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

REGULATIONS ON COMPANY ESTABLISHMENT AND FOREIGN INVESTMENT

The establishment, operation and management of corporate entities in China are governed by the Company Law of PRC (《中華人民共和國公司法》, the "**PRC Company Law**"), which was promulgated by the Standing Committee of the National People's Congress (the "**NPC**") in December 1993 and further amended in December 1999, August 2004, October 2005, December 2013 and October 2018, respectively. According to the PRC Company Law, companies are generally classified into two categories: limited liability companies and companies limited by shares. The PRC Company Law also applies to foreign-invested limited liability companies. According to the PRC Company Law, where laws on foreign investment have other stipulations, such stipulations shall prevail. In December 2021, the draft amendment to the PRC Company Law was published for public comments by the Thirteenth Standing Committee of NPC. The amendment made systemic changes to the existing PRC Company Law. Uncertainties exist regarding the final form of these laws and regulations as well as the interpretation and implementation thereof after promulgation.

Investment activities in the PRC by foreign investors are governed by the Guiding Foreign Investment Direction (《指導外商投資方向規定》), which was promulgated by the State Council in February 2002 and came into effect in April 2002, and the Special Administrative Measures for the Access of Foreign Investment (Negative List) (《外商投資准入特別管理措施(負面清單)(2021年版)》, the "**Negative List**"), which was promulgated by the Ministry of Commerce (the "**MOFCOM**") and National Development and Reform Commission (the "**NDRC**") in December 2021 and came into effect in January 2022. The Negative List set out the restrictive measures in a unified manner, such as the requirements on shareholding percentages and management, for the access of foreign investments, and the industries that are prohibited for foreign investment. The Negative List covers 12 industries, and any field not falling in the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment.

Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the "**Foreign Investment Law**") was promulgated by the NPC in March 2019 and came into effect in January 2020. After the Foreign Investment Law came into effect, the Law on Wholly Foreign-owned Enterprises of the PRC (《中華人民共和國外資企業法》), the Law on Sino-foreign Equity Joint Ventures of the PRC (《中華人民共和國中外合資經營企業法》) and the Law on Sino-foreign Cooperative Joint Ventures of the PRC (《中華人民共和國中外合作經營企業法》) have been repealed simultaneously. The investment activities of foreign natural persons, enterprises or other organizations (hereinafter referred to as "foreign investors") directly or indirectly within the territory of China shall comply with and be governed by the Foreign Investment Law, including: 1) establishing by foreign investors of foreign-invested enterprises in China alone or jointly with other investors; 2) acquiring by foreign investors of

shares, equity, property shares, or other similar interests of Chinese domestic enterprises; 3) investing by foreign investors in new projects in China alone or jointly with other investors; and 4) other forms of investment prescribed by laws, administrative regulations or the State Council.

In December 2019, the State Council promulgated the Regulations on Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》), which came into effect in January 2020. After the Regulations on Implementing the Foreign Investment Law of the PRC came into effect, the Regulation on Implementing the Sino-Foreign Equity Joint Venture Enterprise Law of the PRC (《中華人民共和國中外合資經營企業法實施條例》), Provisional Regulations on the Duration of Sino-Foreign Equity Joint Venture Enterprise (《中外合資經營企業合營期限暫行規定》), the Regulations on Implementing the Wholly Foreign-Invested Enterprise Law of the PRC (《中華人民共和國外資企業法實施細則》) and the Regulations on Implementing the Sino-Foreign Cooperative Joint Venture Enterprise Law of the PRC (《中華人民共和國中外合作經營企業法實施細則》) have been repealed simultaneously.

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

In December 2020, the NDRC and the MOFCOM jointly promulgated the Measures on the Security Review of Foreign Investment (《外商投資安全審查辦法》), effective in January 2021, setting forth provisions concerning the security review mechanism on foreign investment, including the types of investments subject to review, the scopes of review and procedures to review, among others.

REGULATION ON PHARMACEUTICAL PRODUCT DEVELOPMENT, APPROVAL AND REGISTRATION

Drug Regulatory Regime

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the "**Drug Administration Law**") was promulgated by the Standing Committee of the NPC, in September 1984. The last two amendments to the Drug Administration Law were the amendments promulgated in April 2015 and in August 2019. The Regulations for the Implementation of the Drug Administration Law (《藥品管理法實施條例》) was promulgated by the State Council in August 2002, and was last amended in March 2019. The Drug Administration Law and the

Regulations for the Implementation of the Drug Administration Law have jointly established the legal framework for the administration of pharmaceutical products in China, including the research, development and manufacturing of drugs. The Drug Administration Law applies to entities and individuals engaged in the development, production, trade, application, supervision and administration of pharmaceutical products, which regulates and provides for a framework for the administration of pharmaceutical manufacturers, pharmaceutical trading companies and medicinal preparations of medical institutions, and the development, research, manufacturing, distribution, packaging, pricing and advertisements of pharmaceutical products. The Regulations for the Implementation of the Drug Administration Law, at the same time, provide the detailed implementation regulations for the Drug Administration Law.

In 2017, the drug regulatory system entered a new and significant period of reform. The General Office of the State Council and the General Committee of China Communist Party jointly issued an Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (the "**Innovation Opinions**") in October 2017. The expedited programs, the record-filing system, the prioritized review mechanism, the acceptance of foreign clinical data under the Innovation Opinions and other recent reforms encourage drug manufacturers to seek marketing approval in China first in order to develop drugs in highly prioritized therapeutical areas, such as oncology or rare disease areas.

To implement the regulatory reform introduced by Innovation Opinions, the Standing Committee of the NPC, the National Medical Products Administration (the "**NMPA**"), a newly formed government authority as well as other authorities, are currently responsible for revising the laws, regulations and rules regulating the pharmaceutical products and the industry.

In August 2019, the Standing Committee of the NPC promulgated the new Drug Administration Law (the "**2019 Amendment**"), which came into effect in December 2019. The 2019 Amendment contains many of the major reform initiatives implemented by the Chinese government since 2015, including but not limited to the marketing authorization holder system (the "**MAH System**"), conditional approvals of drugs, traceability system of drugs, and the cancelation of relevant certification according to the Good Manufacturing Practice and the Good Supply Practice.

