REGULATORY OVERVIEW

OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section summarizes the major PRC regulatory authorities and PRC laws and regulations that we believe are relevant to our business and operations in the PRC.

REGULATIONS ON PHARMACEUTICAL PRODUCT

Major Regulatory Authorities

The drug industry in the PRC is mainly administered by three governmental agencies: the National Medical Products Administration (國家藥品監督管理局) (the "**NMPA**"), a department under the State Administration for Market Regulation (國家市場監督管理總局), the National Health Commission of the PRC (中華人民共和國國家衛生健康委員會) (the "**NHC**") and the National Healthcare Security Administration (國家醫療保障局) (the "**NHSA**").

The NMPA, which inherits the drug supervision function from its predecessor the China Food and Drug Administration (the "**CFDA**"), or the CFDA (before March 2018), is the primary drug regulator responsible for almost all of the key stages of the life-cycle of pharmaceutical products, including non-clinical researches, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution and pharmacovigilance.

Under the NMPA, the Center for Drug Evaluation (國家藥品監督管理局藥品審評中心) (the "**CDE**") is the core technical review agency for drug registration. It is primarily responsible for conducting technical reviews of clinical trial applications, marketing authorization applications, supplemental applications, etc., evaluating the safety, efficacy, and quality control of pharmaceutical products. It also participates in the development of technical guidelines related to drug registration administration and works to align its review standards with international norms.

The NHC, formerly known as the National Health and Family Planning Commission (the "**NHFPC**"), is China's chief healthcare regulator. It is primarily responsible for drafting national healthcare policy and regulating public health, medical services, and health contingency system, coordinating the healthcare reform, and overseeing the operation of medical institutions and practicing of medical personnel.

The NHSA, established in May 2018, is responsible for drafting and implementing policies, plans and standards on medical insurance, maternity insurance and medical assistance; administering healthcare security funds; formulating a uniform medical insurance catalog and payment standards on drugs, medical disposables and healthcare services; formulating and administering the bidding and tendering policies for drugs and medical disposables.

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 (全國人民代表大會常務委員會) (the "**SCNPC**"), in September 1984, last 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 in August 2002, The currently effective version was revised in December 2024 and took effect on January 20, 2025. According to the newest version of the Implementing Regulations published on January 16, 2026, it will take effect on May 15, 2026.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, establishing the legal framework for pharmaceutical administration. The *Implementation Regulations*, at the same time, provides the detailed implementation regulations on the *Drug Administration Law*.

Application for Clinical Trial

The General Office of the State Council (中華人民共和國國務院辦公廳) and the General Office of the CPC Central Committee (中共中央辦公廳) jointly issued an 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") in October 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.

According to the Decision on Adjusting the *Approval Procedures of Certain Administrative Approval Items for Drugs* (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA on March 17, 2017, the decision on the approval of clinical trials of drugs shall be made by the 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 the 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 in July 2018, if a clinical trial applicant does not receive any negative or questioned opinions from the CDE within 60 days after the date when the trial application is accepted and the fees are paid, the applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the CDE.

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.

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 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 CDE.

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 CFDA in January 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 Phase I and Phase II clinical trials and prior to Phase III clinical trial, the applicant shall submit the application for communication meetings to the CDE to discuss with the CDE the key technical questions including the design of the 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 NMPA on April 1, 2026, 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 the 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 preclinical trial preparation, trial protocols, protection of testees' rights and interests, duties of researchers, sponsors and monitors, as well as data management and statistical analysis.

The GCP Rules stipulate 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 Revised 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 ethics committee in clinical trial process. An ethics 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 ethics 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 ethics 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 in August 2003 and amended in July 2017 by the China Food and Drug Administration (currently known as the NMPA).

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》) in July 2018, as one of the implementing rules for the Innovation Opinions, which provides that overseas clinical data can be submitted for the drug marketing registration applications in China. 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. 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.

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 drug 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.

Drug Manufacturing Regulatory Regime

The Measures for the Supervision and Administration of Drug Manufacturing (《藥品生產監督管理辦法》) were promulgated on January 22, 2020 and effective as of July 1, 2020. These Measures regulate drug manufacturing licensing, production supervision and quality management in the PRC. Any entity engaged in drug manufacturing must obtain a Drug Manufacturing License valid for five years. The marketing authorization holder may manufacture drugs by itself or entrust qualified manufacturers. The marketing authorization holder shall be fully responsible for drug quality throughout the product lifecycle.

The Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) was first issued in 1988 and most recently revised in 2010, effective March 1, 2011. It is a mandatory requirement governing the entire production process to ensure drug quality, safety and consistency, covering organization and personnel, facilities, materials, production control, quality control and product release.

Precursor Chemicals For Drug Production

The Regulations on the Administration of Precursor Chemicals (《易制毒化學品管理條例》) were promulgated on August 26, 2005 and most recently revised in 2018. These Regulations establish a classified licensing and administration system for the production, operation, purchase, transportation and import/export of precursor chemicals to prevent illegal use in drug manufacture.

Pharmacovigilance

Pursuant to the *Pharmacovigilance Quality Control Specifications* (《藥物警戒質量管理規範》) issued by the NMPA on May 7, 2021, and implemented from December 1, 2021, drug marketing authorization holders and drug registration applicants who are permitted to implement drug clinical trials shall establish the pharmacovigilance system to monitor, identify, evaluate and control adverse drug reactions and other drug-related harmful reactions through the effective operation and maintenance of the system. The drug marketing authorization holders shall initiate quality objectives for pharmacovigilance and establish quality assurance system for quality management on pharmacovigilance system and activities with an aim to consistently improve the efficiency of the system and ensure the compliance of the activities with the relevant laws and regulations. The legal representative and the key person-in-charge of a drug marketing authorization holder shall be fully responsible for the pharmacovigilance activities. The drug marketing authorization holders shall complete the information registration in the National Adverse Drug Reaction Monitoring System within 30 days upon the date of obtaining the first drug approval document.

REGULATIONS ON FOREIGN INVESTMENT

Investment activities in the PRC by foreign investors are principally governed by the *Catalog of Encouraged Industries for Foreign Investment* (《鼓勵外商投資產業目錄》) (the "**Encouraged Catalog**"), and the *Special Administrative Measures (Negative List) for Foreign Investment Access* (《外商投資准入特別管理措施(負面清單)》) (the "**Negative List**"), which are promulgated and amended from time to time by the Ministry of Commerce of the PRC (中華人民共和國商務部) (the "**MOFCOM**") and the National Development and Reform Commission (中華人民共和國國家發展和改革委員會) (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.

In March 2019, the FIL was promulgated by National People's Congress (中華人民共和國全國人民代表大會) (the "**NPC**") and came into effect on January 1, 2020, which replaced three then existing laws on foreign investments in China, namely, the *Sino-Foreign Equity Joint Venture Enterprise Law of PRC* (《中華人民共和國中外合資經營企業法》), the *Sino-Foreign Cooperative Joint Venture Enterprise 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-entry national treatment, except for those foreign invested entities that operate in industries deemed to be either "restricted" or "prohibited" in the "negative list", and the State Council shall promulgate or approve a list of special administrative measures for access of foreign investments. To ensure the effective implementation of the FIL, the *Regulations on Implementing the Foreign Investment Law of the PRC* (《中華人民共和國外商投資法實施條例》) (the "**Implementation Regulations**"), was promulgated by State Council in December 2019 and came into effect on January 1, 2020, which further clarified that the state encourages and promotes foreign investment, protects the lawful rights and interests of foreign investors, regulates foreign investment administration, continues to optimize foreign investment environment, and advances a higher-level opening.

In December 2019, the MOFCOM and the State Administration for Market Regulation (國家市場監督管理總局) (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.

REGULATIONS ON INFORMATION SECURITY AND DATA PROTECTION

Data Security and Data Export

The SCNPC promulgated the *Data Security Law of the PRC* (《中華人民共和國數據安全法》) on June 10, 2021, which became effective from September 1, 2021, for the establishment of a data classification and grading protection system to conduct classified and hierarchical protection of data. Entities engaged in data processing activities shall, in accordance with laws and regulations, establish a sound full-process data security management system, organize data security education and training, and take corresponding technical measures and other necessary measures to ensure data security.

