
REGULATORY OVERVIEW

OVERVIEW OF PRC LAWS AND REGULATIONS

Regulations Relating to Company Law

The establishment, operation and management of companies in China is governed by the PRC Company Law (《中華人民共和國公司法》) (the “**PRC Company Law**”), which was passed by the Standing Committee of the National People’s Congress (the “**SCNPC**”) on December 29, 1993 and came into effect on July 1, 1994, and was revised or amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013, October 26 2018 and December 29 2023, respectively. The PRC Company Law applies to both the PRC domestic companies and foreign-invested companies, unless otherwise provided in the relevant foreign investment laws and regulations.

Regulations Relating to Foreign Investment

On March 15, 2019, the National People’s Congress (the “**NPC**”), promulgated the PRC Foreign Investment Law (《中華人民共和國外商投資法》) (the “**FIL**”), which has come into effect on January 1, 2020. The FIL, by means of legislation, establishes the basic framework for the access, promotion, protection and administration of foreign investment in view of investment protection and fair competition.

According to the FIL, foreign investment shall enjoy pre-entry national treatment, except for those foreign invested entities that operate in industries deemed to be either “restricted” or “prohibited” in the “negative list.” The FIL provides that foreign invested entities operating in foreign “restricted” or “prohibited” industries will require entry clearance or other approvals. The FIL does not comment on the concept of “de facto control” or contractual arrangements with consolidated affiliated entities, however, it has a catch-all provision under definition of “foreign investment” to include investments made by foreign investors in China through means stipulated by laws or administrative regulations or other methods prescribed by the State Council of the PRC (the “**State Council**”). Therefore, it still leaves leeway for future laws, administrative regulations or provisions to provide for contractual arrangements as a form of foreign investment. In addition, a foreign investment information reporting system shall be established and foreign investors or foreign-funded enterprises shall submit the investment information to competent departments such as the enterprise registration system and the enterprise credit information publicity system.

On December 30, 2019, the Ministry of Commerce of the PRC (“**MOFCOM**”) and the State Administration for Market Regulation of the PRC (“**SAMR**”) issued the Measures on Reporting of Foreign Investment Information (《外商投資信息報告辦法》) which came into effect on January 1, 2020. According to the Regulation, foreign investors submitting an initial report shall include basic information of the enterprise, the investors and their actual controlling party, investment transaction information etc.

The Special Administrative Measures for Access of Foreign Investment (Negative List) (2024 Edition) (《外商投資准入特別管理措施(負面清單) (2024年版)》), or the 2024 Negative List, which was promulgated jointly by the MOFCOM and the NDRC on September 6, 2024, became effective on November 1, 2024, and replaced the Special Administrative Measures for Access of Foreign Investment (Negative List) (2021 Edition), has listed the special administrative measures for foreign investment in certain industries in the PRC, including requirements on ownership percentage, senior management and etc.

Under the 2024 Negative List, foreign investors are prohibited from investing in the development and application of human stem cell technologies and gene diagnosis and therapy technologies. As a pilot exception to this restriction, the Ministry of Commerce, the National Health Commission and the National Medical Products Administration jointly issued the *Notice on Launching Pilot Programs to Further Open Up the Medical Sector* (《關於在醫療領域開展擴大開放試點工作的通知》) on September 7, 2024, permitting foreign-invested enterprises, from the same date, to engage in the development and application of such technologies within the China (Beijing) Pilot Free Trade Zone, the China (Shanghai) Pilot Free Trade Zone, the China (Guangdong) Pilot Free Trade Zone and the Hainan Free Trade Port for purposes of product registration, marketing authorization and manufacturing. Once the relevant

REGULATORY OVERVIEW

products have obtained marketing authorization and approval for manufacturing, they may be used nationwide. Foreign-invested enterprises participating in the pilot programs remain subject to applicable PRC laws and regulations and must comply with regulatory requirements relating to the administration of human genetic resources, clinical trials of drugs (including international multi-center clinical trials), drug registration and marketing authorization, drug manufacturing and ethical review, and complete the corresponding regulatory procedures in accordance with law.

Regulations on the Scope and Classification of Gene Therapy Medicinal Products

On July 3, 2026, the CDE issued the *Technical Guidelines for the Scope and Classification of Gene Therapy Medicinal Products (2026 Edition)* (《基因治療藥品範圍和歸類技術指導原則(2026年版)》), which came into effect on the date of issuance. The guidelines clarify the scope and classification principles applicable to gene therapy medicinal products.

Pursuant to the guidelines, the classification of gene therapy medicinal products should be determined by taking into account, among other factors, the material basis and active ingredients, manufacturing process and mechanism of action of the relevant product, with the material basis and active ingredients serving as the primary basis for classification. Based on the type of carrier and active ingredients used, gene therapy medicinal products are generally classified into two main categories, namely non-microbial vector-based gene therapy medicinal products and microbial vector-based gene therapy medicinal products. Non-microbial vector-based gene therapy medicinal products are further divided into nucleic acid-based gene therapy medicinal products and nucleic acid-protein complex-based gene therapy medicinal products, while microbial vector-based gene therapy medicinal products are further divided into viral vector-based gene therapy medicinal products and non-viral microbial vector-based gene therapy medicinal products.

For oncolytic virus or oncolytic bacteria medicinal products carrying exogenous target genes, where the viral or live bacterial component acts both as an active ingredient to exert oncolytic effects and as a delivery vector to introduce and express exogenous gene sequences, thereby synergistically stimulating or enhancing the body’s anti-tumor immune response, such products are classified as microbial vector-based gene therapy medicinal products.

Regulations Relating to New Drugs

Prime Regulatory Authorities

In the PRC, pharmaceutical products are monitored and supervised on a national scale by the National Medical Products Administration (the “NMPA”). The local provincial medical products administrative authorities are responsible for supervision and administration of drugs within their respective administrative regions. The NMPA is the regulatory authority responsible for the registration and supervision of drugs under the supervision of the State Administration for Market Regulation (the “SAMR”), including the stages of non-clinical research, clinical trials, marketing approval, production and distribution. The NMPA’s predecessor, the State Drug Administration (the “SDA”), was replaced by the State Food and Drug Administration (the “SFDA”), which was later reorganized into the China Food and Drug Administration (the “CFDA”), as part of the institutional reforms implemented by the State Council. The Center for Drug Evaluation (the “CDE”), which is subordinate to the NMPA, conducts the technical evaluation of each drug and biologic application to assess safety and efficacy.

Development of New Drugs Administration

The PRC Drug Administration Law (《中華人民共和國藥品管理法》) (the “**Drug Administration Law**”) promulgated by the SCNPC in 1984, as amended in February 28, 2001, December 28, 2013, April 24, 2015 and August 26, 2019, and the Implementing Regulations of the PRC Drug Administration Law (the “**Implementing Regulations of the Drug Administration Law**”) (《中華人民共和國藥品管理法實施條例》) promulgated by the State Council effective on September 15, 2002 and amended on February 6, 2016, March 2, 2019, and December 6, 2024, laid down the legal framework for the administration of drugs, including the research, development and manufacturing. The Drug Administration Law applies to entities and individuals engaged in the development, production, trade,

REGULATORY OVERVIEW

application, supervision and administration of drugs. It regulates and prescribes a framework for the administration of drug manufacturers, drug trading companies, and medicinal preparations of medical institutions and the development, research, manufacturing, distribution, packaging, pricing and advertisements of biological products. The Implementing Regulations of the Drug Administration Law serve to provide detailed implementation regulations for the revised Drug Administration Law.