Regulatory Authorities

Pharmaceutical products, medical devices and equipment in China are monitored and supervised on a national scale by the NMPA. The local provincial medical products administrative authorities are responsible for supervision and administration of drugs within their respective administrative regions. The NMPA was newly formed under the SAMR. 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 primary responsibilities of the NMPA include:

- monitoring and supervising the administration of pharmaceutical products, medical appliances and equipment as well as cosmetics in the PRC;
- formulating administrative rules and policies concerning the supervision and administration of the pharmaceutical, medical devices and cosmetics industry;
- evaluating, registering and approving of traditional Chinese medicine, chemical drugs and biological products;
- approving and issuing permits for the manufacture and export/import of pharmaceutical products, medical appliances and equipment;
- approving the establishment of enterprises to be engaged in the manufacture and distribution of pharmaceutical products;
- examining and evaluating the safety of pharmaceutical products, medical devices and cosmetics; and
- managing the significant accidents involving the pharmaceutical products, medical devices and cosmetics.

In 2013, the Ministry of Health (the "**MOH**") and the National Population and Family Planning Commission were integrated into the National Health and Family Planning Commission of the PRC (the "**NHFPC**"). In March 2018, the First Session of the Thirteenth NPC approved the State Council Institutional Reform Proposal (《國務院機構改革方案》), according to which, the responsibilities of NHFPC and certain other governmental authorities are consolidated into the National Health Commission (the "**NHC**"), and the NHFPC shall no longer be reserved. The responsibilities of the NHC include organizing the formulation of national drug policies, the national essential drug system and the National Essential Drug List and drafting the administrative rules for the procurement, distribution and use of national essential drugs.

According to the Decision of the CFDA 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 in March 2017 and came into effect in May 2017, the approval of clinical trial application should be issued by the Center for Drug Evaluation (the "**CDE**") in the name of the CFDA.

Regulations on the Clinical Trials and Registration of Drugs

Administrative Measures for Drug Registration

The Administrative Measures for Drug Registration (《藥品註冊管理辦法》) ("**Registration Measures**") was promulgated by SFDA in February 2005 and was latest amended in January 2020, which came into effect in July 2020. The Registration Measures mainly cover: (1) definitions of drug marketing registration applications and regulatory responsibilities of the drug administration; (2) general requirements for drug marketing registration; (3) clinical trials; (4) application, examination and approval of drugs; (5) supplemental applications and re-registrations of drugs; (6) inspections; (7) registration standards and specifications; (8) time limit; (9) associated review of drugs, excipients and packaging materials; (10) expedited registration of drugs; and (11) liabilities and other supplementary provisions.

According to the Registration Measures, 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 chemical drugs shall be categorized by innovative chemical drugs, improved new chemical drugs, generic chemical drugs, etc.

In March 2016, the CFDA issued the Reform Plan for Registration Category of Chemical Medicine (《化學藥品註冊分類改革工作方案》), which aims to reclass the registration application of chemical drugs stipulated by the Registration Measures promulgated in 2007. According to the Reform Plan for Registration Category of Chemical Medicine, Category 1 drugs refer to innovative chemical drugs that have not been marketed anywhere in the world. Improved new chemical drugs that are not marketed anywhere in the world fall into Category 2 drugs. Generic chemical drugs, that have equivalent quality and efficacy to the originator's drugs have been marketed abroad but not yet in China, can be classified as Category 3 drugs. Generic drugs, that have equivalent quality and efficacy to the originator's drugs and have been marketed in China, fall into Category 4 drugs. Category 5 drugs are drugs which have already been marketed abroad, but are not yet approved in China.

As a support policy and implementing rule of the Registration Measures newly amended in 2020, the NMPA issued the Chemical Drug Registration Classification and Application Data Requirements (《化學藥品註冊分類及申報資料要求》) ("**Classification and Data Requirements**") in June 2020, of which the Chemical Drug Registration Classification came into effect in July 2020 and the Application Data Requirements came into effect October 2020. The Classification and Data Requirements reaffirmed the principles of the classification of chemical drugs set forth by the Reform Plan for Registration Category of Chemical Medicine, and made minor adjustments to the subclassifications of Category 5. According to such drafts, Category 5.1 are innovative chemical drugs and improved new chemical drugs while Category 5.2 are generic chemical drugs, all of which shall have been already marketed abroad but not yet approved in China.

Accelerated Approval for Clinical Trial and Registration

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

The CFDA released the Circular Concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》) in November 2015, which clarified the measures and policies regarding simplifying and accelerating the approval process of clinical trials, including but not limited to an one-time umbrella approval procedure allowing the overall approval of all phases of a drug's clinical trials, replacing the phase-by-phase application and approval procedure, will be adopted for drugs' clinical trial applications.

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

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

Import of Urgently Needed Drug in Boao Pilot Zone

According to the Drug Administration Law, based on urgent medical need by medical institution of certain drug that is not yet registered domestically (the "**Urgently Needed Drug**"), subject to the approval of NMPA or competent provincial government, a small amount of such Urgently Needed Drug may be imported but shall be solely applied for specific medical purpose at the designated medical institution.

The State Council issued the Official Reply of the State Council to Approve the Establishment of Boao Lecheng International Medical Tourism Pilot Zone of Hainan Province (《國務院關於同意設立海南博鰲樂城國際醫療旅遊先行區的批覆》) in February 2013, according to which, Boao Lecheng International Medical Tourism Pilot Zone of Hainan Province (the "**Boao Pilot Zone**") shall be established as a pilot zone where accelerated approval of the import of the Urgently Needed Drug is available. The State Council further issued the Decision on Temporarily Adjusting the Implementation of the Relevant Provisions of the Implementing Measures of the Drug Administration Law in the Boao Lecheng

International Medical Tourism Pilot Zone of Hainan Province (《國務院關於在海南博鰲樂城國際醫療旅遊先行區暫時調整實施<中華人民共和國藥品管理法實施條例>有關規定的決定》) in December 2018, according to which, the State Council empowers the People's Government of Hainan Province (the "**Hainan Government**") to approve the import of the Urgently Needed Drug (excluding vaccines).

