OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

This section summarizes the principal PRC laws, rules and regulations that are relevant to our business.

Principal Regulatory Authorities

NMPA and CDE

The National Medical Products Administration (國家藥品監督管理局) (formerly the China Food and Drug Administration (國家食品藥品監督管理總局) (the "**CFDA**")) (the "**NMPA**") is the department in charge of the pharmaceutical industry of China.

The Center for Drug Evaluation of the NMPA (國家藥品監督管理局藥品審評中心) (the "**CDE**") is the technical evaluation unit for drug registration with the NMPA.

NHC

The National Health Commission (國家衛生健康委員會) (formerly the National Health and Family Planning Commission (國家衛生和計劃生育委員會)) (the "**NHC**"), is the primary national regulator for public health and family planning management.

NHSA

The National Healthcare Security Administration (國家醫療保障局) (the "**NHSA**"), a new authority established in May 2018, is directly under the State Council and is responsible for the management of the healthcare security system.

MOFCOM

The Ministry of Commerce of the PRC (中華人民共和國商務部) (the "**MOFCOM**") is responsible for the overall guidance and management of foreign investment.

PRINCIPAL REGULATORY PROVISIONS

Laws and Regulations on New Drugs

Research and Development of New Drugs

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the "**Drug Administration Law**") promulgated by the Standing Committee of the National People's Congress (the "**SCNPC**") in September 1984, last amended on August 26, 2019 and effective on December 1, 2019, and 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**") promulgated by the State Council in August 2002 and last amended on January 16, 2026 and became effective on May 15, 2026, have laid down the legal framework for the establishment and maintenance of pharmaceutical manufacturing and trading enterprises, as well as for the administration of pharmaceutical products including the development and manufacturing of new drugs. According to the Drug Administration Law and the Implementation Regulations, the PRC encourages the research and development of new drugs, and protects the legal rights and interests in the research and development of new drugs. The developer and clinical trial applicant of any new drug shall truthfully submit the new drug's manufacturing method, quality specifications, results of pharmacological and toxicological tests and the related data, documents and samples to the NMPA for approval before any clinical trial is conducted.

Non-Clinical Research

The Administrative Measures for Good Laboratories Practice (《藥物非臨床研究質量管理規範》("**GLP**")), promulgated by the CFDA in August 2003 and most recently revised by the CFDA in July 2017 with effect from September 1, 2017, shall be complied with for safety non-clinical evaluation of drugs conducted for the purpose of applying for marketing approval. In April 2007, the CFDA issued the Administrative Measures for Certification of Good Laboratory Practice (《藥物非臨床研究質量管理規範認證管理辦法》), which sets out the requirements for institutions applying for GLP certification. On January 19, 2023, the NMPA revised the Administrative Measures for Certification of Good Laboratory Practice (《藥物非臨床研究質量管理規範認證管理辦法》), which has been in effect since July 1, 2023. The NMPA will approve and issue GLP certificates to the applicants that meet the GLP requirements, and the GLP certificates are valid for 5 years. Any entity without such certification must engage a qualified third party to conduct non-clinical studies regulated under relevant laws and regulations.

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 CFDA on March 17, 2017 and effective on May 1, 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. The CFDA issued the Announcement on Certain Policies Pertaining to the Review and Approval of Drug Registration (《關於藥品註冊審評審批若干政策的公告》) on November 11, 2015, according to which, the drug approval process was further simplified by implementing a one-time approval for INDs of new drugs, and no longer adopting declarations, reviews or approvals at different phases. In accordance with the 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.

After obtaining the approval of clinical trial from the NMPA, the applicant must complete the clinical trial registration at the Drug Clinical Trial Information Platform 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 in September 2013. The applicant shall complete the initial registration of the trial within one month after obtaining the approval of clinical trial to obtain an exclusive trial registration number, and then complete the subsequent information registration before the first patient is enrolled in the trial and submit the registration for public disclosure for the first time.

Conduct of Clinical Trial

After obtaining clinical trial approval, the applicant shall conduct clinical trials at qualified clinical trial institutions. The qualified clinical trial institutions refer to those 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. 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》) promulgated by the NMPA and the NHC on April 23, 2020 and effective on July 1, 2020, which stipulates the requirements for the procedures of conducting clinical trials, including pre-clinical trial preparation, trial protocols, protection of subjects' rights and interests, duties of researchers, sponsors and monitors, as well as data management and statistical analysis.

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 the CDE to discuss with the CDE the key technical issues 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》), promulgated by the CDE 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 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.

International Multi-Centre Clinical Trials

According to the International Multi-Center Clinical Trial Guidelines (Trial) (《國際多中心藥物臨床試驗指南(試行)》), which was issued by the CFDA on January 30, 2015 and became effective on March 1, 2015, the sponsor may conduct clinical trials simultaneously at multiple centres in multiple regions in accordance with the same clinical trial protocol, and may also conduct regional clinical trials simultaneously at multiple centres in different countries within a region in accordance with the same clinical trial protocol. If the sponsor plans to use the data derived from international multi-centre clinical trials for approval of drug registration in China, such international multi-center clinical trials shall comply with the provisions concerning clinical trials in the Registration Measures. When planning and implementing international multi-centre clinical trials in China, the sponsor shall comply with the Drug Administration Law, the Implementation Regulations, the Registration Measures and other related laws and regulations, implement the Good Clinical Practice in China, make reference to Good Clinical Practice (臨床試驗質量管理規範) provided by the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (人用藥品註冊技術國際協調會議), and meet the legal and regulatory requirements of the corresponding countries.

The NMPA issued the Technical Guiding Principles for the Acceptance of Overseas Clinical Trial Data of Drugs (《接受藥品境外臨床試驗數據的技術指導原則》) on July 6, 2018, according to which, for drugs applied for registration within the PRC, overseas clinical trial data submitted by the applicant may be accepted as the information for clinical evaluation.

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 applicant must obtain the marketing authorization for a new drug before the drug can be manufactured and sold in the China market. According to the Registration Measures, the holders of any of the following drugs can apply for conditional approval of such drugs: (i) drugs which are used for the treatment of severe life-threatening diseases currently lacking effective treatment and the data of clinical trials can confirm their efficacy and forecast their clinical value; (ii) drugs which are urgently needed for public health and data of clinical trials can demonstrate their efficacy and forecast their clinical value; and (iii) vaccines which are urgently needed to deal with major public health emergencies or other vaccines which the NHC deems to be urgently needed, the benefits of both of which are assessed to be outweigh the risk.

The Opinion on Strengthening the Reform of the Drug and Medical Device Review and Approval Process to Encourage Drug and Medical Device Innovation (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (the "**Innovation Opinion**") established a framework for reforming the evaluation and approval system for drugs, medical devices and equipment.

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

According to the Announcement on Matters Concerning the Optimization of Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》) jointly issued by the NMPA and the NHC in May 2018, 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.