Four Phases of Clinical Trials

On January 15, 2020, SAMR promulgated the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), which came into effect on July 1, 2020. According to the Measures, a clinical development program consists of Phases I, II, III and IV. Phase I refers to the initial clinical pharmacology and safety evaluation studies in humans. Phase II refers to the preliminary evaluation of a drug candidate’s therapeutic effectiveness and safety for particular indications in patients, to provide evidence and support for the design of Phase III clinical trials and to settle the administrative dose regimen. Phase III refers to clinical trials undertaken to confirm the therapeutic effectiveness of a drug. Phase III is used to further verify the drug’s therapeutic effectiveness and safety on patients with target indications, to evaluate the overall benefit-risk relationships of the drug, and ultimately to provide sufficient evidence for the review of drug registration application. Phase IV refers to a new drug’s post-marketing study to assess therapeutic effectiveness and adverse reactions when the drug is widely used, to evaluate the overall benefit-risk relationships of the drug when used among the general population or specific groups and to adjust the administration dose. In accordance with the revised Administrative Measures for Drug Registration, drug clinical trial shall comprise Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial as well as bioequivalence test.

Pursuant to the Circular Concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》) (the “**Several Policies Circular**”), the CDE grants a one-time approval for clinical trial applications for new drugs and does not require separate declarations, reviews or approvals for the subsequent phases of clinical trials. The CDE review focuses on the scientific nature of clinical trial protocols and the control of safety risks to ensure patient safety. Applicants must promptly communicate with the CDE, to resolve problems during clinical trials and make a supplementary report on the latest research materials as the relevant reviewer requires. Upon the completion of Phase I and Phase II clinical trials, the applicant must submit trial results and the clinical trial protocol for the next phase in a timely manner. Where there is no safety problem, applicants can proceed to Phase III clinical trials after discussion with the CDE. The applicants must report serious adverse events that occur during the clinical trials and submit annual research reports. Where clinical trial risks cannot be controlled, the clinical trials must be stopped immediately.

Among the above-mentioned classification of clinical trials, studies in confirmatory clinical trials aim to confirm efficacy and safety, provide a basis for assessing benefit/risk relationships in support of registration, and determine dose-effect relationships. Confirmatory clinical trials are designed to further confirm the preliminary evidence of efficacy and safety of investigational clinical trials in order to provide sufficient evidence to obtain market approval, and the primary objective of the trial is to identify therapeutic benefits.

Approval and Reform for Clinical Trials

According to the Drug Administration Law, the Administrative Measures for Drug Registration and the Implementing Regulations of the Drug Administration Law, the PRC government encourages research and development of new drugs. A new drug refers to “a drug that has not been sold in the Chinese domestic market”. On the basis of the rules set out in the Drug Administration Law and the Administrative Measures for Drug Registration, there are further regulations or legal documents that reformed the evaluation and approval system for drugs, especially the evaluation and approval process for innovative drugs. For example, on August 9, 2015, the State Council promulgated the Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment (《關於改革藥品醫療器械審評審批制度的意見》) (the “**Reform Opinions**”), which established a framework for reforming the evaluation and approval system for drugs. According to the Reform Opinions, the definition of a new drug is revised from “a drug that has not been sold in the Chinese domestic market” to “a drug that has not been sold in both the domestic and overseas markets”. New drugs are divided

REGULATORY OVERVIEW

into innovative drugs and improved drugs. In accordance with the Reform Opinions, the State Council encourages clinical value-oriented drug innovation, optimizing the review and approval procedures for innovative drugs, accelerating the review of innovative drugs with urgent clinical demand.

In November 2015, CFDA promulgated the Circular Concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》), which further clarified the measures and policies regarding simplifying and accelerating the approval process on the basis of the Reform Opinions.

In addition, on May 17, 2018, the NMPA and National Health Commission jointly promulgated the Circular on Issues Concerning Optimizing Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》), which further simplified and accelerated the clinical trial approval process.

The revised Administrative Measures for Drug Registration prescribe some procedures for expedited registration of drug marketing, including procedures for breakthrough therapy designation, procedures for conditional approval, procedures for prioritized review and approval and special examination and approval procedure, which will further simplify and facilitate the procedures of drug marketing.

In accordance with the Administrative Measures for Drug Registration, the CDE shall organize the pharmaceutical, medical and other technical personnel to conduct technical examination of the new drug. Subsequent to technical review, the review opinion and relevant application document shall be submitted to the SFDA (replaced by the CFDA in 2013 and the NMPA in 2018). The SFDA makes decision on whether to give an approval in accordance with the technical review opinion. According to the Decision of the China Food and Drug Administration on Adjusting the Approval Procedures under the Administrative Approval Items for Certain Drugs (《國家食品藥品監督管理總局關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA on March 17, 2017 and as of effect on May 1, 2017, decision on the approval of clinical trials of drugs (including domestic and imported drugs) to be made by the CFDA have been adjusted and are to be made by the CDE in the name of the CFDA.

Clinical Trial Registration

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

According to the revised Drug Administrative Law and the revised Administrative Measures for Drug Registration, where an applicant submits an application for drug clinical trial upon completion of pharmacy, pharmacology and toxicology etc. Which support the drug clinical trial, the relevant research materials shall be submitted in accordance with the requirements on declaration materials. Upon form examination, where the declaration materials are found to comply with the requirements, the application shall be accepted. The CDE shall organize pharmacists, medical personnel and other technicians to review the accepted application for drug clinical trial. A decision on approval or non-approval of the application for drug clinical trial shall be made within 60 days from acceptance of application, and the applicant shall be notified of the examination and approval outcome through the CDE website; where

REGULATORY OVERVIEW

the applicant is not notified within the stipulated period, the application shall be deemed approved, and the applicant may conduct drug clinical trial in accordance with the submitted scheme. And applicants proposing to conduct bioequivalence test shall complete filing formalities for bioequivalence test on the CDE website in accordance with the requirements.

Investigator Initiated Trials

Under the PRC laws, compared to industry-sponsored trials, or the ISTs, investigator-initiated trials, or IITs, generally refer to clinical trials initiated by investigators that are not intended for the purpose of new drug marketing. IITs are mainly regulated under the Administrative Measures for Clinical Trials Conducted by Medical and Health Institutions (《醫療衛生機構開展臨床研究項目管理辦法》), jointly issued by the National Health and Family Planning Commission, the CFDA and the National Administration of Traditional Chinese Medicine on October 16, 2014. The Administrative Measures for Clinical Trials Conducted by Medical and Health Institutions primarily set forth management requirements for medical and health institutions in order to regulate their clinical research activities.

To improve the administration of IITs, the National Health Commission, the National Administration of Traditional Chinese Medicine, and the National Disease Control and Prevention Administration jointly issued the Administrative Measures for Medical and Health Institutions to Conduct Investigator-Initiated Clinical Research (《醫療衛生機構開展研究者發起的臨床研究管理辦法》) on September 18, 2024, which stipulates, among others, requirements applicable to IITs, including detailed provisions on organizational structure and management, project initiation, financial management, and implementation management, and also streamlines overall supervision of IITs. These Administrative Measures provide clearer guidance for the initiation and conduct of IITs and are expected to be conducive to the long-term, sustainable development and the generation of standardized, high-quality clinical research outcomes.

In the U.S., the regulatory framework for IITs primarily involves the FDA through the Federal Food, Drug, and Cosmetic Act (FDCA) and Title 21 of the Code of Federal Regulations (CFR). Drugs, including biologics, are regulated under Title 21 of the CFR Part 312 (Investigational New Drug application, IND) which states that any clinical use of an unapproved drug requires an IND or must qualify for an exemption. The FDA requires the “sponsor-investigator” to first make the determination on whether an IND is needed before the study begins. Even if “sponsor-investigator” believes an exemption applies, the FDA requires a confirmation, often via a direct consultation with the FDA.