Pilot Commercialization

The Hainan Government promulgated the Interim Provisions on the Administration of Imported Drugs of Urgent Need in Boao Lecheng International Medical Tourism Pilot Zone of Hainan Province (《海南博鰲樂城國際醫療旅遊先行區臨床急需進口藥品管理暫行規定》) in April 2019, according to which, a qualified medical institution in the Boao Pilot Zone may apply for the import of certain Urgently Needed Drug (excluding vaccines and other drugs under special management) and apply to patient on case by case basis. Such application shall be subject to the evaluation and approval of Hainan Provincial Health Commission and the Medical Products Administration of Hainan Province, as well as the customs formalities with Haikou Customs According to the Administration of Imported Drugs of Urgent Need in Boao Lecheng International Medical Tourism Pilot Zone of Hainan Province, the urgently needed imported drugs referred to 1) drugs that are approved for sale in the United States, the European Union, Japan, and other countries or regions, and 2) have not been approved for registration in China, 3) and cannot be substituted by domestically registered varieties, which are urgently needed by designated medical institutions in the pilot free trade zone due to clinical needs. However, this does not include drugs that are subject to special management, such as vaccines. As advised by our PRC Legal Advisor, after evaluation by Hainan Medical Products Administration, CU-40102 and CU-10201 have been approved for patients in Boao Pilot Zone in Hainan Province.

Trial Exemptions and Acceptance of Foreign Data

The NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data (《接受藥品境外臨床試驗數據的技術指導原則》) in July 2018, as one of the implementing rules for the Innovation Opinions, which provides that overseas clinical data can be submitted for the drug marketing registration applications in China. Such applications can be in the form of waivers to China-based clinical trials, bridging trials and direct drug marketing registration. According to the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data, sponsors may use the data of foreign clinical trials to support drug marketing registration in China, provided that sponsors must ensure the authenticity, integrity, accuracy and traceability of foreign clinical trial data and such data must be obtained consistent with the relevant requirements under the Good Clinical Practice of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (the "**ICH**"). Moreover, sponsors shall ensure the scientific design of overseas clinical trials, the compliance of clinical trial quality management system requirements, and the accuracy and integrity of statistical analysis of data. To ensure that the clinical trial design and statistical analysis of the data are scientific and reasonable, for the drugs with simultaneous R&D at home and abroad and forthcoming clinical trials in China, the sponsors may, prior to

implementing registrational clinical trials, contact the CDE to ensure the compliance of registrational clinical trials' design with the essential technical requirements for drug registration in China. Sponsors must also comply with other relevant sections of the Registration Measures when applying for drug marketing registrations in China using foreign clinical trial data.

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

Drug Clinical Trial Application

According to the Registration Measures, after the completion of the pharmaceutical, pharmacological and toxicological research of the drug clinical trial, the applicant may submit relevant research materials to CDE for applying for the approval to conduct drug clinical trial. The CDE will organize pharmaceutical, medical and other technicians to review the application and to decide whether to approve the drug clinical trial within 60 days of the date of acceptance of the application. Once the decision is made, the result will be notified to the applicant through the website of the CDE and if no notice of decision is issued within the aforementioned time limit, the application of clinical trial shall be deemed as approval. The Registration Measures further requires that the applicant shall, prior to conducting the drug clinical trial, register the information of the drug clinical trial plan, etc. on the Drug Clinical Trial Information Platform. During the drug clinical trials, the applicant shall update registration information continuously, and register information of the outcome of the drug clinical trial upon completion. The applicant shall be responsible for the authenticity of the drug clinical trial information published on the platform. Pursuant to the Notice on the Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) promulgated by CFDA in September 2013, the applicant shall complete the trial pre-registration within one month after obtaining the approval of the clinical trial application in order to obtain the trial's unique registration number and complete registration of certain follow-up information before the first subject's enrollment in the trial. If the registration is not completed within one year after the approval, the applicant shall submit an explanation, and if the first submission is not completed within three years, the approval of the clinical trial application shall automatically expire.

Clinical Trial Process and Good Clinical Practices

According to the Registration Measures, a clinical trial consists of Phases I, II, III and IV clinical trial as well as bioequivalence trial. Based on the characteristics of drugs and research objective, the research contents shall include clinical pharmacology research, exploratory clinical trial, confirmatory clinical trial and post-marketing research. Clinical drug trial shall be carried out in institutions for clinical drug trial that have corresponding conditions and that have undergone recordation formalities as required. The applicant filing an application for clinical drug trial after completing the pharmaceutical research, pharmacological and toxicological research, and other researches supporting clinical drug trial shall submit relevant research materials according to the requirements for the application materials. The applicant who intends to carry out a bioequivalence test shall, after undergoing the recordation formalities for bioequivalence test at the website of the Center for Drug Evaluation as required, carry out relevant research work according to the plan recorded. The clinical drug trial to be carried out shall be examined and approved by the ethics committee and the management of drugs used in a clinical drug trial shall satisfy the relevant requirements of the GCP. The applicant who is approved to carry out clinical drug trial shall, before carrying out subsequent clinical drug trial by stages, develop corresponding plan for clinical drug trial, carry out clinical drug trial upon examination and with consent of the ethics committee, and submit corresponding plan for clinical drug trial and supporting materials on the website of the Center for Drug Evaluation. Where indications (or functions) are intended to be added for a drug approved for clinical drug trial and the use of a drug in combination with other drugs is added, the applicant shall file a new application for clinical drug trial, and may only carry out new clinical drug trial with approval.

