substance-over-form.

The Overseas Listing Regulations also stipulate the circumstances where the overseas offering and listing is explicitly prohibited, including: (i) financing through listing is expressly prohibited by laws, administrative regulations or relevant rules of the state; (ii) the overseas offering and listing may endanger national security as determined by the relevant competent department under the State Council after examination according to the law; (iii) a domestic enterprise or its controlling shareholder or actual controller has committed a criminal crime of corruption, bribery, embezzlement, misappropriation of property or disrupting the economic order of the socialist market in the last three years; (iv) domestic enterprise is under formal investigation according to the law for being suspected of any crime or major violation of laws and regulations, but no clear conclusions have been made; (v) there is a major dispute over ownership of the equity held by the controlling shareholder or a shareholder controlled by the controlling shareholder or the actual controller.

CSRC Requirements on Confidentiality and Archives Administration

On 24 February 2023, the CSRC, the MOF, National Administration of State Secrets Protection and National Archives Administration of China jointly released the revised Provisions on Strengthening the Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》, the "**Archives Administration Provisions**"), which came into effect on 31 March 2023. The Archives Administration Provisions shall apply to both (i) the PRC companies seeking direct listing on the overseas stock exchange and (ii) the PRC operating entities of a foreign company seeking listing on the overseas stock exchange that qualifies as an "indirect listing" (above (i) and (ii) collectively, "**Domestic Companies**").

According to the Archives Administration Provisions, the Domestic Companies shall establish and implement a solid confidentiality and archives administration system. If a Domestic Company decides to disclose any documents or materials containing state secrets, work secrets of governmental agencies or any information that may be detrimental to national security or public interest once leaked, proper governmental approval procedures should be followed. After obtaining the governmental clearance, the Domestic Company disclosing such information, as one party, and the securities companies and securities services providers receiving such information, as the other party, shall also enter into non-disclosure agreements, setting forth the confidentiality obligations of the securities companies and securities services providers. When providing above information to the securities companies and securities services providers retained by it, the Domestic Companies are also required to issue a written statement outlining its compliance with the relevant regulatory requirements and procedures.

In terms of providing accounting archives or copies thereof to any other entities or persons (such as securities companies, securities services providers and overseas regulators), the Archives Administration Provisions stipulate that relevant governmental procedures should be followed.

Any violation of the above regulations may subject the Domestic Companies to regulatory penalties under the PRC Law of Safeguarding State Secrets (《中華人民共和國保守國家秘密法》) and the PRC Law of Archives (《中華人民共和國檔案法》) and even criminal liabilities to the extent applicable.

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.

U.S. Government Regulation of Drug and Biological Products

In the United States, the FDA regulates drugs under the Federal Food Drug and Cosmetic Act (the "**FDCA**"), its implementing regulations, and biologics implemented under the FDCA and the Public Health Service Act (the "**PHSA**") 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.

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.

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 re-approve 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. 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 pharmacokinetics and pharmacodynamics information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is 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.

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**.

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 current Good Manufacturing Practice ("**cGMP**") requirements. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions.

U.S. Review and Approval Processes

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 a BLA. Unless deferred or waived, 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. The submission of a BLA is subject to the payment of a substantial user fee and an annual prescription drug program fee.

Within 60 days of its receipt, the FDA reviews the BLA to ensure that it is sufficiently complete for substantive review before it accepts the BLA for filing. After accepting the 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 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. The FDA may refer the 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 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 letter describing all of the specific deficiencies that the FDA identified in the 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 complete response 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 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 BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

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.

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 use surrogate endpoints and have greater 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.

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, rather than the standard review of ten months under the Prescription Drug User Fee Act (the "**PDUFA**") guidelines. These six- and ten-month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast-track designation are also likely to be considered appropriate to receive a priority review.

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 rigorous post-marketing compliance requirements, including the completion of post-approval clinical trial to confirm the effect on the clinical endpoint. 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.

Breakthrough 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 shall 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.

Orphan Drugs

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 United States or for which a manufacturer has no reasonable expectation of recovering drug treatment research and development costs. 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 circumstance.

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 may not market or promote 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 off-label uses 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 BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy (the "**REMS**"), to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the 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 noncompliance 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 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 adverse events 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.