The Registration Measures has incorporated the previous reform in respect of the accelerated approval for clinical trial and drug marketing registration and introduces four procedures for expedited marketing registration of drugs, which are procedures for groundbreaking therapeutic drugs, procedures for conditional approval, procedures for prioritized reviews and approval, and procedures for special examination and approval:

(i) Procedures for ground-breaking therapeutic drugs: during the drug clinical trials, for an innovative drug or improved new drug used for prevention and treatment of life-threatening illnesses or illnesses which have a serious impact on quality of life and for which there is no other effective prevention and treatment method or there is adequate evidence to prove that the said innovative drug or improved new drug has obvious clinical advantages over existing treatment approach, the applicant may request for application of procedures for ground-breaking therapeutic drugs.

(ii) Procedures for conditional approval: during the drug clinical trials, for drugs which fall under the following circumstances, an application for conditional approval of marketing registration may be submitted: (i) for drugs for treatment of life-threatening illnesses for which there is no effective treatment approach, the clinical trial of drugs already has data to prove efficacy and is able to forecast the clinical value; (ii) for drugs urgently needed for public health, the clinical trial of drugs already has data to prove efficacy and is able to forecast the clinical value; and (iii) for other vaccines urgently needed for major public health emergencies or deemed by the NHC to be urgently needed, its benefits outweigh the risks according to the evaluation.

(iii) Procedures for prioritized reviews and approval: at the time of the drug marketing registration, drugs have obvious clinical value may apply for application of procedures for prioritized review and approval, including (i) clinically and urgently needed but insufficient drug, innovative drugs and improved new drugs for prevention and treatment of major contagious diseases and rare diseases; (ii) new pharmaceutical product types, dosage form and specifications of pediatric drugs which comply with pediatric physiological characteristics; (iii) vaccines and innovative vaccines urgently needed for prevention and control of diseases; (iv) drug included in the procedures for groundbreaking therapeutic drug; (v) drug which comply with conditional approval criteria; and (vi) other circumstances of prioritized review stipulated by the NMPA.

(iv) Procedures for special examination and approval: at the time of a threat or occurrence of public health emergency, the NMPA may, in accordance with law, decide to implement special examination and approval for urgently needed drug required for the prevention and treatment during the public health emergency.

Marketing Authorization Holder Mechanism

Pursuant to the Drug Administration Law, China 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.

Pharmacovigilance

According to the Good Pharmacovigilance Practices (《藥物警戒質量管理規範》) which was issued by the NMPA on May 7, 2021 and became effective on December 1, 2021, the drug marketing authorization holder and the drug registration applicant who has been approved to conduct drug clinical trials shall establish a pharmacovigilance system, through the effective operation and maintenance of which, they can monitor, identify, evaluate and control the adverse drug reactions and other drug-related harmful reactions. The drug marketing authorization holder shall formulate pharmacovigilance quality objectives, establish a quality assurance system, and conduct quality management of the pharmacovigilance system and activities, so as to continuously improve the operation efficiency of the pharmacovigilance system and ensure that pharmacovigilance activities continue to comply with the requirements of relevant laws and regulations. The legal representative or the key person-in-charge of the drug marketing authorization holder is fully responsible for the pharmacovigilance activities. The drug marketing authorization holder shall complete information registration in the National Adverse Drug Reaction Monitoring System within 30 days after obtaining the first drug approval document.

Gathering, Collection and Filing of Human Genetic Resources

According to the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》), issued by the Ministry of Science and Technology (the "MOST") in July 2015, and the Circular on Implementing Administrative Licensing for the Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (《關於實施人類遺傳資源採集、收集、買賣、出口、出境審批行政許可的通知》), issued by the MOST in August 2015, foreign-invested applicants conducting clinical trials to collect or gather human genetic resources must file a record with the China Human Genetic Resources Management Office through the online system. The MOST promulgated the Notice on Optimizing the Administrative Examination and Approval Process of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》) in October 2017 (effective from December 2017), which has simplified the approval process for the gathering and collection of human genetic resources for the marketing of drugs in China. The MOST issued the Notice on Updating the Service Guidelines, Filing, and Pre-reporting Scope and Procedures for Administrative Licensing Matters Related to Human Genetic Resources (《關於更新人類遺傳資源行政許可事項服務指南、備案以及事先報告範圍和程序的通知》) on July 14, 2023 (effective from July 14, 2023), further refining the approval process for the gathering and collection of human genetic resources required for the marketing of drugs in China.

Pursuant to the Regulations on the Administration of Human Genetic Resources of the People's Republic of China (《中華人民共和國人類遺傳資源管理條例》) which was promulgated by the State Council in May 2019, newly amended in March 2024 and came into effect on May 1, 2024, the state supports the rational use of human genetic resources for scientific research, development of the biomedical industry, improvement of diagnosis and treatment technology, improvement of China's ability to guarantee biosecurity and improvement of the level of people's health. Foreign organizations, individuals and institutions established or actually controlled by them shall not gather or preserve Chinese genetic resources within the territory of the PRC, or provide Chinese genetic resources to foreign countries. In addition, the gathering, preservation, utilization and external provision of Chinese genetic resources shall (i) conform to ethical principles and conduct ethical review in accordance with relevant regulations; (ii) respect the privacy of the human genetic resource providers, obtain their prior consents, and protect their lawful rights and interests; (iii) comply with technical specification promulgated by the competent healthcare authorities the State Council.

The Biosecurity Law of the PRC (《中華人民共和國生物安全法》) (the "**Biosecurity Law**") was promulgated by SCNPC on October 17, 2020, and was last amended and became effective on April 26, 2024. The Biosecurity Law establishes a comprehensive legislative framework for the pre-existing regulations in such areas as epidemic control of infectious diseases for humans, animals and plants, research, development, and application of biology technology, biosecurity management of pathogenic microbial laboratories, security management of human genetic resources and biological resources, countermeasures for microbial resistance, and prevention of bioterrorism and defending threats of biological weapons. According to the Biosecurity Law, the research and development activities of high-risk and medium-risk biotechnology shall be carried out by a legal person organization established within the territory of the PRC in accordance with the law, upon obtaining the approval or record-filing. The establishment of a pathogenic microorganism laboratory shall be subject to approval or record-filing requirements in accordance with the law. In addition, (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 competent health department under the State Council, (ii) preserving China's human genetic resources, (iii) using China's human genetic resources to carry out international scientific research cooperation, or (iv) transporting, mailing, and carrying China's human genetic resource materials out of the country, are subject to the approval by the competent healthcare authority.