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

To improve the quality of clinical trials, the SFDA and NHC promulgated the Good Clinical Trial Practice for Drugs (《藥物臨床試驗質量管理規範》) (the "**GCP Rules**") in August 2003 which was further amended in April 2020 and came into effect in July 2020. According to the GCP Rules, clinical trial means systematical investigation of drugs conducted on human subjects (patients or healthy volunteers) to prove or reveal the clinical, pharmacological and other pharmacodynamic effects, adverse reactions or absorption, distribution, metabolism and excretion of the drug being investigated. In order to ensure the quality of clinical trials and the safety of human subjects, the GCP Rules provides comprehensive and substantive requirements on the design and conduct of clinical trials in China. In particular, the GCP Rules enhances the protection for study subjects and tightens the control over bio-samples collected under clinical trials.

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

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

The GCP Rules also summarizes the role of ethic committee in clinical trial process. An ethic committee shall consist of experts working in the medical, pharmaceutical and other fields. The clinical trial protocol may not be executed unless approved by the ethic committee. Pursuant to the Announcement on Issuing the Guidelines for Ethical Review Work of Drug Clinical Trials (《關於印發藥物臨床試驗倫理審查工作指導原則的通知》) promulgated by SFDA in November 2010, the ethics committee shall carry out a review on the project of clinical trial on the drug to decide if it is rational in terms of science and ethics, and shall be subject to guidance and supervision under the drug supervisory and administrative departments. In November 2019, the NMPA and the NHC jointly promulgated the Notice on Issuing the Administration of Drug Clinical Trial Institution (《關於發佈藥物臨床試驗機構管理規定的公告》), which stipulates that each clinical trial institution shall maintain an ethic committee responsible for the ethical review of drug clinical trial.

Communication with the CDE

According to the Circular 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》) promulgated by the NMPA in July 2018, 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 Session to CDE to discuss with CDE the key technical questions including the design of Phase III clinical trial protocol.

Within 60 days after the acceptance of and the fees paid for the clinical trial applications, the applicant may conduct the clinical trials for the drug in accordance with the clinical trial protocol submitted, if the applicant has not received any negative or questioning opinion from the CDE.

The NMPA amended 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》) in December 2020, which mainly improves the procedure of communication, unifies and refines the communication requirements and further classifies the Type II meeting. During the research and development periods and in the registration applications of, among others, the innovative 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 periods of drugs, mainly including meetings before the clinical trial application, meetings upon the completion of Phase II trials and before the commencement of Phase III trials, meetings before submitting a drug marketing application, and meetings for risk evaluation and control. Type III meetings refer to meetings not classified as Type I or Type II.

Drug Marketing Registration

According to the Registration Measures, the applicant may submit an application for drug marketing registration to CDE upon completion of relevant research on pharmacy, pharmacology, toxicology and drug clinical trials, determination the quality standards of the drug, validation of commercial-scale production processes and preparation for acceptance of verification and inspection conducted by professional technical institution designated by competent NMPA. The CDE will organize pharmaceutical, medical and other technicians to conduct comprehensive review of the safety, efficacy and quality controllability, among others, of the drug according to the application materials submitted by the applicant, the results of the verification and inspection conducted by professional technical institution, etc. If the comprehensive review conclusion is affirmative, the drug shall be approved for marketing and a drug registration certificate will be issued containing the information of the drug approval number, the marketing authorization holders (the "**MAH**") and the manufacturer.

Pilot Plan for the MAH System

The MAH System was formally established by the 2019 Amendment and symbolized the general application of the MAH System throughout the country. According to which: (i) an MAH refers to enterprise or drug research and development institute which has obtained a drug registration certificate; (ii) an MAH shall be 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 study, clinical trial, manufacturing and operation, post-market launch study, monitoring, reporting and handling of adverse reactions of the drugs; (iii) the legal representative and the key person-in-charge of a drug MAH shall be fully responsible for the

quality of drugs; (iv) an MAH may either engage in drug manufacturing on its own or may engage licensed contract manufacturers for manufacturing; (v) an MAH may either engage in drug sales on its own or may engage licensed contract distributor for drug sales; (vi) upon approval by the drug administrative department of the State Council, an MAH may transfer the drug registration certificate for a certain drug obtained by it to a qualified transferee and upon the completion of the transfer, such transferee will be the new MAH for that drug.

Approval or Filing of Human Genetic Resources

The Interim Administrative Measures on Human Genetic Resources (《人類遺傳資源管理暫行辦法》), promulgated by the Ministry of Science and Technology and the MOH in June 1998, aimed at protecting and fair utilizing human genetic resources in the PRC. The Ministry of Science and Technology promulgated the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) in July 2015, according to which, the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organization of China shall apply for approval of the China Human Genetic Resources Management Office through the online system. The Ministry of Science and Technology further 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》) in October 2017, which became effective in December 2017 and simplified the approval of sampling and collecting human genetic resources for the purpose of listing a drug in the PRC.

The Regulations of the PRC on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》), promulgated by the State Council in May 2019 and came into effect in July 2019, repeals The Interim Administrative Measures on Human Genetic Resources (《人類遺傳資源管理暫行辦法》) simultaneously and further stipulates that in order to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China's human genetic resources at clinical institutions without export of human genetic resource materials. However, the type, quantity and usage of the human genetic resource to be used shall be filed with the administrative department of science and technology under the State Council before clinical trials.

On October 17, 2020, the SCNPC promulgated the Biosecurity Law of the PRC (《中華人民共和國生物安全法》) (the "**Biosecurity Law**") which became effective on April 15, 2021, establishing a comprehensive legislative framework on the current regulations in the areas including epidemic control of human, animal and plant infectious diseases, security of biotechnology research, development and application, biosafety management of pathogenic microbiology laboratories, security management of human genetic resources and biological resources, countermeasures against microbial resistance and prevention of bioterrorism and threat of biological weapons. According to the Biosecurity Law, the high-risk and medium-risk biotechnology research and development activities shall be carried out by legal entities

lawfully established in the PRC, and shall be approved or filed; the establishment of a pathogenic microbiology laboratory shall be lawfully approved or filed; (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 department of science and technology under the State Council, (ii) preserving human genetic resources of the PRC, (iii) using human genetic resources of the PRC to carry out international scientific research cooperation, or (iv) transporting, mailing or exiting human genetic resource materials of the PRC, shall be approved by the competent department of science and technology.