Patient Protection and Affordable Health Care Act

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "**ACA**"), became law in the United States in March 2010, and have driven healthcare reform in the United States by extending health insurance coverage and substantially changing the way healthcare financed by both governmental and private insurers in the United States. With regard to pharmaceutical products specifically, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. Among other things, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, and mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs.

Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA, and there may be additional challenges and amendments to the ACA in the future. Since January 2017, former President Trump has signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have passed, for example, the Tax Act enacted by the Congress in 2017 which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. There may be other efforts to challenge, repeal or replace the ACA.

Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product development and FDA review of 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 BLA submission, and all of the review phase, which is the time between 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 United States Patent and Trademark Office (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 the patent owner may apply for no more than four subsequent interim extensions. 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 a BLA has not been submitted.

Recently Proposed Pending Legislation in the U.S. Congress: 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. The bill was reintroduced to the U.S. House of Representatives on May 10, 2024 by Representative Brad Wenstrup (R-OH) after Rep. Gallagher retired. The pending legislation was referred to the House Committee on Oversight and Accountability, and passed by a vote of 306-81 in the House. The pending legislation was referred to the U.S. Senate, and it has been referred to 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.

The Act, if reintroduced and subsequently enacted in the proposed form, generally the Act 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 would define biotechnology company of concern to mean five named entities and any subsidiary, parent or successor of them plus any other entity that:

1. is subject to the jurisdiction, direction, control, or operates on behalf of the government of a foreign adversary;

2. is to any extent involved in the manufacturing, distribution, provision, or procurement of a biotechnology equipment or service; and

3. poses a risk to the national security of the United States based on —

    a. engaging in joint research with, being supported by, or being affiliated with a foreign adversary's military, internal security forces, or intelligence agencies;

    b. providing multiomic data obtained via biotechnology equipment or services to the government of a foreign adversary; or

    c. obtaining human multiomic data via the biotechnology equipment or services without express and informed consent.

The five named entities include: BGI, MGI, Complete Genomics, WuXi AppTec, and WuXi Biologics.

The Act would define biotechnology equipment or service to mean:

1. equipment, including genetic sequencers, mass spectrometers, polymerase chain reaction machines, or any other instrument, apparatus, machine, or device, including components and accessories thereof, that is designed for use in the research, development, production, or analysis of biological materials as well as any software, firmware, or other digital components that are specifically designed for use in, and necessary for the operation of, such equipment;

2. any service for the research, development, production, analysis, detection, or provision of information, including data storage and transmission related to biological materials, including —

    a. advising, consulting, or support services with respect to the use or implementation of an instrument, apparatus, machine, or device described in Section 3(i)(2)(A) of the Act; and

    b. disease detection, genealogical information, and related services; and

3. any other service, instrument, apparatus, machine, component, accessory, device, software, or firmware that the Director of the Office of Management and Budget, in consultation with the heads of Executive agencies, as determined appropriate by the Director of the Office of Management and Budget, determines appropriate.

A policy 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.

Although the Act would not have direct consequences to us, the Act could, if it were to become law, have secondary consequences to our business. Although the reagents we use may not be "biotechnology equipment" under the Act, certain sequencing equipment we purchase could be deemed biotechnology equipment since that equipment is designed for use in research, development or analysis of biological materials. Further, although the Act in its current form would not bar us from acquiring genetic sequencing equipment from a biotechnology company of concern, the Act, in its current state, if adopted, would ban the U.S. government from contracting with us, or with our customers if, in the performance of the contracts with the customers, we use equipment captured by the Act after the effective date of the prohibition. Because the Act is pending legislation, the U.S. Congress or the President of the United States, or both, could require changes to the legislation modifying it, which changes could include expanding its scope or reach. As a result, we continue to reassess our supply chain to ensure compliance with current applicable law and the possibilities which could arise under the Act and we continue to review our existing contractual obligations.

For the Act to become law in the United States, it must undergo a legislative process involving negotiation and agreement between the U.S. House of Representatives and the U.S. Senate on the terms of the pending legislation. This negotiation typically results in a conference report that consolidates the viewpoints of both chambers. Subsequently, both the House and the Senate must vote to approve the conference report. Finally, the legislation requires the signature of the President of the United States to become law. Throughout this process, amendments to the Act may be proposed and considered, potentially altering its text and expanding or modifying compliance obligations. Once adopted, U.S. agencies may 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 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.