On December 28, 2021, the Cyberspace Administration of China (國家互聯網信息辦公室) (the "**CAC**") and other twelve PRC regulatory authorities jointly revised and promulgated the *Measures for Cybersecurity Review* (《網絡安全審查辦法》) (the "**Cyber Review Measures**"), which came into effect on February 15, 2022. The Cyber Review Measures stipulate that, among others, (i) when the purchase of network products and services by a critical information infrastructures operator (the "**CIIO**") (關鍵信息基礎設施運營者) or the data processing activities conducted by a network platform operator (網絡平台運營者) affect or may affect national security, a cybersecurity review shall be conducted pursuant to the Cyber Review Measures; (ii) an application for cybersecurity review shall be made by an issuer who is a network platform operator holding personal information of more than one million users before such issuer applies to list its securities abroad; and (iii) the relevant PRC governmental authorities may initiate cybersecurity review if such governmental authorities determine that the issuer's network products or services, or data processing activities affect or may affect national security. According to the *Measures on Security Assessment of Cross-border Data Transfer* (《數據出境安全評估辦法》) issued by the CAC on July 7, 2022 and effective on September 1, 2022, a data processor that provides data overseas under any of the following circumstances shall apply to the national cyberspace administration for the security assessment of the outbound data transfer through local provincial cyberspace administration: (i) a data processor provides important data abroad; (ii) the CIIO or the data processor that has processed the personal information of more than one million people provides personal information abroad; (iii) the data processor that has provided the personal information of over 100,000 people or the sensitive personal information of over 10,000 people cumulatively since January 1 of the previous year provides personal information abroad; and (iv) any other circumstance where an application for the security assessment of outbound data transfer is required by the national cyberspace administration.

According to the *Measures for Standard Contract for Outbound Transfer of Personal Information* (《個人信息出境標準合同辦法》) issued by the CAC on February 22, 2023 and effective from June 1, 2023, to provide personal information to an overseas recipient through the conclusion of the standard contract, a personal information processor shall meet all of the following circumstances: (i) it is not a CIIO; (ii) it has processed the personal information of less than one million individuals; (iii) it has cumulatively provided the personal information of less than 100,000 individuals to overseas recipients since January 1 of the previous year; and (iv) it has cumulatively provided the sensitive personal information of less than 10,000 individuals since January 1 of the previous year. In addition, the Measures for Standard Contract for Outbound Transfer of Personal

Information require that all Outbound Transfers of personal information that have been carried out before June 1, 2023 and do not comply with the provisions of the Measures for Standard Contract for Outbound Transfer of Personal Information be rectified within six months.

According to the *Provisions on Promoting and Regulating Cross-border Data Flows* (《促進和規範數據跨境流動規定》), which was promulgated by the CAC on March 22, 2024 and came into effect on the same day, if the data have not been informed or publicly announced as important data by relevant departments or regions, data handlers are not required to declare security assessment for cross-border provision of the data as important data.

Personal Information Protection

According to the *Civil Code of the PRC* (《中華人民共和國民法典》), personal information of natural persons is protected by law. If any organization or individual needs to obtain other people's personal information, they should obtain it in accordance with the law, ensure the security of the information, and must not illegally collect, use, process, or transmit other people's personal information or illegally buy, sell, provide, or disclose the information. The *Personal Information Protection Law of the PRC* (《中華人民共和國個人信息保護法》) promulgated by the SCNPC on August 20, 2021 and implemented on November 1, 2021 further emphasizes the obligations and responsibilities of processors for the protection of personal information, and requests higher level of protective measures on the processing of sensitive personal information.

According to the *Cybersecurity Law of the PRC* (《中華人民共和國網絡安全法》) last amended on October 28, 2025 and took effect on January 1, 2026, network operators must follow the principles of legality, legitimacy and necessity when collecting and using personal information, publicly disclose the rules for collection and use, clearly state the purpose, method and scope of collecting and using information, and obtain the consent of the person whose data is being collected. Network operators shall not collect personal information unrelated to the services they provide. Network operators are not allowed to leak, tamper with, or damage the personal information they collect, and are not allowed to provide personal information to others without the consent of the person whose data is being collected. However, this does not apply to cases where a specific individual cannot be identified and the identity cannot be recovered after processing. Network operators should take technical measures and other necessary measures to ensure the security of the personal information they collect and prevent leakage, damage and loss of information.

REGULATIONS ON INTELLECTUAL PROPERTY

Pursuant to the *Patent Law of the PRC* (《中華人民共和國專利法》) latest amended by the SCNPC on October 17, 2020 and came into effect on June 1, 2021 and the *Implementation Rules of the Patent Law of the PRC* (《中華人民共和國專利法實施細則》) latest amended by the State Council on December 11, 2023 and came into effect on January 20, 2024, patents in China are divided into three types, i.e., invention patent, utility patent and design patent. The duration of a patent right for invention is 20 years, the duration of a patent right for utility model is 10 years, and the duration of a patent right for design is 15 years, all calculated from the date of application.