The MOST promulgated the Implementing Rules of the Regulations on the Administration of Human Genetic Resources (《人類遺傳資源管理條例實施細則》) (the "**Implementing Rules**") on May 26, 2023, which came into effect on July 1, 2023. The Implementing Rules further provide detailed implementation provisions for the management of human genetic resources in China, including the following:

(a) clarifying the scope of human genetic resource information, which shall include information resources generated from human genetic resource materials (such as human genes and genome data) and exclude clinical data, image data, protein data and metabolic data;

(b) clarifying the criteria to constitute a foreign organization, which shall include (i) any foreign organization or individual that holds directly or indirectly more than 50% of the shares, equity interests, voting rights, property shares or other interests in the institution, (ii) any foreign organization or individual that is able to dominate or have material effect on the decision-making or management of the institution through its voting right or other interests, although the shares, equity interests, voting rights, property share or other interests it directly or indirectly holds in the institution is less than 50%, (iii) any foreign organization or individual that is able to dominate or have material effect on the decision-making or management of the institution through investment relationship, contract or other arrangement; and (iv) other situations stipulated by laws, regulations and rules;

(c) listing the situations where security review may be required, which shall include: (i) human genetic resource information of important genetic families; (ii) human genetic resources information of specific regions, (iii) exome sequencing and genome sequencing information resources with a population greater than 500 cases; and (iv) other situation that may affect the public health, national security and social public interest of the PRC.

Administrative Protection and Monitoring Periods for New Drugs

According to the Implementation Regulations and the Reform Plan for Registration Category of Chemical Drugs (《化學藥品註冊分類改革工作方案》) issued on March 4, 2016, the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of five years for new Category 1 drugs approved to be manufactured, commencing from the date of approval, to continually monitor the safety of those new drugs. During the monitoring period of a new drug, the NMPA will not approve any other enterprises' applications to manufacture or import the said drug.

Laws and Regulations on the Manufacturing of Drugs

Drug Manufacturing License

Pursuant to the Drug Administration Law, the state adopts an industry entry permit system for drug manufacturers. The conduct of drug manufacturing activities shall be approved and granted with a Drug Manufacturing License (《藥品生產許可證》) by the drug regulatory authority of the people's government at provincial, autonomous regional or municipal level. The Drug Manufacturing License shall indicate the validity period and the scope of production, and shall be reviewed for renewing upon expiration.

The Good Manufacturing Practices

The Good Manufacturing Practices (《藥品生產質量管理規範》), which was promulgated by the Ministry of Health of the PRC (the "**MOH**", now known as the NHC) in March 1988, newly amended in January 2011 and came into effect in March 1, 2011, provides guidance for the quality management, organization and staffing, production premises and facilities, equipment, material and products, recognition and inspection, documentation maintenance, manufacture management, quality control and quality assurance, contractual manufacture and contractual inspection for the products, product delivery and recalls of a drug manufacturer in a systematical manner.

Prior to December 1, 2019, establishment of a new drug manufacturer, construction of new production premise for a drug manufacturer or production of new dosage form are required to submit application for good manufacturing practice certification (GMP certification) with the drug regulatory authority in accordance with relevant provisions. If the Good Manufacturing Practices are satisfied, a GMP certificate will be issued. Pursuant to the Announcement on the Relevant Issues Concerning the Implementation of the Drug Administration Law of the PRC (《關於貫徹實施<中華人民共和國藥品管理法>有關事項的公告》), promulgated by the NMPA on November 29, 2019, and the Drug Administration Law, the GMP and Good Supply Practice (GSP) certifications have been cancelled, applications for GMP and GSP certifications are no longer accepted, and GMP and GSP certificates are no longer issued. When engaging in drug manufacturing activities, a manufacturer shall comply with the GMP and establish a sound GMP management system, to ensure that the entire process of drug manufacturing maintain to meet the statutory requirements, and meet the GMP requirements enacted by the NMPA in accordance with the law. The legal representative and the key person-in-charge of a drug manufacturer are fully responsible for the drug manufacturing activities of the enterprise.

The Administrative Measures for the Inspection of Pharmaceuticals (Trial) (《藥品檢查管理辦法(試行)》) was promulgated by the NMPA on May 24, 2021 and amended on July 19, 2023, and the Certification Measures for Good Manufacturing Practice for Drugs was repealed simultaneously. The Administrative Measures for the Inspection of Pharmaceuticals (Trial) stipulates that if a drug manufacturer applies for a drug manufacturing license for the first time, it will be subject to on-site inspection under relevant contents of the GMP. If a drug manufacturer applies for re-issuance of drug manufacturing license, relevant authorities shall conduct examination pursuant to risk management principle, taking into account the enterprise's compliance with pharmaceutical administration laws and regulations, operation status of GMP and quality system, and may conduct GMP compliance inspection where necessary.

Entrusted Manufacturing of Drugs

Pursuant to the Administrative Regulations for the Entrusted Manufacturing of Drugs (《藥品委託生產監督管理規定》) issued by the CFDA in August 2014, only when a drug manufacturer temporarily lacks manufacturing conditions due to technology upgrade or is unable to ensure market supply due to insufficient manufacturing capabilities can such drug manufacturer entrust the manufacturing of the drug to another drug manufacturer. Such entrusted manufacturing arrangements shall be approved by the provincial branch of the NMPA.

The Administrative Measures on Supervision of Drug Manufacturing (《藥品生產監督管理辦法》) promulgated by the State Administration for Market Regulation (the "**SAMR**") on January 22, 2020 and effective on July 1, 2020 further implements the drug marketing authorization holder system as stipulated in the Drug Administration Law. Drug marketing authorization holders entrusting others to manufacture drugs shall enter into entrustment agreements and quality agreements with qualified drug manufacturing enterprises and submit the relevant agreements together with the actual manufacturing site application materials to the competent drug administrative authority in order to apply for the Drug Manufacturing License. The drug marketing authorization holder shall follow the Guidelines for the Quality Agreements of Entrusted Manufacturing of Drugs (《藥品委託生產質量協議指南》) formulated by the NMPA to supervise the entrusted party to fulfill the obligations agreed upon in the agreement. The entrusted party shall not re-entrust a third party to manufacture the drugs for which it has accepted the manufacturing entrustment. A drug marketing authorization holder shall establish a drug quality assurance system which shall be independently managed by professionals for the quality control of drugs. A drug marketing authorization holder shall regularly examine the quality management system of drug producers and drug trading companies entrusted by it to ensure that they remain capable in quality assurance and control.

The legal representative and the key person-in-charge of a drug marketing authorization holder shall be fully responsible for the quality of drugs, while the legal representative and the key person-in-charge of a drug manufacturer shall be fully responsible for the manufacturing activities of its own. The drug marketing authorization holder and drug manufacturers shall establish and implement a drug traceability system, assign traceability labels to sales packaging of their drugs in accordance with regulations, implement drug traceability through information-based means, record and keep drug traceability data in a timely manner, and provide traceability information to the drug traceability collaborative service platform.

REGULATIONS RELATING TO MEDICAL INDUSTRY

Pharmaceutical Representatives

The Measures for the Administration of Pharmaceutical Representatives (《醫藥代表管理辦法》), formulated and issued jointly by the NHC, the NHSA and other competent authorities, shall come into full effect on August 1, 2026. It defines medical representatives, specify their eligibility and filing requirements, and regulate industry conduct. It imposes primary and overall accountability on marketing authorization holders via mandatory filing and stringent rules, requiring them to fully oversee the recruitment, authorization, registration and ongoing management of pharmaceutical representatives.