In March 2022, the Ministry of Science and Technology issued Seeking Public Comments on the Implementation Rules for the Administrative Regulation on Human Genetic Resources (Exposure Draft) (《人類遺傳資源管理條例實施細則(徵求意見稿)》), which aims to further improve the efficiency of the administration of human genetic resources in China.

REGULATIONS ON DRUG MANUFACTURING AND DISTRIBUTION

Drug Manufacturing

According to the Drug Administration Law and the Implementing Regulations of the Drug Administration Law, a drug manufacturing enterprise is required to obtain a drug manufacturing license from the relevant provincial drug administration authority of the PRC. The grant of such license is subject to an inspection of the manufacturing facilities, and an inspection to determine whether the sanitary condition, quality assurance systems, management structure and equipment meet the required standards. According to the Regulations of Implementation of the Drug Administration Law and the Measures on the Supervision and Administration of the Manufacture of Drugs (《藥品生產監督管理辦法》) (the "**GMP Rules**"), promulgated in August 2004 and amended in November 2017 and January 2020, respectively, the drug manufacturing license is valid for five years and shall be renewed at least six months prior to its expiration date upon a re-examination by the relevant authority. In addition, the name, legal representative, registered address and unified social credit code specified in the drug manufacturing certificate shall be identical to that set forth in the business license as approved and issued by the industrial and commercial administrative department. According to such measures, to the extent the MAH does not manufacture the drug but through contract manufacturing organization, the MAH shall apply for drug manufacturing license with the provincial counterpart of the NMPA, subject itself to inspections and other regulatory oversight by the agency.

The Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) was promulgated in March 1988 and was latest amended in January 2011. The Good Manufacturing Practice for Drugs comprises a set of detailed standard guidelines governing the manufacture of drugs, which includes institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, raw material management, maintenance of sales records and management of customer complaints and adverse event reports.

On November 29, 2019, the NMPA issued the Announcement on Matters relating to 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》), which confirmed that the GMP certification would be canceled from December 1, 2019, and no application for GMP certification would be accepted and no GMP certificate would be granted. However, according to the Drug Administrative Law, drug manufacturers shall still comply with the GMP, establish and improve the GMP system, and ensure the whole drug production process consistently in compliance with statutory requirements.

On May 24, 2021, the NMPA issued the Administrative Measures for Drug Inspection (Trial) (《藥品檢查管理辦法(試行)》) which became effective on the same day, and the Administrative Measures for the Certification of Good Manufacturing Practice was repealed. The Administrative Measures for Drug Inspection (Trial) provided that onsite inspections shall be conducted pursuant to the GMP on a drug manufacturer applying for the drug manufacturing license for the first time, while for the drug manufacturers applying for the renewal of drug manufacturing licenses, the review shall be conducted based on the risk management principles, in combination with the drug manufacturers' compliance with the laws and regulations of drug administration, and the operation of the GMP and quality management system, and inspections on the drug manufacturers' conformity to the GMP may be conducted where necessary.

Drug Distribution

According to the Drug Administration Law and its implementing regulations and the Measures for the Supervision and Administration of Circulation of Pharmaceuticals (《藥品流通監督管理辦法》), which was promulgated by the SFDA in January 2007 and came into effect in May 2007, pharmaceutical enterprise shall be responsible for the quality of pharmaceuticals they manufacture, operate or use, purchase, sale, transportation, storage.

According to the Measures for the Administration of Pharmaceutical Operation Certificate (《藥品經營許可證管理辦法》) which was promulgated in February 2004 and amended in November 2017 by the CFDA, a Medicine Operation Certificate is valid for five years. Each holder of the Medicine Operation Certificate must apply for an extension of its permit six months prior to expiration. The establishment of a wholesale pharmaceutical distribution company requires the approval of the provincial medicine administrative authorities. Upon approval, the authority will grant a Medicine Operation Certificate in respect of the wholesale pharmaceutical product distribution company. The establishment of a retail pharmacy store requires the approval of the local medicine administrative authorities at or above the county level. Upon approval, the authority will grant a Medicine Operation Certificate in respect of the retail pharmacy store.

Advertising of Drugs

According to the Advertising Law of the PRC (《中華人民共和國廣告法》), which was promulgated by the Standing Committee of the NPC in October, 1994 and last amended in April, 2021, certain contents such as statement on cure rate or efficiency shall not be included in the advertisement of drugs.

Pursuant to the Interim Measures for the Administration of Internet Advertisement (《互聯網廣告管理暫行辦法》) which was promulgated by the State Administration for Industry and Commerce ("**SAIC**") in July, 2016 and became effective as of September, 2016, the Internet advertisement must be visibly marked as "advertisement". Advertisements for special commodities or services such as medical treatment, pharmaceuticals, foods for special medical purposes and other health foods must be reviewed by competent authorities before online publication.

Pursuant to the Measures for Administration of Medical Advertisement (《醫療廣告管理辦法》), which was jointly promulgated by the SAIC and the MOH in September, 1993, and was amended in November 10, 2006 and effective in January, 2007, medical advertisements shall be reviewed by relevant health authorities and obtain a Medical Advertisement Examination Certificate before being released. Medical Advertisement Examination Certificate is valid for one year and may be renewed upon application.

According to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food, and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) issued by the State Administration for Market Regulation in December, 2019 and came into effect in March, 2020, the advertisements for drugs shall not be released without being reviewed and the contents of a drug advertisement shall be based on the drug instructions approved by the drug administration departments.