In accordance with the Trademark Law of the PRC (《中華人民共和國商標法》) which was latest amended by the SCNPC on April 23, 2019, with the latest revision effective on November 1, 2019, and the Implementation Regulations for the Trademark Law of the PRC (《中華人民共和國商標法實施條例》) which was latest amended by the State Council on April 29, 2014, with the latest revision effective on May 1, 2014, trademarks approved and registered by the Trademark Office of the National Intellectual Property Administration are registered trademarks, including commodity trademarks, service marks, collective trademarks, and certification marks; the validity period of a registered trademark is 10 years, calculated from the date of approval of registration. A trademark registrant intending to continue to use the registered trademark upon expiry of the period of validity shall undergo the renewal formalities within 12 months before expiry according to the relevant provisions. Each renewal is valid for 10 years and is calculated from the day after the previous validity period of the trademark expires.

REGULATIONS ON LEASING

According to the Civil Code of the PRC (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and implemented on January 1, 2021, the creation, modification, transfer, and extinction of real property rights that are subject to registration in accordance with the law shall take effect when they are recorded in the real estate registration book. A real estate ownership certificate is the proof that the owner has the right to the real estate. Pursuant to the Administrative Measures for Commodity Housing Leasing (《商品房屋租賃管理辦法》) promulgated by the Ministry of Housing and Urban-Rural Development on December 1, 2010 and came into effect on February 1, 2011, the parties to house leasing shall, within 30 days after the execution of the house leasing contract, go through the house leasing registration and filing formalities with the competent construction (real-estate) departments of the People's Government of the municipality directly under the Central Government, city or county at the place where the leased house is located. If a violation of the measures occurs, the party shall be ordered to rectify within a prescribed time limit. and if any party fails to do so, it shall be imposed of a fine of more than RMB1,000 and less than RMB10,000.

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 (中華人民共和國應急管理部) 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 *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 (中華人民共和國住房和城鄉建設部) on April 1, 2020 and latest amended on August 21, 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 and effective on December 26, 1989, and most recently amended on April 24, 2014. The *Environmental Protection Law* has been formulated for the purpose of protecting and improving both the living and the ecological environment, preventing and controlling pollution and other public hazards and safeguarding people's health. According to the provisions of the *Environmental Protection Law*, in addition to other relevant laws and regulations of the PRC, the Ministry of Ecology and Environment (中華人民共和國生態環境部) 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 PRC* (《中華人民共和國環境影響評價法》), which was latest amended on December 29, 2018. According to the *Environmental Impact Assessment Law*, the State Council implemented the environmental impact assessment to classify construction projects according to the impact of the construction projects on the environment. 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 revised on July 16, 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.

On November 30, 2020, Ministry of Ecology and Environment of the PRC (中華人民共和國生態環境部) 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 January 1, 2021. 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.

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 in 1995 and was latest amended on April 29, 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 circumstance, order it to suspend business or close down upon the approval of the government authorities.

REGULATIONS ON EMPLOYMENT AND SOCIAL WELFARE

According to the *Labor Law of the PRC* (《中華人民共和國勞動法》) promulgated by the SCNPC on July 5, 1994 and last amended on December 29, 2018, the *Labor Contract Law of the PRC* (《中華人民共和國勞動合同法》) promulgated by the SCNPC on June 29, 2007 and amended on December 28, 2012, and the *Implementing Regulations of the Labor Contract Law of the PRC* (《中華人民共和國勞動合同法實施條例》) promulgated by the State Council on September 18, 2008 and came into effect on the same day, employers must enter into written labor contracts with full-time employees. All employers shall comply with local minimum wage standards. Employers must establish a system for labor safety and sanitation, strictly comply with national standards, and provide relevant education to their employees. Violations of the *Labor Contract Law* and the *Labor Law* may result in fines, and in serious cases, other administrative and criminal liabilities may be incurred.