Under 21 CFR 312.3(b), the “sponsor-investigator” is required to comply with duties for both sponsors and investigators. Among others, key obligations include:

- *Conduct and Oversight.* The sponsor-investigator must conduct the study according to the protocol and applicable regulations to protect rights, safety and welfare of the study participants.
- *Informed Consent.* Each study participant must give voluntary, informed consent before enrollment. The consent form must disclose that the drug is investigational and describes risks consistent with the application regulations.
- *Institutional Review Board (IRB) Review.* Before starting the study, the sponsor-investigator must obtain IRB approval of the protocol. The IRB will scrutinize the study throughout the study to ensure the risks are minimized and reasonable. The study may not be changed without IRB approval except to eliminate immediate safety hazards.
- *Recordkeeping.* The sponsor-investigator must keep detailed records. For drug trials, it is required to maintain accurate case histories for each participant (including signed consent forms and medical records) and records of drug disposition, with retention until at least 2 years after marketing approval or study termination.

REGULATORY OVERVIEW

- *Investigational Product Management.* The sponsor-investigator must control the test article that a drug may only be administered under the sponsor-investigator’s supervision and cannot be distributed to unauthorized persons.
- *Monitoring.* The sponsor-investigator must ensure proper monitoring of the investigations, typically engaging institutional support.
- *Safety Reporting.* The sponsor-investigator must follow all safety-reporting rules such as reports of serious adverse events (SAEs) and annual IND reports summarizing trial progress and safety within the required timelines.
- *Regulatory Submissions.* The sponsor-investigator must timely file or amend the IND as needed.

Conduct of Clinical Trials

As for clinical trials, they should follow the requirements of the Administration of Good Clinical Practice of Pharmaceutical Products (《藥物臨床試驗質量管理規範》) (the “**GCP Administration**”) promulgated by the SFDA in August 2003 and amended on April 23, 2020 and effect on July 1, 2020. In principle, the research contents of clinical trials should include clinical safety evaluation, pharmacokinetics study, pharmacodynamics study, dose exploration study and confirmatory clinical trials.

The Opinions on Deepening the Reform of the Evaluation and Approval System and Inspiring Innovation of Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (the “**Innovation Opinions**”) issued by the Central Committee of the Communist Party of China and the General Office of the State Council on and effective as from October 8, 2017, the institutions for drug clinical trials should establish an independent ethics committee and the clinical trial schemes are subject to examination, approval and signing with approval opinions by the ethics committee before implementation, in order to protect the rights and interests of human subjects in clinical trials. For a multi-centre clinical trial conducted in the PRC, after ethical review by the leader unit of clinical trial, other member units should recognize the review results of the leader unit and should not conduct repeated review.

The conduct of clinical trials must adhere to the Good Clinical Practice (the “**GCP**”) and the protocols approved by the ethics committees of each study site. The sponsor of clinical trials should provide insurance to the human subjects participating in the clinical trial and bear the cost of the treatment and the corresponding financial compensation for the human subjects who suffer harm or death related to the trial. Since 2015, the NMPA has strengthened the enforcement against widespread data integrity issues associated with clinical trials in China. To ensure authenticity and reliability of the clinical data, the NMPA mandates applicants of the pending drug registration submissions to conduct self-inspection and verification of their clinical trial data. Based on the submitted self-inspection results, the NMPA also regularly launches onsite clinical trial audits over selected applications and reject those found with data forgery.

On November 12, 2004, Regulation on the Bio-safety Management of Pathogenic Microbe Labs (《病原微生物實驗室生物安全管理條例》) was promulgated and was lastly amended on December 6, 2024. Under this regulation, laboratories which conduct high-pathogenicity-microorganism-related experimental activities must formulate laboratory infection emergency plans and put on records to regulatory departments of the provincial government where the laboratory is located.

The Regulation on the Bio-safety Management of Pathogenic Microbe Labs stipulates that pathogenic microorganism laboratories are classified into four levels, namely bio-safety levels 1, 2, 3 and 4 in terms of bio-safety protection levels in accordance with national standards on biosafety of laboratories. Laboratories at bio-safety levels 1 and 2 shall not engage in laboratory activities related to highly pathogenic microorganisms. The construction, alternation or expansion of a laboratory at bio-safety level 1 or 2 shall be filed for record with the local counterparts of National Health Commission.

REGULATORY OVERVIEW

New Drug Application

According to the revised Drug Administration Law, for the drugs for diseases which are seriously life-threatening and have no effective means of treatment and the drugs which are urgently needed in public health, if there is available data in clinical trials showing the efficacy and predicting the clinical value, marketing approval may be given with some conditions, and relevant matters shall be stated in the drug registration certificate.

According to the Administrative Measures for Drug Registration, 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. Drug marketing registration applications shall be subject to three categories, namely traditional Chinese drugs, chemical drugs and biological products. Among them, the registration applications of biological products shall be categorized by innovative biological products, new modified biological products, already marketed biological products (including biological similar drugs), etc. If all the regulatory requirements are satisfied, a Drug Registration Certificate with a validity period of five years will be issued by the NMPA.

Special Examination and Fast Track Approval for Antineoplastic Drugs under Current Reform Frame

According to the Provisions on the Administration of Special Examination and Approval of Registration of New Drugs (《新藥註冊特殊審批管理規定》) promulgated by the SFDA on January 7, 2009, special examination and approval for new drugs registration applications applies when (i) the effective constituent of a drug extracted from plants, animals, and minerals, as well as the preparations thereof, have never been marketed in China, and the material medicines and the preparations thereof are newly discovered; (ii) the chemical raw materials for medicines as well as the preparations thereof and the biological product have not been approved for marketing, either in China or abroad; (iii) new drugs with distinctive clinical treatment advantages for diseases such as AIDS, malignant tumor or other rare diseases; or (iv) new drugs for diseases that currently lacking effective treatment. Under the circumstances set out in (i) and (ii), drug registration applicants may make special approval applications in submitting applications for clinical trials of new drugs; under the circumstances set out in (iii) and (iv), drug registration applicants may make special approval applications only in applying for production.

According to the Opinions on Reform of the Review & Approval System of Drugs and Medical Devices (《關於改革藥品醫療器械審評審批制度的意見》), a special review & approval system shall be adopted for innovative drugs to accelerate the review & approval of innovative drugs for prevention and treatment of AIDS, cancer, major infectious diseases, rare diseases and other diseases.

The Reform Opinions promulgated in 2015 further clarified that a fast track clinical trial approval or drug registration pathway will be available to both innovative drugs with distinctive clinical benefits which have not been sold within or outside China as well as drugs using advanced technology, innovative treatment methods or having distinctive treatment advantages.

Pilot Plan for the Marketing Authorization Holder System

On August 15, 2017, the CFDA issued the Circular on the Matters Relating to Promotion of the Pilot Program for the Drug Marketing Authorization Holder System (《關於推進藥品上市許可持有人制度試點工作有關事項的通知》) (the “**MAH Circular**”), which clarified the legal liability of the marketing authorization holder, who is responsible for managing the whole manufacturing and marketing chain and the whole life cycle of drugs and assumes the full legal liability for non-clinical drug study, clinical trials, manufacturing, marketing and distribution and adverse drug reaction monitoring. The marketing authorization holder is permitted to entrust several drug manufacturers under the drug quality management system established by the marketing authorization holder. Pursuant to the MAH Circular, the holder shall submit a report of drug manufacturing, marketing, prescription, techniques, pharmacovigilance, quality control measures and other situations to the CFDA within 20 working days after the end of each year.

REGULATORY OVERVIEW

According to the revised Drug Administration Law and the revised Administrative Measures for Drug Registration, whoever obtains a drug registration certificate is a drug marketing authorization holder. The legal representative and principal person in charge of the drug marketing authorization holders shall be fully responsible for the drug quality. A drug marketing authorization holder may produce or sell the drug by itself or entrust a qualified third party to produce or sell the drug. Drug marketing authorization holders, drug manufacturers, drug distributors and medical institutions shall establish and implement a drug quality trace system to ensure drug traceability. And upon approval by the drug regulatory department under the state council, the drug registration certificate may be transferred. The transferee of the drug registration certificate shall have the ability of quality management, risk prevention and control and liability compensation to ensure the safety and effectiveness of the drug and shall fully fulfil the obligations of drug marketing authorization holders.