OTHER PRC REGULATIONS RELATING TO THE PHARMACEUTICAL INDUSTRY

Regulations on Healthcare System Reform

The PRC government recently promulgated several healthcare reform policies and regulations. In March 2009, the Central Committee of the PRC Communist Party and the State Council jointly issued the Guidelines on Strengthening the Reform of Healthcare System (《關於深化醫藥衛生體制改革的意見》). In December 2016, the State Council issued the Notice on the Issuance of the 13th Five-year Plan on Strengthening the Reform of Healthcare System (《關於印發"十三五"深化醫藥衛生體制改革規劃的通知》). In April 2017, the General Office of the State Council issued the Main Tasks of Healthcare System Reform in 2017 (《深化醫

藥衛生體制改革2017年重點工作任務》). In August 2018, the General Office of the State Council issued the Notice on the Main Tasks of Strengthening the Reform of Healthcare System in second half of 2018 (《關於印發深化醫藥衛生體制改革2018年下半年重點工作任務的通知》). Highlights of these healthcare reform policies and regulations include (1) establishing a basic healthcare system to cover both urban and rural residents and providing the Chinese people with safe, effective, convenient and affordable healthcare services, (2) improving the healthcare system through the reform and development of a graded hierarchical healthcare system, modern hospital management, basic medical insurance, drug supply support and comprehensive supervision, and (3) improving the efficiency and quality of the healthcare system to meet the various medical needs of the Chinese population.

In May 2019, the General Office of the State Council issued the Main Tasks of Healthcare System Reform in 2019 (《深化醫藥衛生體制改革2019年重點工作任務》), highlighting the following policies and regulations (1) reinforcing the degree of cancer prevention and treatment, accelerating the registration and approval of anti-cancer new drugs at home and abroad and remaining the temporary channel of imperative anti-cancer drugs importation open, (2) consolidating and improving the basic medicine system and establishing an inventive and restrictive mechanism for preferential use. Improving the dynamic adjusting mechanism of the National Reimbursement Drug List (the "**NRDL**") and incorporating the eligible therapeutic drugs listing in the National Essential Drug List into the NRDL first in accordance with the procedure. As of the Latest Practicable Date, as advised by our PRC Legal Advisor, the inclusion in the NRDL of localized adipose accumulation medication for the treatment of obesity disease are not mandatory.

In December 2019, the Standing Committee of the NPC promulgated the Law of the People's Republic of China on Promotion of Basic Medical and Health Care (《中華人民共和國基本醫療衛生與健康促進法》), which came into effect in June 2020. Such law established the legal framework for the administration of basic medical and health services for citizens in China, including the administration of basic medical care services, medical care institutions, medical staff, guarantee of drug supply, health promotion and guarantee of medical funds.

In February 2020, the Central Committee of the PRC Communist Party and the State Council jointly promulgated the Opinions on Deepening the Reform of the Healthcare Security System (《中共中央、國務院關於深化醫療保障制度改革的意見》), which envisages that a higher level healthcare system should be established by 2030, which centers on basic medical insurance, is underpinned by medical aid and pursues the common development of supplementary medical insurance, commercial health insurance, charitable donations and medial mutual assistance. To this end, such opinions map out tasks in several respects, including making the mechanism of medical insurance benefits guarantee more impartial and appropriate, improving the robust and sustainable operating mechanism for funds raised, establishing more effective and efficient healthcare payment mechanism and enhancing the supervision and administration on medical security fund and etc.

Regulations on Two-Invoice System

According to the Implementing Opinions on Promoting the "Two-Invoice System" for Drug Procurement By Public Medical Institutions (For Trial Implementation) ("**Two-Invoice System Notice**") (《關於在公立醫療機構藥品採購中推行"兩票制"的實施意見(試行)》) which was issued on December 26, 2016, the two-invoice system is a system that mandates pharmaceutical manufacturers to issue one invoice to pharmaceutical distributors and pharmaceutical distributors to provide another invoice to public medical institutions. Sale of products invoiced from the manufacturer to its wholly owned or controlled distributors, or for imported drugs, to their exclusive distributor, or from a distributor to its wholly owned or controlled subsidiary is excluded.

According to the Two-Invoice System Notice and the Several Opinions of the General Office of the State Council on Further Reform and Improvement in Policies of Drug Production, Circulation and Use (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》), which was issued on January 24, 2017, on a priority basis, the two-invoice system would be promoted in pilot provinces (autonomous regions and municipalities directly under the Central Government) and pilot cities for public hospital reform, with the goal of having it implemented nationwide by 2018. Pharmaceutical companies must comply with the two-invoice system in order to engage in procurement processes with public hospitals.

On July 19, 2019, the General Office of the State Council issued the Circular on the Governance of High-value Medical Consumables Reform Program (《國務院辦公廳關於印發治理高值醫用耗材改革方案的通知》), which indicated local governments are encouraged to adopt the "Two-Invoice System" when taking into consideration the local situation, in order to reduce the circulation of high-value medical consumables and promote the transparency of purchases and sales.

Certain provinces have implemented or are encouraged to implement the "Two-Invoice System" for drugs and medical consumables. On July 23, 2018, eight local government departments of Shaanxi Province, including Deepen Medical and Healthcare System Reform Leading Group Office of Shaanxi Province (陝西省深化醫藥衛生體制改革領導小組辦公室), issued the Notice on Further Promoting the "Two-Invoice System" on Drugs and Medical Consumables (《關於進一步推進藥品和醫用耗材"兩票制"的通知》), which stipulates that on the basis of the full implementation of the "Two-Invoice System" of medical consumables in the urban public medical institutions, primary medical and healthcare institutions at the county level or below shall begin to implement the "Two-Invoice System" for medical consumables starting from August 1, 2018.

REGULATIONS ON COSMETICS

Production and Sales of Cosmetics

According to Regulation on the Supervision and Administration of Cosmetics (《化妝品監督管理條例》) which was promulgated by the State Council in June 2020 and became effective in January 2021, and the Measures for the Supervision and Administration of Production and Distribution of Cosmetics (《化妝品生產經營監督管理辦法》) which was promulgated by SAMR in August 2021 and became effective in January 2022, whoever engages in the production of cosmetics within the territory of the PRC shall file an application for a cosmetics production license with the drug supervision and administration department of the people's government of the province, autonomous region, or municipality directly under the Central Government at the place where it is located. Cosmetic registrants and recordation entities may produce cosmetics by themselves or by entrusting other enterprises. In the case of entrusted production of cosmetics, a cosmetic registrant or recordation entity shall entrust an enterprise that has obtained the corresponding cosmetics production license, and supervise the production activities of the entrusted enterprise to ensure that it produces cosmetics according to statutory requirements. Cosmetic manufacturers and distributors shall store and transport cosmetics in accordance with the provisions of relevant laws and regulations and the requirements indicated on cosmetic labels, and inspect on a regular basis and handle in a timely manner the deteriorated or expired cosmetics. The cosmetic distributors on the E-commerce platform shall disclose the information on the cosmetics they distribute in a comprehensive, truthful, accurate and timely manner. The content of cosmetics advertisements shall be authentic and legal. No cosmetic advertisement may expressly or impliedly indicate that the product has any medical effect, contain any false or misleading information, or deceive or mislead consumers.