Basic Medical Insurance Policy

Pursuant to the Decision on the Establishment of the Urban Employee Basic Medical Insurance Programme (《關於建立城鎮職工基本醫療保險制度的決定》) promulgated by the State Council on December 14, 1998 and the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》) which was promulgated by the NDRC, the CFDA and other authorities, and came into effect on May 12, 1999, all employers in cities and towns, including enterprises (state-owned enterprises, collective enterprises, foreign-invested enterprises, private enterprises, etc.), institutions, public institutions, social organizations, private non-enterprise units and their employees are required to participate in basic medical insurance. Pursuant to the Guiding Opinions on the Pilot of Basic Medical Insurance for Urban Residents (《關於開展城鎮居民基本醫療保險試點的指導意見》) promulgated by the State Council on July 10, 2007, urban residents

(not urban employees) in the pilot areas can voluntarily participate in the basic medical insurance for urban residents. Pursuant to the Opinions of the State Council on the Integration of the Basic Medical Insurance System for Urban and Rural Residents (《國務院關於整合城鄉居民基本醫療保險制度的意見》) promulgated by the State Council on January 3, 2016, a unified basic medical insurance system for urban and rural residents was established, including the existing urban residents' medical insurance and all the insured personnel of New Rural Cooperative Medical System, covering all urban and rural residents except those who should be covered by the employee's basic medical insurance.

Medical Insurance Catalogue

Pursuant to the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》), the scope of medical insurance coverage for pharmaceutical products needs to be managed through the formulation of the Medical Insurance Catalogue. A pharmaceutical product listed in the Medical Insurance Catalogue must be clinically needed, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements: it is set forth in the Pharmacopoeia of the PRC (current edition) (《中華人民共和國藥典》(現行版)); it meets the standards promulgated by the NMPA; and if imported, it is approved by the NMPA for import. According to the Opinions of the NHSA and the Ministry of Finance on Establishing a List-Based System for Healthcare Security Benefits (《國家醫保局、財政部關於建立醫療保障待遇清單制度的意見》), which came into effect in January 2021, all provinces shall implement the NRDL in a strict manner, and shall not have the discretion to formulate the catalogue or increase the drugs in any form, or adjust the limited payment scope of drugs in the catalogue. After several adjustments, the currently effective medical insurance catalogue is the National Insurance Drug List for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (2024) (《國家基本醫療保險、工傷保險和生育保險藥品目錄(2024年)》) which came into effect since January 1, 2025.

National Essential Drug List

On January 27, 2026, the NHC and ten other ministries and commissions jointly issued the Administrative Measures for the National Essential Medicine List (《國家基本藥物目錄管理辦法》). The State implements the essential drugs system and selects an appropriate number of essential drug varieties to meet the basic medication needs for disease prevention and treatment. Essential drugs refer to drugs that meet the basic medication needs for disease prevention and treatment, are suitable for the current stage of national conditions and support capacity, have appropriate dosage forms, reasonable prices, guaranteed supply and equitable accessibility. The State publishes the National Essential Medicine List and dynamically adjusts the list based on clinical application practices, changes in drug standards and the launch of new drugs. The selection and adjustment of essential drugs adhere to the principles of equal emphasis on traditional Chinese medicine and Western medicine, combined use of Chinese and Western medicines, and clinical priority, with reasonable reference to international experience. National essential drugs include chemical drugs and biological products, as well as traditional Chinese medicines (including prepared slices of Chinese medicinal materials and Chinese patent medicines).

Laws and Regulations on Intellectual Properties

Patent

Patents in the PRC are mainly protected by the Patent Law of the PRC (《中華人民共和國專利法》), which was promulgated by the SCNPC on March 12, 1984, last amended on October 17, 2020 and became effective 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》) (the "**Implementation Rules**"), which was promulgated by the State Council on June 15, 2001 and last amended on December 11, 2023 and became effective on January 20, 2024. The Patent Law and the Implementation Rules provide for three types of patents, "invention", "utility model" and "design." "Invention" refers to any new technical solution relating to a product, a process or improvement thereof; "utility model" refers to any new technical solution relating to the shape, structure, or their combination, of a product, which is suitable for practical use; and "design" refers to any new design of the shape, pattern, color or

the combination of any two of them, of a product, which creates an aesthetic feeling and is suitable for industrial application. The duration of a patent right for "invention" is twenty (20) years, the duration of a patent right for "utility model" is ten (10) years, and the duration of a patent right for "design" is fifteen (15) years, from the date of application. According to the Patent Law of the PRC, for the purpose of public health, the patent administrative department of the State Council may grant mandatory licensing to manufacture and export patented drugs to countries or regions in comply with provisions of the relevant international treaty participated by the PRC.

The newly amended Patent Law of the PRC introduces patent extension compensation to patents of new drugs that launched in the PRC, and stipulates that the Patent Administration Department under the State Council shall, upon request of the patentee, extend the patent term of relevant invention patents of the new drug that is approved to be listed on the market in China, to compensate for the time spent for the review and examination and approval of the listing of a new drug on the market. The compensated extension shall not exceed five (5) years, and the total valid patent term after the new drug is approved for the market shall not exceed fourteen (14) years. Such newly adopted patent term extension rule benefits the Company through providing longer protection terms of patents applied or registered in the PRC and related to our products. During the period of patent term compensation for a patent for invention related to a new drug, the scope of protection of the patent is limited to the new drug and its approved indications related to the technical program; within the scope of protection, the patentee enjoys the same rights and undertakes the same obligations as before the patent term compensation.

Trademarks

Registered trademarks in the PRC are mainly protected by 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 Rules of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》), which were promulgated by the State Council on August 3, 2002 and latest amended on April 29, 2014 and came into effect on May 1, 2014. The Trademark Office is responsible for the registration and administration of trademarks throughout China and grants a term of ten (10) years to registered trademarks. A trademark registrant shall make an application for renewal within twelve (12) months before the expiration in accordance with the requirements. If such an application cannot be filed within that period, an extension period of six months may be granted. The period of validity for each renewal of registration shall be ten (10) years as of the next day of the previous period of validity. If the formalities for renewal have not been handled upon expiration of period of validity, the registered trademarks will be deregistered.

Domain Names

Domain names are regulated under the Administrative Measures on the Internet Domain Names (《互聯網域名管理辦法》) issued by the MIIT on August 24, 2017 and effective from November 1, 2017. The MIIT is the main regulatory authority responsible for the administration of the PRC internet domain names. Domain names registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

Trade Secret

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 SCNPC, as amended on June 27, 2025 and became effective on October 15, 2025, 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) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion, or any other means; (ii) disclosing, using, or allowing another person to use a trade secret acquired from the right

holder by any means as specified in the item (i) above; (iii) disclosing, using, or allowing another person use a trade secret in its possession, in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; (iv) abetting a person, or tempting or helping another person into or in acquiring, disclosing, using, or allowing another person to use the trade secret of the right holder in violation of his or her confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and impose fine on the infringing parties.