The PRC Drug Administration Law was revised by the SCNPC on August 26, 2019 and came into effect on December 1, 2019, provides that (i) the MAH system will be applicable throughout the country; (ii) the legal representative and the key person-in-charge of a drug marketing authorization holder shall be fully responsible for the quality of drugs.

Monitoring Periods for New Drugs

According to the Implementing Regulations of the Drug Administration Law (《中華人民共和國藥品管理法實施條例》), the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of not more than five years for new drugs approved to be manufactured, commencing from the date of approval, to continually monitor the safety of such new drugs. During the monitoring period of a new drug, no approval shall be granted to any other manufacturer to produce or import the said drug.

Drug Manufacturing

On December 28, 1992, the MOH published the Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) (the “**GMP Regulations**”) to regulate the manufacturing practice of drugs. The GMP Regulations came into effect immediately and was amended on June 18, 1999 and January 17, 2011 respectively. According to the latest GMP Regulations which was promulgated by the MOH on January 17, 2011 and came into effect on March 1, 2011, the manufacturer should establish a quality management system. The system should cover all factors that influence the quality of drugs, including all organized and planned activities with the objective of ensuring that the drugs are of the quality required for their intended use. The basic requirements of production and quality control of drug manufacturing shall include but not limited to: (i) all manufacturing processes are clearly defined, systematically reviewed and shown to be capable of consistently manufacturing drugs of the required quality and complying with their specifications; (ii) steps of manufacturing processes and significant changes to the process are validated; (iii) all necessary resources are provided, including appropriately qualified and trained personnel, adequate premises and space, suitable equipment and services, correct starting materials, packaging materials and labels, approved master manufacturing documents and operation procedures and suitable storage and transport; (iv) operators are trained to carry out procedures correctly; and (v) records should be made during the entire manufacture and any deviations are investigated and recorded accordingly.

Pursuant to the Administrative Measures for Drug Registration, drugs used for clinical trials shall be manufactured in facilities in compliance with the GMP Regulations. The manufacturing process shall strictly meet the requirements of the GMP Regulations. According to the revised Administrative Measures for Drug Registration, upon approval of marketing of drugs, a drug marketing authorization holder shall manufacture the drug in accordance with the manufacturing process and quality standards approved by the NMPA, and carry out refinement and implementation in accordance with the GMP rules.

On January 22, 2020, the SAMR promulgated the newly revised Administrative Measures on Supervision of Drug Manufacturing (《藥品生產監督管理辦法》) (the “**Revised Administrative Measures of Drug Manufacturing**”), which has taken effect on July 1, 2020. The Revised Administrative Measures of Drug Manufacturing further implement the drug marketing authorization

REGULATORY OVERVIEW

holder system as stipulated in the Revised Drug Administrative Law. The Revised Administrative Measures of Drug Manufacturing no longer require GMP Certification for drug manufacturing enterprises, but the competent drug administrative authorities shall, based on regulatory needs, conduct compliance inspection of drug manufacturing quality control examination before drug marketing.

Contract Manufacturing of Drugs

Pursuant to the Administrative Regulations for the Contract 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 domestic drug manufacturer. Such contract manufacturing arrangements shall be approved by the provincial branch of the NMPA.

Pursuant to the Revised Administrative Measures of Drug Manufacturing, drug marketing authorization holders entrusting others to manufacture drugs shall enter into outsourcing 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.

Hazardous Chemicals

According to Measures on Administration of Pharmaceutical Precursor Chemicals (《藥品類易制毒化學品管理辦法》), which was issued on March 18, 2010 and effective from May 1, 2010, the State conducts a purchasing-approval system towards the purchase of pharmaceutical precursor chemicals. Anyone who purchases pharmaceutical precursor chemicals must apply for the Certificate for Purchasing Pharmaceutical Precursor Chemicals which is made by National Medical Products Administration. The certificate is effective for 3 months.

Sampling and Collecting Human Genetic Resources Filing

On June 10, 1998, the Ministry of Science and Technology and the MOH promulgated the Interim Administrative Measures on Human Genetic Resources (《人類遺傳資源管理暫行辦法》), which established the rules for protecting and utilizing human genetic resources in the PRC.

On July 2, 2015, the Ministry of Science and Technology issued 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》), which became effective on July 2, 2015 according to the Circular on Implementing the Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources (《關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》), which clarified that the sampling and collection of human genetic resources through clinical trials shall be required to be filed with the China Human Genetic Resources Management Office through the online system.

On October 26, 2017, the Ministry of Science and Technology promulgated the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》) simplifying the approval of sampling and collecting human genetic resources for the purpose of listing a drug in the PRC.

On May 28, 2019, the State Council promulgated the Administrative Regulations on 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 came into effect on July 1, 2019, and latest amended on March 10, 2024 and came into effect on May 1, 2024. According to the provisions therein, the State shall support the rational utilization of human genetic resources to carry out scientific research, develop the biomedical industry, improve diagnosis and treatment technologies, improve the biosafety guarantee capabilities of China and improve the people's health protection level. And foreign organizations, individuals and the institutions established or actually controlled thereby shall not collect or preserve China's human genetic resources

REGULATORY OVERVIEW

within the territory of China. Nor shall they provide China’s human genetic resources out of the country. Whoever utilizes China’s human genetic resources for international cooperation in scientific research shall meet the conditions stipulated in this regulation, which include conducting such cooperation through collaboration with Chinese research institutions, higher education institutions, medical institutions, or enterprises (i.e., the Chinese entities), and both parties shall jointly submit an application to the Administrative Department of Health under the State Council for approval. Examination and approval shall not be required for international cooperation in clinical tests based on China’s human genetic resources conducted in clinical institutions in order to obtain marketing authorization in China with respect to relevant drugs and medical instruments, provided that such cooperation does not involve the provision of human genetic resource materials abroad. However, both parties shall, prior to clinical tests, submit the categories, quantities, and purposes of the human genetic resources to be utilized to the Administrative Department of Health under the State Council for filing. In the course of conducting international scientific research cooperation involving the utilization of China’s human genetic resources, if there is any change to the parties, research objectives, research content, cooperation period, or other material matters, the relevant change approval procedures must be completed. The Administrative Department of Health under the State Council and the Administrative Department of Human Genetic Resources under the people’s governments of the provinces, autonomous regions, and municipalities directly under the Central Government shall strengthen the supervision of such filings. Both parties may utilize the information of human genetic resources generated from international cooperation in scientific research on the basis of China’s human genetic resources. Furthermore, collection, preservation, utilization and external provision of China’s human genetic resources shall comply with the ethical principles of human genetic resources providers and be subject to ethical review in accordance with relevant regulations of the State.

On May 26, 2023, the Ministry of Science and Technology issued the Implementation Rules for the Administrative Regulation on Human Genetic Resources (《人類遺傳資源管理條例實施細則》), which came into effect on July 1, 2023, optimizing the scope of administrative licensing and record-keeping, enhancing the operability of the human genetic resources administration system, and implementing the registration and reporting system for the management of human genetic resources.

In compliance with the applicable laws and regulations stated above, the Group has conducted international scientific research collaborations involving the utilization of China’s human genetic resources through cooperation with relevant Chinese entities and has obtained the necessary approvals pursuant to applicable laws and regulations.

Regulations Relating to Production Safety

According to the Safety Production Law of the PRC (《中華人民共和國安全生產法》) (the “**Safety Production Law**”), which was promulgated on June 29, 2002 and amended on August 27, 2009, August 31, 2014 and June 10, 2021, respectively, and to be effective on September 1, 2021, production and business operation entities shall provide their employees with education and training on work safety to ensure that the employees acquire the necessary knowledge about work safety, are familiar with the relevant rules for work safety and safe operating procedures, master the safety operating skills for the posts, understand the emergency handling measures for accidents and are aware of their rights and obligations in respect of work safety. No employee who fails to pass the examination after receiving education and training on work safety may be assigned to posts. The safety facilities of a production or business operation entity for engineering projects to be built, renovated or expanded (hereinafter collectively referred to as construction projects) shall be designed, constructed, and put into operation and used simultaneously with the principal part of the projects. Investments into safety facilities shall be included in the budgetary estimates for the construction projects. Our laboratories and production facilities are subject to and must comply with the Safety Production Law.