According to the Safety and Technical Standards for Cosmetics (Version 2015) (《化妝品安全技術規範(2015年版)》) promulgated by the SFDA in the December 2015 and came into effect in December 2016, the production of cosmetics shall comply with the requirements of the specifications for the production of cosmetics, and the production process of cosmetics shall be scientific and reasonable to ensure product safety.

According to the Measures for the Administration of Cosmetic Labels (《化妝品標籤管理辦法》) which was promulgated by the NMPA in May 2021 and came into effect in May 2022, the smallest sales unit of cosmetics shall be labeled. The labels shall comply with the requirements of the relevant laws, administrative regulations, departmental rules, compulsory national standards and technical specifications. The contents of the labels shall be lawful, authentic, complete and accurate and consistent with the relevant contents registered or filed for record.

Registration and Recordation of Cosmetics

According to Regulation on the Supervision and Administration of Cosmetics (《化妝品監督管理條例》), within the territory of the PRC, the medical products administration conducts registration administration of special cosmetics and new cosmetic raw materials with a high degree of risks, and conducts recordation administration of general cosmetics and other new cosmetic raw materials. According to the Measures for the Administration of the Registration and Recordation of Cosmetics (《化妝品註冊備案管理辦法》), which was promulgated by the SAMR in January 2021 and came into effect in May 2021, a registrant or recordation entity of cosmetics and new cosmetic raw materials shall, when applying for registration or undergoing recordation formalities, comply with the requirements of applicable laws, administrative regulations, compulsory national standards and technical specifications, and be responsible for the veracity and scientificity of the materials submitted, including but not limited to the Administrative Provisions of Cosmetics Registration and Filing Documents (《化妝品註冊備案資料管理規定》), the Administrative Provisions on Materials for Registration and Record Filing of New Cosmetic Ingredients (《化妝品新原料註冊備案資料管理規定》), the Classification Rules and Catalogue of Cosmetics (《化妝品分類規則和分類目錄》), the Technical Guideline for Safety Assessment of Cosmetics (Version 2021) (《化妝品安全評估技術導則(2021年版)》), the Standards for Cosmetic Efficacy Claim Evaluation (《化妝品功效宣稱評價規範》), all of which was promulgated by the NMPA and came into effect in May 2021, the Supervision and the Administration measures of Children's Cosmetics (《兒童化妝品監督管理規定》) which was promulgated by the NMPA and came into effect in January 2022, the Specifications for the Implementation of Cosmetics Registration and Filing Inspection (《化妝品註冊和備案檢驗工作規範》) which was promulgated by the NMPA and came into effect in September 2019.

According to Notice of the State Food and Drug Administration on Issuing the Provisions on the Acceptance of Cosmetic Administrative Licensing Application (《國家食品藥品監督管理局關於印發<化妝品行政許可申報受理規定>的通知》),which was promulgated by the SFDA in December 2009 and came into effect in April 2010, and Notice of the State Food and Drug Administration on Strengthening the Administration of the Recordation of Domestic Non-special Use Cosmetics (《國家食品藥品監督管理局關於加強國產非特殊用途化妝品備案管理工作的通知》), which was promulgated by the SFDA and came into effect in April 2009, domestic special-use cosmetics are subject to administrative licensing management, and domestic non-special-use cosmetics are subject to recordation administration.

Regulations on Advertising relating to Cosmetics

The Advertising Law of the PRC (《中華人民共和國廣告法》), which was promulgated by the NPC latest amended with immediate effect from April 2021, regulates commercial advertising activities in the PRC and sets out the obligations of advertisers, advertising operators, advertising publishers, and advertisement endorser. Advertisers shall be responsible for the veracity of their advertisement content. The goods or services come with a gift in an advertisement shall specify, the type, specification, quantity, period and method of such gift. Any advertiser in violation of the foregoing requirements will be ordered to stop publishing of

advertisement, and a fine of not more than RMB100,000 may be imposed. Except for medical, pharmaceutical and medical machinery advertisements, no other advertisements shall involve illness treatment function, use medical jargon or jargon which misleads readers to confuse the promoted product with medicine or medical machinery. Any advertiser in violation of such requirements will be ordered to cease publishing such advertisements and imposed some fine, the business license of the offender may be revoked in severe circumstances, and the relevant authorities may revoke the approval document for examination and refuse to accept applications submitted by such advertiser for one year.

The Interim Measures for the Administration of Internet Advertising (《互聯網廣告管理暫行辦法》), which was promulgated by the SAIC, in July 2016 with effect from September 2016, regulates that in internet advertising activities, internet advertisers are responsible for the authenticity of the content of advertisements and all online advertisements must be marked "Advertisement" so that viewers can easily identify them as such.

OTHER SIGNIFICANT PRC REGULATIONS AFFECTING OUR BUSINESS IN THE PRC

Regulations on Enterprise Investment Projects

According to Regulations on the Administration of Approval and Filing of Enterprise Investment Projects (Order No. 673 of the State Council of the people's Republic of China) (《企業投資項目核准和備案管理條例》,中華人民共和國國務院令第673號) implemented in February 2017, projects related to national security, major productivity distribution, strategic resource development and major public interests are subject to approval management. The specific project scope, the approval authority and the approval power shall be implemented in accordance with the catalog of investment projects approved by the government.

According to the Notice of the State Council on Issuing the Catalogue of Investment Projects Approved by the Government (2016 version) (國務院關於發佈政府核准的投資項目目錄(2016年本)的通知》,國發[2016]72號) implemented in December 2016, the cross-border and cross-provincial (district, city) trunk pipeline network projects shall be approved by the competent investment department of the State Council, and the cross-border projects shall be reported to the State Council for the record, and other projects are approved by local governments.