Laws and Regulations on Foreign Direct Investment

Since January 1, 2020, the Foreign Investment Law of the PRC (the "**Foreign Investment Law**") issued by the National People's Congress (the "**NPC**") of the PRC became effective, superseding the Law of the PRC on Chinese-Foreign Equity Joint Ventures (《中華人民共和國中外合資經營企業法》), the Law of the PRC on Foreign-Capital Enterprises (《中華人民共和國外資企業法》), and the Law of the PRC on Chinese-Foreign Contractual Joint Ventures (《中華人民共和國中外合作經營企業法》). Since then, the Foreign Investment Law becomes the fundamental law to regulate the foreign-capital enterprises invested wholly or partially by foreign investors. The nature, organization and rules of foreign-invested enterprises are subject to the Company Law and other PRC laws. Chinese government implements a pre-entry national treatment with negative list management system for foreign investment, abolishing the previous approval and registration management system for the establishment and changes of foreign-invested enterprises. Pre-entry National Treatment refers to the treatment accorded to foreign investors and their investments at the stage of investment entry which is no less favorable than the treatment accorded to domestic investors and their investments. Negative List refers to a special administrative measure for the entry of foreign investment in specific sectors as imposed by the PRC. Foreign investments out of negative list would enjoy national treatment. Current negative list is the Special Administrative Measures for Foreign Investment Access (Negative List) (2024 Edition) (《外商投資准入特別管理措施(負面清單)(2024年版)》) published by the NDRC and the MOFCOM on September 6, 2024 and effective from November 1, 2024, listing the equity requirements, executive requirements and other special administrative measures on foreign investment access in the industries governed by the negative list.

Foreign investment information reporting is subject to the Measures for Reporting of Foreign Investment Information (《外商投資信息報告辦法》) jointly developed by the MOFCOM and the SAMR, effective from January 1, 2020, under which, the MOFCOM is responsible for governing and directing nationwide reporting of foreign investment information. The commercial authority in county or above level people's government, or relevant authority in free-trade pilot zone or national level economic and technological development zone is responsible for local reporting of foreign investment information within its own jurisdiction. A foreign investor directly or indirectly investing in China shall report its investing information through corporate registration system and national enterprise credit information publicity system to local commercial authority, in the form of initial report, change report, de-registration report, annual report etc. A foreign investor who sets up a foreign-invested enterprise in China or who mergers or acquires the equities of a non-foreign enterprise in China shall submit initial report through corporate registration system at the time of establishing said foreign-invested enterprise or at the time of change registration of said merged/acquired enterprise. If the change in the information of initial reports involves corporate change registration (filing), then the foreign-invested enterprise shall submit change report through corporate registration system at the time of corporate change registration (filing). If the change of information doesn't involve corporate change registration (filing), then the foreign-invested enterprise shall submit change report through corporate registration system. A foreign-invested listed company may report the information on change of investors and their shares, only when the cumulative shareholding of foreign investors exceeds 5% or their controlling or relatively controlling position changes.

Regulations on Foreign Investment Security Review

The Foreign Investment Security Review Measures (《外商投資安全審查辦法》) jointly published by the NDRC and the MOFCOM on December 19, 2020, effective from January 18, 2021, provide for the security review mechanism on foreign investment, including the types of investments subject to review, review scopes, and procedures, among others.

Laws and Regulations on Overseas Investment

Under the Measures for Overseas Investment Management (《境外投資管理辦法》) published by the MOFCOM on March 16, 2009 and revised on September 6, 2014 and the Measures for the Administration of Overseas Investment by Enterprises (《企業境外投資管理辦法》) published by the NDRC on December 26, 2017 and effective from March 1, 2018, a Chinese enterprise (the "**investor**") contemplating overseas investment (the "**project**") shall perform project approval, filing and other procedures, report relevant information, and coordinate with supervision and examination. The sensitive project invested directly by the investor or through its controlled overseas enterprise shall be approved. The non-sensitive project directly invested by the investor, that is, the non-sensitive project involving the investor's directly investing assets, equities or financing or guarantee shall be filed.

Regulations on Product Liability

The Product Quality Law of the PRC (《中華人民共和國產品質量法》) (the "**Product Quality Law**") published by the SCNPC on February 22, 1993 and last amended on December 29, 2018, which is a major law on product quality supervision and management, under which, a producer shall be liable for the quality of its product. A seller shall take measures to maintain the quality of product it sells. The producer shall be liable for compensation, if its product has defects causing damages to natural persons or properties other than the defective product. In any of the following circumstances, the producer shall not be liable for compensation: (1) the product is not put in circulation; (2) the damage is not yet triggered by the defects when the product is put in circulation; or (3) the defects is unidentifiable by existing level of science and technology when the product is put in circulation. The seller shall be liable for compensation, if (1) the product is defective at the fault of seller, causing personal harm or property damage or (2) the seller fails to specify the producer and the supplier of such defective product. If a defective product causes personal harm and property damage, then the affected person may claim compensation from the producer or the seller of the said product.

Under the Civil Code of the PRC (《中華人民共和國民法典》) published by the NPC on May 28, 2020 and effective from January 1, 2021, if a defective medicine harms a patient, then the affected patient may claim compensation from the marketing authorization holder or producer of the medicine, or from the medical center. If the affected patient claims compensation from the medical center, then after compensation, the medical center may seek recourse from the marketing authorization holder or producer of the said medicine.

The Consumer Rights Protection Law of the PRC (《中華人民共和國消費者權益保護法》) published on October 31, 1993, last amended on October 25, 2013 and effective from March 15, 2014 aims to protect consumers' rights when they are buying, using goods or taking services. An operator who provides consumers with goods it produces or sells and/or renders services shall obey this law.

Regulations on Production Safety

The Production Safety Law of the PRC (《中華人民共和國安全生產法》) published by the SCNPC on June 29, 2002, last amended on June 10, 2021 and effective from September 1, 2021 is a fundamental law to regulate production safety, under which, an entity failing to meet the conditions for production safety shall not be engaged in production. A producer shall educate or

train its workers on production safety, to ensure its workers are aware of necessary knowledge about production safety, familiar with production safety related regulations and safety operating procedures, master the safety operating skills on job, understand emergency response measures and know their rights and obligations in production safety.

Regulations on Environmental Protection and Fire Safety

Under the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) published by the SCNPC on December 26, 1989, last amended on April 24, 2014 and effective from January 1, 2015, the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》) published by the SCNPC on October 28, 2002 and last amended on December 29, 2018, and the Regulations on Environmental Protection Management for Construction Projects (《建設項目環境保護管理條例》) published by the State Council on November 29, 1998, last amended on July 16, 2017 and effective from October 1, 2017, an enterprise planning for construction project shall appoint eligible professionals to provide the environmental impact report, environmental impact assessment form, or environmental impact register relating to the project. The environmental impact report, environmental impact assessment form, or environmental impact register shall be filed to or approved by relevant environmental authority before commencement of any construction project.