Regulations Relating to Prevention of Occupational Diseases

On October 27, 2001, the SCNPC promulgated the Law of the People’s Republic of China on the Prevention and Control of Occupational Diseases (《中華人民共和國職業病防治法》), which became effective on May 1, 2002 and was amended on December 31, 2011, July 2, 2016, November 4, 2017 and December 29, 2018, respectively. In accordance with the Law on the Prevention and Control of

REGULATORY OVERVIEW

Occupational Diseases, the expenditure entailed by the facilities included in a construction projects, for the prevention and control of occupational diseases shall be included in the budget of the project, and such facilities shall be designed, constructed, and put into production and use at the same time with the main body of the construction project. And before accepting a construction project upon its completion in the acceptance inspection, the construction unit shall have the effect of occupational disease hazard control assessed in relation to the project. In addition, the employer shall take certain measures as prescribed therein for prevention and treatment of occupational diseases in the course of work.

Regulations Relating to Environment Protection

According to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) promulgated by the SCNPC on December 26, 1989 and amended on April 24, 2014, the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》) promulgated by the SCNPC on October 28, 2002 and amended on July 2, 2016 and December 29, 2018, the Administrative Regulations on the Environmental Protection of Construction Project (《建設項目環境保護管理條例》) promulgated by the State Council on November 29, 1998 and amended on July 16, 2017, and other relevant environmental laws and regulations, enterprises which plan to construct projects shall engage qualified professionals to provide the assessment reports, assessment form, or registration form on the environmental impact of such projects. The assessment reports, assessment form, or registration form shall be filed with or approved by the relevant environmental protection bureau prior to the commencement of any construction work.

Enterprises generating environmental pollution in the PRC must comply with the Law of the PRC on the Prevention and Control of Water Pollution (《中華人民共和國水污染防治法》), effective from November 1, 1984 and most recently amended on June 27, 2017, the Law of the PRC on the Prevention and Control of Atmospheric Pollution (《中華人民共和國大氣污染防治法》), effective from June 1, 1988 and most recently amended on October 26, 2018, the Law of the PRC on the Prevention and Control of Noise Pollution (《中華人民共和國噪聲污染防治法》) effective from June 5, 2022, and the Law of the PRC on the Prevention and Control of Environmental Pollution of Solid Waste (《中華人民共和國固體廢物污染環境防治法》), effective from April 1, 1996 and most recently amended on April 29, 2020. These laws regulate extensive issues in relation to environmental protections including waste water discharge, air pollution control, noise emission and solid waste pollution control. Pursuant to these laws, all the enterprises that may cause environmental pollution in the course of their production and business operation shall introduce environmental protection measures in their plants and establish a reliable system for environmental protection.

Furthermore, according to the Measures on Administration of Permitting Municipal Sewage Discharging into Sewage Drain Network (《城鎮污水排入排水管網許可管理辦法》), entities and individuals which discharge pollutant water into municipal sewage drain network must firstly acquire an approval license, excepting that this individual is a municipal resident. Under such case, municipal residents don't need to acquire the approval license.

According to the Regulation on Administration of Permitting of Pollutant Discharges (《排污許可管理條例》), which was issued on January 24, 2021 and effective on March 1, 2021, pollution discharging entities must acquire an approval and discharge pollution accordingly.

Pursuant to the Administrative Measures for Pollutant Discharge Licensing (for Trial Implementation) (《排污許可管理辦法(試行)》) promulgated on January 10, 2018 and partially revised on August 22, 2019 by the original environmental protection department, now known as the Ministry of Ecology and Environment (the “MEE”), and the Administrative Measures for Pollutant Discharge Licensing (《排污許可管理辦法》), which was promulgated on April 1, 2024 and scheduled to be implemented on July 1, 2024, the enterprises, public institutions and other production operators included in the catalog of classified management of pollutant discharge licenses for stationary pollution sources shall apply for and obtain a pollutant discharge permit as per the prescribed time limit; and those are not included in the catalog are not required to do so for the time of being.

REGULATORY OVERVIEW

Pursuant to the Classified Management Catalog of Pollutant Discharge Permits for Stationary Sources of Pollution (2019 Edition) (《固定污染源排污許可分類管理名錄(2019年版)》), which was promulgated by the Ministry of Ecology and Environment and became effective on December 20, 2019, a pollutant discharge entity subject to registration management is not required to apply for a pollutant discharge permit. It shall fill in the pollutant discharge registration form on the management information platform of state pollutant discharge permits, and register with its basic information, pollutant discharge route, pollutant discharge standards implemented, pollution prevention and control measures adopted, and other information.

Regulations Relating to Fire Prevention

The Fire Prevention Law of the PRC (《中華人民共和國消防法》) (the “**Fire Prevention Law**”) was adopted on April 29, 1998, amended on October 28, 2008, April 23, 2019 and April 29, 2021. According to the Fire Prevention Law and other relevant laws and regulations of the PRC, the emergency management authority of the State Council and its local counterparts at or above county level shall monitor and administer the fire prevention affairs. The fire and rescue department of such a people’s government is responsible for implementation. The Fire Prevention Law provides that the fire prevention design or construction of a construction project must conform to the national fire prevention technical standards.

Regulations Relating to Intellectual Property Rights

China became a member of the World Trade Organization and a party to the Agreement on Trade-Related Aspects of Intellectual Property Rights (《與貿易有關的知識產權協定》) on December 11, 2001. In addition, China has entered into several international conventions on intellectual property rights, including without limitation, the Paris Convention for the Protection of Industrial Property (《保護工業產權巴黎公約》), the Madrid Agreement Concerning the International Registration of Marks (《商標國際註冊馬德里協議》) and the Patent Cooperation Treaty (《專利合作公約》).

Copyright

The Copyright Law of the PRC (《中華人民共和國著作權法》) (the “**Copyright Law**”), which was promulgated by the SCNPC on September 7, 1990, came into effect on June 1, 1991 and was amended on October 27, 2001, February 26, 2010, November 11, 2020 and came into effect on June 1, 2021. Copyrights include personal rights such as the right of publication and that of attribution as well as property rights such as the right of production and that of distribution. Reproducing, distributing, performing, projecting, broadcasting or compiling a work or communicating the same to the public via an information network without permission from the owner of the copyright therein, unless otherwise provided in the Copyright Law, shall constitute infringements of copyrights. The infringer shall, according to the circumstances of the case, undertake to cease the infringement, take remedial action, and offer an apology, pay damages, etc.

The Measures for the Registration of Computer Software Copyright (《計算機軟件著作權登記辦法》), which was promulgated by the National Copyright Administration on February 20, 2002, and came into effect on the same day, regulates the registration of software copyright, the exclusive licensing contract and assignment contracts of software copyright. The National Copyright Administration is mainly responsible for the registration and management of national software copyright and designates the China Copyright Protection Center as the agency for software registration. The China Copyright Protection Center will grant certificates of registration to computer software copyright applicants.

Patents

Pursuant to the Patent Law of the PRC (《中華人民共和國專利法》) (the “**Patent Law**”) promulgated by the SCNPC on March 12, 1984, amended on September 4, 1992, August 25, 2000, December 27, 2008, October 17, 2020, and effective from 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》), promulgated by the State Council on December 21, 1992 and as amended on June 15, 2001, December 28, 2002, January 9, 2010, and

REGULATORY OVERVIEW

December 11, 2023, there are three types of patents in the PRC: invention patents, utility model patents and design patents. The protection period is 20 years for an invention patent and 10 years for a utility model patent and a design patent, commencing from their respective application dates. Any individual or entity that utilizes a patent or conducts any other activity in infringement of a patent without prior authorization of the patent holder shall pay compensation to the patent holder and is subject to a fine imposed by relevant administrative authorities and, if constituting a crime, shall be held criminally liable in accordance with the law. According to the Patent Law, for public health purposes, the State Intellectual Property Office of the PRC may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which PRC has acceded. In addition, pursuant to the Patent Law, any organization or individual that applies for a patent in a foreign country for an invention or utility model patent established in China is required to report to the State Intellectual Property Office for confidentiality examination. Furthermore, the Patent Law introduces patent extensions to patents of new drugs that launched in the PRC.