In accordance with the *Labor Contract Law* and the *Interim Provisions on Labor Dispatching* (《劳務派遣暫行規定》) promulgated by the Ministry of Human Resources and Social Security of the PRC (中華人民共和國人力資源和社會保障部) on January 24, 2014 and effective on March 1, 2014, it specified the scope and proportion of the usage of the laborer, execution and performance of labor dispatch agreements and legal liability. An employer shall strictly control the number of dispatched laborers which shall not exceed 10% of the total number of its workers. An employer that is in violation thereof shall be ordered to make correction by the labor administrative department. Where no correction is made by the prescribed deadline, the employer shall be subject to a fine ranging from RMB5,000 to RMB10,000 for each dispatched worker.

The *Social Insurance Law of the PRC* (《中華人民共和國社會保險法》) (the "**Social Insurance Law**") issued by the SCNPC in 2010 and latest amended on December 29, 2018, has established social insurance systems of basic pension insurance, basic medical insurance, work-related injury insurance, unemployment insurance and maternity insurance and has elaborated in detail the legal obligations and liabilities of employers who fail to comply with relevant laws and regulations on social insurance. According to the *Social Insurance Law and the Provisional Regulations on Collection and Payment of Social Insurance Premiums* (《社會保險費徵繳暫行條例》) promulgated by the State Council on January 22, 1999 and most recently amended on March 24, 2019 and effective from the same date, enterprises shall register social insurance with local social insurance and pay or withhold relevant social insurance for or on behalf of its employees. Any employer that fails to make social insurance contributions may be ordered to rectify the non-compliance and pay the required contributions within a prescribed time limit and be subject to a late fee. If the employer still fails to rectify the failure to make the relevant contributions within the prescribed time, it may be subject to a fine ranging from one to three times the amount overdue.

In accordance with the *Regulations on the Administration of Housing Provident Funds* (《住房公積金管理條例》) promulgated by the State Council on April 3, 1999, and amended on March 24, 2002, and March 24, 2019, enterprises must register 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. In case of overdue payment or underpayment by employers, orders for payment within a specified period will be made by the housing fund management center. Where employers fail to make payment within such period, enforcement by the people's court will be applied. In case of failure to register and open accounts for depositing employees' housing provident funds, the housing fund management center shall order employers to go through the formalities within a specified period, where employers fail to do such formalities within the prescribed time, a fine of not less than RMB10,000 nor more than RMB50,000 shall be imposed.

REGULATIONS ON TAXATION AND FOREIGN EXCHANGE

Enterprise Income Tax (the "EIT")

According to the *Enterprise Income Tax Law* (《中華人民共和國企業所得稅法》) promulgated by the NPC on March 16, 2007 and amended by the SCNPC of the PRC on February 24, 2017 and December 29, 2018, and the *Implementation Regulations of the Enterprise Income Tax Law of the PRC* (《中華人民共和國企業所得稅法實施條例》) promulgated by the State Council on December 6, 2007 and last amended on December 6, 2024, save for limited exceptions, the enterprise income tax rate applicable to both domestic enterprises and foreign-invested enterprises is 25%. Enterprises are classified as either "resident enterprises" or "non-resident enterprises." Other than enterprises incorporated within the PRC, enterprises established outside China whose de facto management bodies are located in China are deemed "resident enterprises" and shall be subject to the uniform 25% enterprise income tax rate in respect of their worldwide income. A non-resident enterprise refers to an entity established under foreign law whose de facto management bodies are not situated within the PRC but which maintains an establishment or place of business in the PRC, or which has no establishment or place of business in the PRC but derives income sourced from within the PRC. An

income tax rate of 20% shall normally apply to dividends distributed to non-resident enterprise investors outside the PRC that do not have an establishment or place of business in the PRC, or that possess such establishment or place of business yet the relevant income is not effectively connected therewith, in respect of dividends sourced from within the territory of the PRC.

According to the *Administrative Measures for Determination of High and New Tech Enterprises* (《高新技術企業認定管理辦法》), which was promulgated by the Ministry of Science and Technology, the Ministry of Finance, and the State Taxation Administration on January 29, 2016 and became effective on January 1, 2016, an enterprise which is recognized as a high and new technology enterprise may apply for a preferential enterprise income tax rate of 15% pursuant to the EIT Law, its implementation regulations and relevant PRC law.