An enterprise engaged in industry, building, catering, medical and other activities discharging wastewater to urban drainage facilities shall lawfully apply for wastewater discharge permit to local urban drainage authority, according to the Regulations on Urban Drainage and Sewage Treatment (《城鎮排水與污水處理條例》) published on October 2, 2013 and effective from January 1, 2014, and the Measures for Administration of the Permit for Discharging Urban Sewage into Drainage Pipelines (《城鎮污水排入排水管網許可管理辦法》) published on January 22, 2015, last amended on December 1, 2022 and effective from February 1, 2023. The discharging entities covered by the urban drainage facilities shall lawfully discharge wastewater into urban drainage facilities. To do so, the discharging entities shall apply for drainage permit accordingly, and those failing to obtain such permit shall not discharge wastewater into urban drainage facilities.

Under the Regulations on Administration of Pollutant Discharge Permits (《排污許可管理辦法》) issued by the Ministry of Ecology and Environment on April 1, 2024 and effective from July 1, 2024, corporate, public entities and other producers subject to discharge permit administration shall apply for discharge permit and discharge pollutants according to the permit; those failing to obtain the permit shall not discharge pollutants. According to the Catalogue of Classified Management of Discharge Permits for Stationary Pollution Sources (2019 Version) (《固定污染源排污許可分類管理名錄(2019年版)》), the manufacturing of biological pharmaceuticals falls in the scope of classified management of discharge permits for stationary pollution sources.

Under the Fire Protection Law of the PRC (《中華人民共和國消防法》) published by the SCNPC in April 1998, last amended on and effective from April 29, 2021, and the Interim Provisions on the Administration of Fire Protection Design Review and Acceptance of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) (the "**Interim Provisions**") published by the Ministry of Housing and Urban-Rural Development on April 1, 2020 and last amended on August 21, 2023, the fire protection design and construction of construction projects shall comply with the national technical standards for fire protection in construction, and implement the fire protection design review and acceptance system for construction projects. If a construction project is put in use without fire safety inspection, or it fails to meet the fire safety requirements, then the project will be ordered to stop construction, stop use or stop operation, and be fined.

Laws and Regulations on Hazardous Chemicals

The Regulations on the Safety Management of Hazardous Chemicals (《危險化學品安全管理條例》) (the "**Hazardous Chemicals Regulations**") published by the State Council on January 26, 2002 and last amended on December 7, 2013, which imposes regulatory requirements on the production safety, storage, use, operation and transportation of hazardous chemicals. An enterprise

that has lawfully obtained the hazardous chemicals safety production permit, hazardous chemicals safety use permit, and hazardous chemicals operation permit may purchase highly toxic chemicals and explosive precursors with such permits. A manufacturer of civilian explosives who holds a civilian explosive production permit may purchase explosive precursors. An entity other than the above enterprises, which intends to purchase highly toxic chemicals, shall apply for highly toxic chemicals purchase permit to the local public security authority at the county level; to purchase explosive precursors, the entity shall hold the explanation as to the legitimate use of the chemicals issued by the entity.

Under the Regulations on Drug Precursors Management (《易製毒化學品管理條例》) published by the State Council on August 26, 2005, effective from November 1, 2005, revised respectively on July 29, 2014, February 6, 2016 and September 18, 2018, China regulates the production, operation, purchase, transportation, import and export of drug precursors. There are 3 kinds of drug precursors. The first kind is major raw materials that can be used for drug production. The second kind and the third kind are chemical agents that can be used for drug production. An enterprise applying for buying the first kind of drug precursors shall submit relevant certificates, subject to approval by local provincial, regional, or municipal drug authority, and obtain the purchase permit. An entity intending to buy the second kind and/or the third kind of drug precursors shall file the types and quantities of required drug precursors to the local public security authority at the county level before purchase.

Under the Measures for the Public Security Management of Explosives Precursors (《易製爆危險化學品治安管理辦法》) published by the Ministry of Public Security on July 6, 2019 and effective from August 10, 2019, an enterprise that has lawfully obtained the hazardous chemicals safety production permit, hazardous chemicals safety use permit, and hazardous chemicals operation permit may purchase explosive precursors with such permits. The purchaser of explosive precursors shall file the types, quantities and flow information of purchased explosive precursors to the local public security authority at the county level, within 5 days after purchase.

Regulations on Occupational Diseases Prevention and Treatment

The Law of the PRC on Prevention and Treatment of Occupational Diseases (《中華人民共和國職業病防治法》) (the "**Occupational Diseases Law**") published by the SCNPC on October 27, 2001 and last amended on December 29, 2018 is a fundamental law on the prevention and treatment of occupational diseases, under which, the cost of occupational diseases prevention facilities in the construction project shall be included in the budget of construction project, and designed, constructed and put in production at the same time with main works. Before acceptance upon completion, the constructing entity shall evaluate the results of occupational diseases control. In addition, the employer shall take required management measures to prevent occupational diseases during work.

Regulations on Employment and Social Security

Under the Labour Law of the PRC (《中華人民共和國勞動法》) published by the SCNPC on July 5, 1994 and last amended on December 29, 2018, and the Labour Contract Law of the PRC (《中華人民共和國勞動合同法》) published by the SCNPC on June 29, 2007, last amended on December 28, 2012 and effective from July 1, 2013, an employer shall sign a labour contract in writing with full time workers. The employer shall perform the local minimum salary standards. The employer shall establish a sound management system, protect workers' rights, *inter alia*, establish occupational health safety system, and provide professional training for workers to prevent occupational hazards. When the employer is recruiting workers, it shall truthfully tell workers the job content, job conditions, job place, occupational hazards, production safety conditions, labour compensation and other conditions.

Under the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) published on October 28, 2010 and revised on December 29, 2018, an employer shall contribute to social insurance funds for its workers, including basic pension insurance, basic medical insurance, unemployment insurance, maternity insurance and work-related injury insurance. If the employer fails to timely contribute to social insurance funds in full, then the social insurance funds collector shall order it to contribute or replenish by deadline, and charge overdue penalty at the rate of 0.05% per day overdue from the date of failure; if the employer fails to contribute by the deadline, then relevant administrative authority shall charge a penalty as 1 to 3 times the amount of underpayment.

Under the Regulations on the Management of Housing Provident Fund (《住房公積金管理條例》) published on April 3, 1999 and last amended on March 24, 2019, an entity shall contribute to workers' housing provident fund. If the entity doesn't contribute to the housing provident fund in full or at all, then the housing provident fund management center shall order the entity to contribute by deadline; if the entity fails to contribute by the deadline, then the management center may apply to the people's court for enforcement.