Trade Secrets

Pursuant to the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》), promulgated by the SCNPC on September 2, 1993, amended on November 4, 2017 and on April 23, 2019, the term “trade secrets” refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the PRC Anti-Unfair Competition Law, business persons are prohibited from infringing others’ trade secrets by: (i) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, solicitation or coercion; (ii) disclosing, using or permitting others to use the trade secrets obtained illegally under item (i) above; (iii) disclosing, using or permitting others to use the trade secrets, in violation of confidentiality obligations or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (iv) instigating, inducing or assisting others to violate confidentiality obligation or any requirements of the legal owners or holders on keeping confidentiality of commercial secrets, obtaining, disclosing, using or allowing others to use the commercial secrets of the legal owners or holders. Natural persons, legal persons and unincorporated organizations other than business operators committing any of the illegal acts stipulated in the preceding paragraph shall be deemed to have infringed upon trade secrets. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others’ trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties.

Trademarks

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》), promulgated by the SCNPC on August 23, 1982, amended on February 22, 1993, October 27, 2001, August 30, 2013 and April 23, 2019 and effective from November 1, 2019, the period of validity for a registered trademark is 10 years, commencing from the date of registration. Upon expiry of the period of validity, the registrant shall go through the formalities for renewal within twelve months prior to the date of expiry, if intending to continue to use the trademark. Where the registrant fails to do so, a grace period of six months may be granted. The period of validity for each renewal of registration is 10 years, commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be canceled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided according to law.

Domain Names

Domain names are protected under the Measures on Administration of Domain Names for the Chinese Internet (《中國互聯網絡域名管理辦法》) promulgated by the Ministry of Industry and Information Technology (the “MIIT”), on November 5, 2004 and effective from December 20, 2004, which was replaced by the Administrative Measures on the Internet Domain Names (《互聯網域名管理

REGULATORY OVERVIEW

辦法》) issued by the MIIT as of August 24, 2017. The MIIT is the main regulatory body responsible for the administration of PRC internet domain names. Domain name registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

On November 27, 2017, the MIIT promulgated the Notice of the Ministry of Industry and Information Technology on Regulating the Use of Domain Names in Providing Internet-based Information Services (《工業和信息化部關於規範互聯網信息服務使用域名的通知》), which became effective on January 1, 2018. Pursuant to the notice, the domain name used by an Internet-based information service provider in providing Internet-based information services must be registered and owned by such provider in accordance with the law.

Regulations Relating to Labor and Social Insurance

Pursuant to the PRC Labor Law (《中華人民共和國勞動法》), which was promulgated by the SCNPC on July 5, 1994 and became effective on January 1, 1995 and subsequently amended on August 27, 2009 and December 29, 2018, the PRC Labor Contract Law (《中華人民共和國勞動合同法》), which was promulgated by the SCNPC on June 29, 2007 and subsequently amended on December 28, 2012 and became effective on July 1, 2013, and the Implementing Regulations of the Employment Contracts Law of the PRC (《中華人民共和國勞動合同法實施條例》), which was promulgated by the State Council and effective on September 18, 2008, labor contracts in written form shall be executed to establish labor relationships between employers and employees. In addition, wages cannot be lower than local minimum wage. The employers must establish a system for labor safety and sanitation, strictly abide by State rules and standards, provide education regarding labor safety and sanitation to its employees, provide employees with labor safety and sanitation conditions and necessary protection materials in compliance with State rules, and carry out regular health examinations for employees engaged in work involving occupational hazards.

Under applicable PRC laws, including the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which was promulgated by the SCNPC on October 28, 2010 and became effective on July 1, 2011 and amended on December 29, 2018, the Interim Regulations on the Collection and Payment of Social Security Funds (《社會保險費徵繳暫行條例》), which was promulgated by the State Council and became effective on January 22, 1999 and amended on March 24, 2019, and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), which was promulgated by the State Council and became effective on April 3, 1999, amended on March 24, 2002 and March 24, 2019, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance, maternity insurance and to housing provident funds. These payments are made to local administrative authorities and any employer who fails to contribute may be fined and ordered to make the deficit good within a stipulated time limit.

On July 31, 2025, the PRC 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)》), which took effect on September 1, 2025. Article 19(1) thereof stipulates that if an employer and an employee agree or the employee undertakes that social insurance contributions need not be paid, the court shall deem such agreement or undertaking invalid. Furthermore, where an employer fails to pay social insurance contributions in accordance with the law, and the employee seeks to terminate the labor contract and claims economic compensation from the employer pursuant to Article 38(3) of the PRC Labor Contract Law, the court shall support such claims in accordance with the law, which clarifies that employees are entitled to request termination of their labor contracts and receive corresponding economic compensation under the PRC Labor Contract Law if the employer fails to make social insurance contributions in accordance with the law.

REGULATORY OVERVIEW

Regulations Relating to Employee Stock Option Plans

On February 15, 2012, the State Administration of Foreign Exchange (the “SAFE”) issued the Circular on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plans of Overseas Publicly Listed Companies (《關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》) (the “Share Incentive Rules”). Under the Share Incentive Rules and relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. In addition, the State Administration of Taxation (the “SAT”) has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in the PRC who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax. The PRC subsidiaries of an overseas listed company have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold individual income tax of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC subsidiaries fail to withhold, their individual income tax according to relevant laws, rules and regulations, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC government authorities.

Regulations Relating to Taxation and Dividend Distribution

Enterprise Income Tax

Because we carry out our PRC business operations through operating subsidiaries organized under the PRC law, our PRC operations and our operating subsidiaries in China are subject to PRC tax laws and regulations, which indirectly affect your investment in our shares. Pursuant to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (the “EIT Law”), promulgated by the National People’s Congress on March 16, 2007, which became effective on January 1, 2008 and was amended on February 24, 2017 and December 29, 2018, the income tax rate for both domestic and foreign-invested enterprises is 25% commencing on January 1, 2008 with certain exceptions. In order to clarify certain provisions of the EIT Law, the State Council promulgated the Implementation Rules of the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》) (the “EIT Implementation Rules”) on December 6, 2007, which became effective on January 1, 2008 and was last amended on December 6, 2024 and became effective on January 20, 2025. Under the EIT Law and the EIT Implementation Rules, enterprises are classified as either “resident enterprises” or “non-resident enterprises”. Pursuant to the EIT Law and the EIT Implementation Rules, besides enterprises established within the PRC, enterprises established outside China whose “de facto management bodies” are located in China are considered “resident enterprises” and subject to the uniform 25% enterprise income tax rate for their global income. In addition, the EIT Law provides that a non-resident enterprise refers to an entity established under foreign law whose “de facto management bodies” are not within the PRC but which have an establishment or place of business in the PRC, or which do not have an establishment or place of business in the PRC but have income sourced within the PRC. A non-resident enterprise having offices or establishments inside the PRC is subject to enterprise income tax for the income derived in the PRC and the income derived from outside the PRC but with actual connection with such offices or establishments in the PRC.