Value Added Tax (the "VAT")

The SCNPC promulgated the *PRC Value-added Tax Law* (《中華人民共和國增值税法》) on December 25, 2024, which came into effect on January 1, 2026. The State Council promulgated the *Implementation Regulations of the Value-Added Tax Law of the PRC* (《中華人民共和國增值税法實施條例》) on December 25, 2025, which came into effect on January 1, 2026. According to the PRC Value-added Tax Law and the Implementation Regulations of the Value-Added Tax Law of the PRC, the VAT rate for general VAT taxpayers engaged in the sale of goods, services, leasing of tangible movable assets, or importation of goods is adjusted to 13% and 6%; the VAT rate for general VAT taxpayers engaged in, among others, the provision of transportation services, postal services, basic telecommunication services, construction services, the leasing and sale of real property, and the transfer of land use rights is adjusted to 9%. With effect from January 1, 2026, the *Interim Regulations of the PRC on Value-added Tax* (《中華人民共和國增值税暫行條例》) have been repealed.

Foreign Exchange regulation

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 on 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 State Administration of Foreign Exchange (the "**SAFE**"), upon compliance 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 capital of foreign-invested enterprises nationwide. In June 2016, SAFE further promulgated the *Circular on the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account* (《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. Pursuant to SAFE Circular 19 and SAFE Circular 16, the flow and use of the Renminbi capital converted from foreign currency denominated registered capital of a foreign-invested company is regulated such that Renminbi capital may not be used for business beyond its business scope or to provide loans to persons other than affiliates unless otherwise permitted under its business scope.

In October 2019, SAFE issued the *Circular on Further Facilitating Cross-border Trade and Investment* (《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》), issued by SAFE in April 2020, under the prerequisite of ensuring true and compliant use of funds and compliance with the prevailing administrative provisions on the 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.

REGULATIONS ON OVERSEAS LISTINGS

Pursuant to the *Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies* (《境內企業境外發行證券和上市管理試行辦法》) promulgated by the China Securities Regulatory Commission (中國證券監督管理委員會) (the "**CSRC**") on February 17, 2023, which became effective on March 31, 2023, it regulates the overseas securities offering and listing activities of domestic companies, whether directly or indirectly: (1) where a PRC company carries out securities offering and listing in an overseas market, it shall go through the filing procedures with the CSRC and submit relevant information, and shall submit the initial filing materials within three working days of submitting the initial public offering and listing application documents; and (2) PRC companies that are directly or indirectly listing in overseas markets and intend to conduct subsequent offerings in the same overseas markets shall go through the filing procedures with the CSRC and report relevant information; they shall also submit the filing within three working days of the completion date of the subsequent offering. In addition, no overseas offering and listing shall be conducted under any of the following circumstances: (1) it is prohibited by the PRC laws, administrative regulations or relevant rules of the state to conduct overseas offering and listing; (2) overseas offering and listing may endanger national security as reviewed and determined by the relevant competent department of the State Council in accordance with the laws; (3) a domestic enterprise or its controlling shareholder or actual controller has committed a criminal crime in the last three years; (4) a domestic enterprise is under investigation according to the laws for being suspected of crimes or major violations of laws and regulations and no conclusion has yet been made thereof; or (5) there is a major dispute over ownership of the equity interests held by the controlling shareholder or the shareholder controlled by the controlling shareholder or the actual controller.

According to the Provisions on Strengthening the Confidentiality and Archives Management of Overseas Securities Offering and Listing by Domestic Enterprises (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) (the "**Archives Provisions**") promulgated by the CSRC, the Ministry of Finance of the People's Republic of China (中華人民共和國財政部), the State Secrets Bureau (中華人民共和國國家保密局) and the State Archives Administration of the PRC (中華人民共和國國家檔案局) on February 24, 2023 and implemented from March 31, 2023, domestic enterprises, securities companies and securities service institutions providing corresponding services shall strictly comply with the relevant requirements for confidentiality and archives management, establish and improve confidentiality and file management systems, and take the necessary measures to implement confidentiality and archives management responsibilities, in the direct or indirect overseas securities offering or listing activities by domestic enterprises. According to the Archives Provisions, during the process of domestic enterprises conducting offering and listing overseas, if documents or data involving state secrets or adversely affecting national security or the public interest need to be

provided or publicly disclosed to relevant securities companies, securities service agencies, overseas regulatory authorities and other units and individuals, the relevant approval/filing and other regulatory procedures shall be completed.

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 PK and PD 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.

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

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

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

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

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

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

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

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

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

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