On July 31, 2025, the Supreme People's Court promulgated the Supreme People's Court's Interpretation (II) on Several Issues Concerning the Application of Law in Labor Dispute Cases (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)》) (the "Judicial Interpretation (II)"), which took effect on September 1, 2025. Article 19(1) of the Juridical Interpretation (II) stipulates that if an employer and an employee agree or the employee undertakes that social insurance contributions need not 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, the relevant employee has the right to terminate the labor contract and claim economic compensation from the employer pursuant to Article 38(3) of the Labor Contract Law. During the Track Record Period and as of the Latest Practicable Date, we did not sign any written documents with any of our employees pursuant to which the employee undertakes that their social insurance premiums need not be paid, and we have made social insurance contributions for all of our employees as required under applicable laws and regulations. As advised by our PRC Legal Advisor, the risk that we will be subject to the payment of material compensation for not making social insurance contributions under the Judicial Interpretation (II) is remote, according to the currently applicable regulatory policies.

Regulations on Information Security and Data Privacy

Data Security and Export

The Data Security Law of the PRC (《中華人民共和國數據安全法》) published by the SCNPC on June 10, 2021 and effective from September 1, 2021 has set up the data classification-based and hierarchical protection system to protect data with categorization and classification. A data operating organization shall, in accordance with laws and regulations, establish a sound full-process data security management system, take data security education and training, take corresponding technical measures and other necessary measures, to protect data security.

Under the Measures for the Security Assessment of Data Export (《數據出境安全評估辦法》) issued by the Cyberspace Administration of China on July 7, 2022 and effective from September 1, 2022, a data processor who provides data to overseas shall apply for data export security assessment through the local cybersecurity authority at the provincial level to national cybersecurity authority, in any of the following circumstances: (i) data processor provides important data to overseas; (ii) key information infrastructure operator or data processor handling over 1 million persons' information provides important data to overseas, or key information infrastructure operator or personal information processor handling over 1 million persons' information provides personal information to overseas; or personal information processor provides personal information to overseas, who cumulatively provides over 100,000 persons' information or over 10,000 persons' sensitive information to overseas since the 1 January of previous year.

Personal Privacy Protection

Under the Civil Code, a natural person's personal information is protected by laws. Any organization or individual person wanting other individual's personal information shall obtain it lawfully and ensure information security, shall not illegally collect, use, process or transmit other's personal information, and shall not illegally trade, offer or publicize other's personal information. The Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) published by the SCNPC on August 20, 2021 and effective from November 1, 2021 further stresses on the processor's obligation and responsibility for protecting personal information, and requires higher level of protection in the processing of sensitive personal information.

Under the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》) published by the SCNPC on November 7, 2016 and effective from June 1, 2017, a cyber operator who collects, uses personal information shall abide by the principles of legality, fairness and necessity, publish the rules of collecting and using information, specify the purpose, manner and scope of using information, and obtain the consent of subjects.

Laws and Regulations on Anti-Money Laundering, Anti-corruption and Anti-bribery

Laws and Regulations on Anti-Money Laundering

Under the Anti-Money Laundering Law of the PRC (《中華人民共和國反洗錢法》) published by the SCNPC on November 8, 2024 and effective from January 1, 2025, a financial institution shall lawfully establish and improve the internal control system for combating money laundering, set up a special body or designate an internal body to lead the anti-money laundering efforts; an entity or person having business relationship with a financial institution shall cooperatively take the customer due diligence (CDD) investigation with the financial institution, provide true and valid identity certificate or other ID documents, fill out accurate and complete ID information, and truthfully offer the information on transaction and fund.

Laws and Regulations on Anti-corruption

Under the Criminal Law of the PRC (《中華人民共和國刑法》), as last amended by the SCNPC on December 29, 2023, the crime of duty embezzlement is the misappropriation of a firm's property by an employee of such firm by taking advantage of his/her position, if the amount of embezzlement is large, then the embezzler shall be subject to a fixed sentence of up to 3 years or a detention, with penalty; if the amount is significant, the embezzler shall be subject to a fixed sentence of 3-10 years, with penalty; if the amount is huge, the embezzler shall be subject to a fixed sentence of over 10 years or even a life sentence, with penalty.

Laws and Regulations on Anti-bribery

Under the Law against Unfair Competition of the PRC (《中華人民共和國反不正當競爭法》) published by the SCNPC (as amended on and effective from October 15, 2025 and the Interim Provisions on Prohibition of Commercial Bribery (《關於禁止商業賄賂行為的暫行規定》) published by the State Administration for Industry and Commerce on November 15, 1996, any operator shall not pay or undertake to pay economic benefits (i.e. cash, other property or by other means) to the counterparty or a third party that may influence the transaction, inducing it to seek trading chance or competitive edge for the operator. An operator who breaks the foregoing anti-bribery provisions shall be subject to administrative punishment or criminal liability depending on the severity.

Under the Provisions on the Establishment of Commercial Bribery Blacklist in the Pharmaceutical Purchase and Sales Industries (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》) published by the National Health and Family Planning Commission (now the National Health Commission), and effective from March 1, 2014, a pharmaceutical manufacturer/operator and its agent involved in criminal, investigative, or administrative proceedings related to commercial

bribery will be included by relevant governmental authority in the blacklist of commercial bribery, with the consequences: within 2 years from the publication of the commercial bribery blacklist, (i) public medical institutions or medical and health institutions receiving financial subsidies within relevant provincial jurisdiction shall not purchase its products, and (ii) other public medical institutions or medical and health institutions receiving financial subsidies within relevant provincial jurisdiction shall underrate its product during the centralized tendering process. If such firm or its agent is blacklisted twice within 5 years, then all public medical institutions or medical and health institutions receiving financial subsidies across China shall not purchase its product within 2 years from the blacklisting.

Regulations on Taxation

Corporate Income Tax ("VAT")

Under the Corporate Income Tax Law (《企業所得税法》) published by the SCNPC and last amended on December 29, 2018 and the Regulations on the Implementation of Corporate Income Tax Law (《企業所得税法實施條例》) published by the State Council and last amended in January 2025, either foreign-invested enterprises or domestic enterprises shall be subject to corporate income tax at the rate of 25% uniformly, except for special industries or projects subject to tax preferences. Qualified small low-profit enterprises shall be subject to corporate income tax at a lower rate of 20%. Government-supported key high-new technology enterprises may be subject to corporate income tax at a lower rate of 15%.

Value-added Tax

Under the Interim Regulations on Value-Added Tax of the PRC (《中華人民共和國增值税暫行條例》) published by the State Council and last amended on November 19, 2017 and the Implementing Rules of the Interim Regulations on Value-Added Tax of the PRC (《中華人民共和國增值税暫行條例實施細則》) published by the MOF, last amended on October 28, 2011 and effective from November 1, 2011, every entity or person selling goods, providing the services of processing, repair and maintenance or importing goods in the territory of China is VAT payer.

Under the Notice from the MOF and the SAT on Adjusting the Value-Added Tax Rate (《財政部 税務總局關於調整增值税税率的通知》) effective from May 2018, the VAT rate for selling and importing goods is adjusted from 17% and 11% to 16% and 10% respectively.