Value-added Tax

According to the Temporary Regulations on Value added Tax of the PRC (《中華人民共和國增值稅暫行條例》) (the “VAT Regulations”), which was promulgated by the State Council on December 13, 1993, came into effect on January 1, 1994, and was amended on November 10, 2008, on February 6, 2016 and November 19, 2017 respectively, and the Detailed Rules for the Implementation of the VAT Regulations (《中華人民共和國增值稅暫行條例實施細則》), which was promulgated by the Ministry of Finance (the “MOF”) and came into effect on December 25, 1993 and was amended on December 15, 2008 and October 28, 2011, all taxpayers selling goods, providing processing, repairing or replacement services or importing goods within the PRC shall pay value added tax. Other than those as specified in the VAT Regulations, the tax rate of 17% shall be levied on general taxpayers selling or importing

REGULATORY OVERVIEW

various goods; the tax rate of 17% shall be levied on the taxpayers providing processing, repairing or replacement service; the applicable rate for the export of goods by taxpayers shall be nil, unless otherwise stipulated. According to the Notice of the Ministry of Finance and the State Administration of Taxation on Adjusting Value added Tax Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) issued on April 4, 2018 and became effective on May 1, 2018, the deduction rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively. According to the Notice of the Ministry of Finance, the State Administration of Taxation and the General Administration of Customs on Relevant Policies for Deepening Value Added Tax Reform (《關於深化增值稅改革有關政策的公告》) issued on March 20, 2019 and became effective on April 1, 2019, the value added tax rate was reduced to 13% and 9%, respectively.

On December 25, 2024, the SCNPC promulgated the Value-added Tax Law of the PRC (《中華人民共和國增值稅法》) (“**VAT Law**”), which came into effect on 1 January 2026, and the Provisional Regulations of the PRC on Value-Added Tax (《中華人民共和國增值稅暫行條例》) were repealed concurrently. Pursuant to the VAT Law, entities and individuals (including individual industrial and commercial proprietors) selling goods, services, intangible assets, real estate and importing goods within the territory of the PRC are taxpayers of value-added tax (“**VAT**”) and shall pay VAT in accordance with the provisions of the law. Unless stated otherwise, for payers who sell goods, and provide processing, repairs and replacement services and rental services of tangible movable assets as well as import goods, the tax rate shall be 13%, and be, in certain specified circumstances, 9%, 6% and 0%.

Withholding Tax and International Tax Treaties

Pursuant to an Arrangement Between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) and other applicable PRC laws, if a Hong Kong resident enterprise is determined by the competent PRC tax authority to have satisfied the relevant conditions and requirements under such Double Tax Avoidance Arrangement and other applicable laws, the 10% withholding tax on the dividends the Hong Kong resident enterprise receives from a PRC resident enterprise may be reduced to 5%. However, based on the Circular on Certain Issues with Respect to the Enforcement of Dividend Provisions in Tax Treaties issued on February 20, 2009 (《關於執行稅收協定股息條款有關問題的通知》) by the SAT, if the relevant PRC tax authorities determine, in their discretion, that a company benefits from such reduced income tax rate due to a structure or arrangement that is primarily tax-driven, such PRC tax authorities may adjust the preferential tax treatment; and based on the Announcement on Certain Issues with Respect to the “Beneficial Owner” in Tax Treaties (《國家稅務總局關於稅收協定中“受益所有人”有關問題的公告》), issued on February 3, 2018 and effective on April 1, 2018, if an applicant’s business activities do not constitute substantive business activities, it could result in the negative determination of the applicant’s status as a “beneficial owner”, and consequently, the applicant could be precluded from enjoying the above-mentioned reduced income tax rate of 5% under thence Arrangement.

Circular 7

On February 3, 2015, the SAT issued the Announcement of the State Administration of Taxation on Certain Issues Concerning the Enterprise Income Tax on the Indirect Transfer of Properties by Non-resident Enterprises (《關於非居民企業間接轉讓財產企業所得稅若干問題的公告》) (the “**Circular 7**”). The Circular 7 stipulates that when a non-resident enterprise transfers its assets (including equity interests) in an overseas holding company which directly or indirectly owns PRC taxable properties, including shares in a PRC company (the “**PRC Taxable Assets**”), for the purposes of avoiding PRC enterprise income taxes through an arrangement without reasonable commercial purpose, such indirect transfer should be reclassified and recognized to be a direct transfer of the assets (including equity interests) of a PRC resident enterprise in accordance with the EIT Law, unless the overall arrangements relating to an indirect transfer of PRC Taxable Assets fulfil one of the conditions as stipulated under the Circular 7.

REGULATORY OVERVIEW

Dividend Distribution

The principal regulations governing distribution of dividends paid by wholly foreign owned enterprises include the PRC Company Law and the FIL. Under these laws and regulations, foreign-invested enterprises in China may pay dividends only out of their accumulated profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, a wholly foreign-owned enterprise in China is required to set aside at least 10% of its after-tax profit based on PRC accounting standards each year to its general reserves until the accumulative amount of such reserves reach 50% of its registered capital. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year.

Regulations Relating to Foreign Exchange

Foreign Exchange Administration

The principal regulation governing foreign currency exchange in China is the Foreign Exchange Administration Regulations of the PRC (《中華人民共和國外匯管理條例》), which were promulgated by the State Council on January 29, 1996, came into effect on April 1, 1996, and amended on January 14, 1997 and August 5, 2008, set out that foreign exchange receipts of domestic institutions or individuals may be transferred to China or deposited abroad and that the SAFE shall specify the conditions for transfer to China or overseas and other requirements in accordance with the international receipts, payments status and requirements of foreign exchange control. Foreign exchange receipts for current account transactions may be retained or sold to financial institutions engaged in the settlement or sale of foreign exchange. Domestic institutions or individuals that make direct investments abroad, are engaged in the distribution, sale of valuable securities or derivative products overseas should register according to SAFE regulations. Such institutions or individuals subject to prior approval or record-filing with relevant authorities shall complete the required approval or record-filing prior to foreign exchange registration. The exchange rate for RMB follows a managed floating exchange rate system based on market demand and supply.

The Regulations on the Administration of the Settlement, Sale and Payment of Foreign Exchange (《結匯、售匯及付匯管理規定》), which was promulgated by the People’s Bank of China on June 20, 1996 and came into effect on July 1, 1996, provides that foreign exchange receipts under the current account of foreign-invested enterprises may be retained to the fullest extent specified by the foreign exchange bureau. Any portion in excess of such amount shall be sold to a designated foreign exchange bank or through a foreign exchange swap center.

The Notice of the SAFE on Further Improving and Adjusting Policies Relating to Foreign Exchange Administration in Direct Investment (《國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知》), which was promulgated by the SAFE on November 19, 2012, came into effect on December 17, 2012 and amended on May 4, 2015 and came into effect on the same day, amended on December 30, 2019 and came into effect on the same day, expands on the reform of the foreign exchange administration system, simplifies the administrative approval procedures, and improves foreign exchange administration in direct investment by repealing or adjusting certain approval items for foreign exchange administration in direct investment.

According to the Circular of the State Administration of Foreign Exchange on Reforming the Management Approach regarding the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》) promulgated by SAFE on March 30, 2015, amended on December 30, 2019 and March 23, 2023, voluntary settlement of foreign exchange (the “voluntary settlement”) is implemented for foreign exchange capital funds of foreign-invested enterprises. Voluntary settlement means that the foreign exchange capital funds which have been confirmed by SAFE as cash contribution for equity interest (or have been registered as capital contribution in cash via a bank) in the capital account of the foreign-invested enterprise may carry out a settlement at the bank as and when required according to actual operation needs of the enterprise. The ratio of voluntary settlement of foreign exchange capital funds of a foreign-invested enterprise is set at 100% for the time being. The Renminbi funds arising from the

REGULATORY OVERVIEW

settlement of foreign exchange shall be placed in a special account for administration. If the foreign-invested enterprise has further payment needs, it is still required to truthfully produce relevant authentic certification materials to the bank for review according to regulations. The Renminbi funds obtained from the capital funds and foreign exchange settlement of the foreign-invested enterprise are prohibited from the following uses: (i) shall not be used directly or indirectly for expenses incurred outside the scope of operation or prohibited by laws and regulations of the PRC; (ii) unless otherwise required by laws and regulations, shall not be used directly or indirectly in securities investment; (iii) shall not be used directly or indirectly for lending as entrusted loans denominated in Renminbi (except permitted by the scope of operation), for repayment of inter-company borrowings (including third-party advances) and for repayment of Renminbi-denominated bank loans which have been re-lent to third parties; and (iv) except for foreign-invested real estate enterprises, such Renminbi funds shall not be used to pay for the relevant expenses for the purchase of real estate properties which are not for its own use.