Under the Announcement by the MOF, the SAT and the General Administration of Customs (GACC) on Policies Related to Deepening Value-Added Tax Reform (《財政部 税務總局 海關總署關於深化增值税改革有關政策的公告》) published jointly by the MOF, the SAT and the GACC on March 20, 2019 and effective from April 1, 2019, the VAT rate of selling and importing goods is adjusted from 16% and 10% to 13% and 9% respectively.

Regulations on Foreign Exchange

Forex Regulations

The State Council published the Regulations on Foreign Exchange Control of the PRC (《中華人民共和國外匯管理條例》) on January 29, 1996, effective from April 1, 1996, revised on January 14, 1997 and August 5, 2008 respectively. Foreign exchange payments under current account shall, pursuant to the administrative provisions of the foreign exchange control department of the State Council on payments of foreign currencies and purchase of foreign currencies, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in settlement and sale of foreign currencies by presenting the valid document. Domestic entities and domestic individuals making overseas direct investments or engaging in issuance and trading of overseas securities and derivatives shall process registration formalities pursuant to the provisions of the foreign exchange control department of the State Council.

Under the Notice on the Relevant Issues of Foreign Exchange Administration for Overseas Listings (《關於境外上市外匯管理有關問題的通知》) published by the SAFE on December 26, 2014, a Chinese company listed overseas should register such overseas listing with local forex authority of the place where it's registered, within 15 working days from the completion of overseas listing. The funds raised from overseas listing of a Chinese company might be repatriated to China or deposited overseas, while the application of funds should be consistent with the document and other public disclosures.

Regulations on Domestic Enterprises' Overseas Issuance and Listing of Securities

CSRC Requirements for the Filing of Overseas Issuance and Listing

Under the Trial Measures for the Administration of Overseas Issuance and Listing of Securities by Domestic Enterprises (《境內企業境外發行證券和上市管理試行辦法》) (the "**Trial Measures for Overseas Listing**") published by the CSRC on February 17, 2023 and effective from March 31, 2023, in case of overseas issuance and listing of a domestic enterprise, the issuer shall file with the CSRC according to the Trial Measures for Overseas Listing. In case of overseas initial public offering or listing, the issuer shall file with the CSRC within three (3) working days after overseas submission of IPO application.

Overseas Listing Confidentiality and Archiving

Under the Provisions on Strengthening Confidentiality and Archives Administration for Overseas Securities Offering and Listing (《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》) published jointly by the CSRC and other departments on February 24, 2023 and effective from March 31, 2023, during the overseas listing of a domestic enterprise, the domestic enterprise and the securities company or securities service provider shall strictly comply with the PRC laws and regulations and these provisions, enhance their legal sense of national confidentiality and strengthening archives administration, establish and improve the confidentiality and archiving system, take necessary measures to perform confidentiality and archiving responsibilities, shall not disclose national secrets or national authority secrets, and shall not harm national and public interests. 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.

Full Circulation of H Shares

"Full Circulation" means domestic unlisted shares of a H-share listed company are listed and circulated on the Hong Kong Stock Exchange. The CSRC published the Guidelines on Applying for Full Circulation of Unlisted Domestic Shares of H-share Listed Companies (《H股公司境內未上市股份申請"全流通"業務指引》) (the "**Full Circulation Guidelines**") on November 14, 2019, which was partially revised on August 10, 2023 under the Decision of the CSRC on the Amendment and Repeal of Certain Securities and Futures Regulatory Documents (《中國證券監督管理委員會關於修改、廢止部分證券期貨制度文件的決定》). For a domestic enterprise seeking direct overseas listing, shareholders holding such enterprise's domestic unlisted shares who apply for the conversion of its domestic unlisted shares into overseas listed shares shall comply with the relevant provisions of the CSRC and entrust such domestic enterprise to file with the CSRC.

Upon filing of full circulation with the CSRC, the H-share listed company shall report to the CSRC within 15 days after transfer registration of involved shares with China Securities Depository and Clearing Corporation Limited ("**CSDCC**").

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") and its implementing regulations, and biologics under both the FDCA and the Public Health Service Act (the "PHSA") as well as their respective implementing regulations. Both drugs and biologics are also subject to other federal, state and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals and subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with applicable U.S. requirements at any time, whether during the product development process, the approval process, or after 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 the 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. The 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 that involve the administration of an investigational product to humans must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practice regulations. This includes the requirement that all research subjects provide informed consent in writing before participating in any clinical trial. Furthermore, an Institutional Review Board (the "IRB") must review and approve any clinical trial protocol before the trial commences at any institution, and the IRB must conduct continuing review and grant re-approval at least annually. Each new clinical protocol and any amendments thereto must be submitted to the FDA for review, and to the IRB for approval. An IRB may suspend or terminate its 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 is associated with unexpected serious harm to subjects.

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

- Phase I clinical trials generally involve a limited number of healthy volunteers or disease-affected patients who are initially administered a single dose followed by 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 dosage 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 necessary data to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish its 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 to the FDA at least annually. Safety reports must be submitted to the FDA and the investigators within 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify the 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 for 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 the process for manufacturing the product at a commercial scale in accordance with current Good Manufacturing Practice ("cGMP") requirements. The process of obtaining regulatory approvals and ensuring compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with 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, a BLA, or supplement 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 in which the product is safe and effective. The submission of a BLA is subject to 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 the 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 a 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 specific deficiencies identified in the BLA, which must be satisfactorily addressed before approval. The deficiencies identified may be minor (e.g., requiring labeling changes) or major (e.g., requiring additional clinical trials). Additionally, the complete response letter may include recommended actions that the applicant could take to place the application in a condition for approval. The applicant may either resubmit the BLA, addressing all 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 the product's safety and effectiveness following 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 designed 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 with no available therapy and that it demonstrates the potential to address an unmet medical need. Under the fast-track program, the sponsor of a drug candidate may request FDA to designate the product as a fast-track product for a specific indication concurrently with or after the submission 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 grant 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**"), so that it 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 at the time of their first use or first publication. Furthermore, 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 ensure 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 ensure 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 problems occurring 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. Any violation found, including failure to conform to cGMP regulations, could result in enforcement actions, and any problem identified with a product after approval may result in restrictions on the product, manufacturer or holder of the approved BLA, including recall.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval of a drug or biologic if compliance with regulatory requirements and standards is not maintained or if problems occur after the product is marketed. 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; implementation of post-market studies or clinical trials to assess new safety risks; or implementation 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 Reconciliation Act (collectively, the "ACA"), became law in the United States in March 2010, and has 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, the United States Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While the United States 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 United States 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 eliminated, effective from January 1, 2021, the health insurer tax. There may be other efforts to challenge, repeal or replace the ACA.

Patent Term Restoration and Market 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 14 years from the date of FDA approval of the product. Only one patent for 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.