The Circular of Further Simplifying and Improving the Direct Investment-related Foreign Exchange Administration Policies (《關於進一步簡化和改進直接投資外匯管理政策的通知》) (the “**Circular 13**”), which became effective on June 1, 2015 and was amended on December 30, 2019, cancels the administrative approvals of foreign exchange registration of direct domestic investment and direct overseas investment and simplifies the procedure of foreign exchange-related registration. Pursuant to Circular 13, investors should register with local banks for direct domestic investment and direct overseas investment, including the initial and amended registrations under Circular 37.

The Circular on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《關於改革和規範資本項目結匯管理政策的通知》) (the “**Circular 16**”) was promulgated by SAFE on June 9, 2016 and was amended on December 4, 2023. Pursuant to Circular 16, enterprises registered in the PRC may also convert their foreign debts from foreign currency to Renminbi on a self-discretionary basis. Circular 16 reiterates the principle that Renminbi converted from foreign currency-denominated capital of a company may not be directly or indirectly used for purposes beyond its business scope or prohibited by PRC Laws, while such converted Renminbi shall not be provided as loans to its non-affiliated entities.

On January 26, 2017, SAFE promulgated the Circular on Further Improving Reform of Foreign Exchange Administration and Optimizing Genuineness and Compliance Verification (《國家外匯管理局關於進一步推進外匯管理改革完善真實合規性審核的通知》), which stipulates several capital control measures with respect to the outbound remittance of profit from domestic entities to offshore entities, including (i) banks should check board resolutions regarding profit distribution, the original version of tax filing records, and audited financial statements pursuant to the principle of genuine transactions; and (ii) domestic entities should hold income to account for previous years’ losses before remitting the profits. Moreover, pursuant to this circular, domestic entities should make detailed explanations of the sources of capital and utilization arrangements, and provide board resolutions, contracts, and other proof when completing the registration procedures in connection with an outbound investment.

On October 23, 2019, the SAFE promulgated the Notice for Further Advancing the Facilitation of Cross-border Trade and Investment (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》), which was amended on December 4, 2023. The Notice allows all Foreign Investment Enterprises to use Renminbi converted from foreign currency-denominated capital for equity investments in China, as long as the equity investment is genuine, does not violate applicable laws, and complies with the negative list on foreign investment. However, since this circular is newly promulgated, it is unclear how the SAFE and competent banks will carry it out in practice. According to the Circular of SAFE on Optimizing Foreign Exchange Administration to Support the Development of Foreign-related Business (《國家外匯管理局關於優化外匯管理支持涉外業務發展的通知》) (the “**SAFE Circular 8**”) promulgated on April 10, 2020 and came into effect on June 1, 2020 by the SAFE, the reform of facilitating the payments of incomes under the capital accounts shall be promoted nationwide. Under the prerequisite of ensuring true and compliant use of funds and compliance and complying with the prevailing administrative provisions on use of income from capital projects, enterprises that satisfy the criteria are allowed to use income under the capital account, such as capital funds, foreign debt and overseas listing, etc., for domestic payment, without the need to provide proof materials for veracity to the bank beforehand for each transaction.

REGULATORY OVERVIEW

Circular 37

The Circular on Issues Relating to the Administration of Foreign Exchange in Fund-raising and Return Investment Activities of Domestic Residents Conducted via Offshore Special Purpose Companies (《關於境內居民通過境外特殊目的公司融資及返程投資外匯管理有關問題的通知》) (the “**Circular 75**”), which was promulgated by the SAFE on October 21, 2005, and came into effective on November 1, 2005. Under Circular 75, Chinese residents must register with the relevant local SAFE branch prior to their establishment or control of an offshore entity established for the purpose of overseas equity financing involving onshore assets or equity interests held by them, and must also make filings with SAFE thereafter upon the occurrence of certain material capital changes. The registration and filing procedures under Circular 75 are prerequisites for other approval and registration procedures necessary for capital inflow from the offshore entity, such as inbound investments or shareholders loans, or capital outflow to the offshore entity, such as the payment of profits or dividends, liquidating distributions, equity sale proceeds, or the return of funds upon a capital reduction.

The Circular on Relevant Issues Concerning Foreign Exchange Administration for PRC Residents to Engage in Overseas Investment and Financing and Inbound Investment via Special Purpose Vehicles (《國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) (the “**Circular 37**”, which has replaced Circular 75), which was promulgated by the SAFE on July 4, 2014 and came into effective on the same date, states that (i) a PRC resident, including a PRC resident natural person or a PRC legal person, shall register with the local branch of the SAFE before it contributes the assets of or its equity interest into a special purpose vehicle for the purpose of investment and financing and (ii) when the special purpose vehicle undergoes change of basic information, such as change in PRC resident natural person shareholder, name or operating period, or occurrence of a material event, such as change in share capital of a PRC resident natural person, performance of merger or split, the PRC resident shall register such change with the local branch of the SAFE in a timely manner.

Regulations Relating to [REDACTED]

On July 6, 2021, the Opinions on Strictly Cracking Down Illegal Securities Activities in Accordance with the Law (《關於依法從嚴打擊證券違法活動的意見》) was jointly issued by the Central Committee of the Communist Party of China and the General Office of the State Council, which steps up scrutiny of overseas listings by companies and calls for strengthening cooperation in cross-border regulation, amending relevant laws and regulations on cyber security, cross-border data transmission and confidential information management, including the confidentiality requirement and file management related to the issuance and listing of securities overseas, enforcing the primary responsibility of the enterprises for information security of Chinese-based overseas listed companies and promoting the construction of relevant regulatory systems to deal with the risks and incidents faced by Chinese-based overseas-listed companies.

On February 17, 2023, the CSRC promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “**Trial Measures**”) and five relevant guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures provide that (i) domestic companies that seek to offer or list securities overseas, both directly and indirectly, should complete a filing procedure and submit relevant information to the CSRC; in the event of subsequent offering and occurrence of certain major events, domestic companies shall also complete relevant filing procedures and submit information to the CSRC; if a domestic company fails to complete the filing procedures, omits any material fact, falsifies any content or contains any misleading statement in its filing documents, such domestic company may be subject to administrative penalties, such as an order to rectify, warnings, fines, and its controlling shareholders, actual controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines; and (ii) where an issuer makes an application for initial [REDACTED] and listing in an overseas market, the issuer shall file with the CSRC within three business days after such application is submitted.

REGULATORY OVERVIEW

The CSRC and other three relevant government authorities promulgated the Provisions on Strengthening the Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) (the “**Provision on Confidentiality**”) on February 24, 2023, and came into effect on March 31, 2023. Pursuant to the Provision on Confidentiality, when a domestic company provides or publicly discloses the documents and materials involving state secrets and working secrets of state organs to the relevant securities companies, securities service institutions, overseas regulatory authorities and other entities and individuals, or provides or publicly discloses such the documents and materials through its overseas listing subjects, it shall report to the competent department with the examination and approval authority for approval, and file with the same level secrecy administration department. Domestic companies providing accounting archives or copies thereof to entities and individuals such as securities companies, securities service institutions and overseas regulatory authorities shall perform the relevant procedures according to relevant regulations. The working papers formed within the territory of the PRC by the securities companies and securities service institutions that provide related services for the overseas offering and listing of domestic enterprises shall be kept within the territory of the PRC. Cross-border transferring of such working papers shall go through the examination and approval formalities in accordance with the relevant regulations.