Regulations on Construction

Construction Work Planning Permit

According to the Urban and Rural Planning Law of the PRC (《中華人民共和國城鄉規劃法》), where construction work is conducted in a city or town planning area, the relevant construction entity or individual shall apply for a Construction Work Planning Permit from a competent urban and rural planning administrative department of the People's Government at

the municipal or county level or the People's Government at the municipal or county level or to the People's Government of town as recognized by the People's Government of a province, autonomous region or municipality.

Construction Work Commencement Permit

According to the Construction Law of the PRC (《中華人民共和國建築法》) promulgated by the Standing Committee of National People's Congress in November 1997 and last amended in April 2019, a construction entity shall, prior to the commencement of a construction project, apply for a Construction Work Commencement Permit from a competent department of the Construction Administration of the People's Government at or above the county level of the place where the project is located pursuant to the relevant regulations, except for small projects below the threshold value set by the competent construction administrative department under the State Council. Construction projects which have obtained approval of construction commencement reports in accordance with the procedures stipulated by the State Council under its authority are no longer required to apply for construction licenses.

Acceptance on Completion of Construction

Under the Construction Law of the PRC (《中華人民共和國建築法》) (the "**Construction Law**") promulgated by the SCNPC in November 1997, with effect in March 1998, last amended in April 2019 and newly effective on the same date, enterprises engaged in construction, engineering survey, engineering design and supervision shall apply for the qualifications of different grades according to its registered capital, professional and technical personnel, technical equipment and achievements and after passing the qualification examination, could separately obtain qualification certificates of commensurate grades for construction, surveying, design, supervision, only with which, can it undertake construction, survey, design, and supervision activities within the scope set out in its qualifications.

Pursuant to the Administrative Measures for Construction Permits of Building Projects (《建築工程施工許可管理辦法》) promulgated by Ministry of Construction (predecessor of the Ministry of Housing and Urban-Rural Development (the "**MOHURD**")) in October 1999 with effect in December 1999, last amended in March 2021 and newly effective on the same day, within the territory of PRC, when engaged in the construction, decoration of buildings and the subsidiary facilities, installation of supporting lines, pipelines and equipment, as well as the construction of municipal infrastructure projects in cities and towns, the construction unit shall, before starting construction, in accordance with the provisions of the Measures, report to the local competent authorities of housing and urban-rural construction at or above the county level where the projects are located and apply for a construction permit. Construction projects with the investment of less than RMB300,000 or a construction area of less than 300 m^2 are not required for construction permits.

Pursuant to the Administrative Measures for the Administration of Completion Acceptance and Filing of Housing Construction and Municipal Infrastructure Projects (《房屋建築和市政基礎設施工程竣工驗收備案管理辦法》) promulgated by the MOHURD in October 2009 with effect on the same day, for newly-built, expanded and re-built housing and municipal infrastructure projects within the territory of the PRC, the institution which has carried out such construction shall, within 15 days from the date of acceptance and of the relative project, file with the competent construction department of the local people's government at or above the county level where such project is located.

Regulations on Environment Protection

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), which was promulgated by the SCNPC in December 1989, last amended in April 2014 and came into effect in January 2015, outlines the authorities and duties of various environmental protection regulatory agencies. The Ministry of Environmental Protection is authorized to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC. Pursuant to the Environmental Impact Assessment Law of the People's Republic of China (《中華人民共和國環境影響評價法》) promulgated by the SCNPC in October 2002, and most recently amended in December 2018, the PRC government implements administration by classification on the environmental impact of construction projects according to the level of impact on the environment. The construction unit shall prepare an environmental impact report or an environmental impact form or complete an environmental impact registration form (the "**Environmental Impact Assessment Documents**") for reporting and filing purposes. If the Environmental Impact Assessment Documents of a construction project have not been reviewed by the approving authority in accordance with the law or have not been granted approval after the review, the construction unit is prohibited from commencing construction works.

The Regulations on Urban Drainage and Sewage Treatment (《城鎮排水與污水處理條例》), which was promulgated by the State Council in October 2013 and came into effect in January 2014, require that urban entities and individuals shall dispose sewage through urban drainage facilities covering their geographical area in accordance with relevant rules. Companies or other entities engaging in medical activities shall apply for a Sewage Disposal Drainage License (污水排入排水管網許可證) before disposing sewage into urban drainage facilities. Sewage-disposing entities and individuals shall pay sewage treatment fee in accordance with relevant rules.

The Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》), which was promulgated by the State Council in November 1998, amended in July 2017 and came into effect in October 2017, stipulate that, depending on the impact of the construction project on the environment, an construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form.

Regulations on Fire Protection

The Fire Prevention Law of the PRC (《中華人民共和國消防法》) (the "**Fire Prevention Law**"), which was promulgated in April 1998 and most recently amended in April 2021, provides that fire control design and construction of a construction project shall comply with the State's fire control technical standards for construction projects. Developers, designers, builders, project supervisors, etc. shall be responsible for the quality of the fire control design and construction of the construction project pursuant to the law. The development project fire safety design examination and acceptance system shall be implemented for development projects which are required to have fire safety design in accordance with the national fire protection technical standards for project construction. According to Interim Regulations on Administration of Examination and Acceptance of Fire Control Design of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) issued by the MOHURD on April 1, 2020, an examination system for fire prevention design and acceptance only applies to special construction projects, and for other projects, a record-filing and spot check system would be applied.

Regulations on Hazardous Wastes

Pursuant to the Measures for the Administration of Permit for Operation of Hazardous Wastes (《危險廢物經營許可證管理辦法》) issued by the State Council in May 2004, last revised in February 2016 and became effective on the same day, any entity undertaking the business activities of collection, storage and disposal of hazardous wastes within the territory of the PRC shall obtain the permit for operation of hazardous wastes in accordance with the provisions of the Measures. The permit for operation of hazardous wastes shall be divided into the permit for comprehensive operation of the collection, storage and disposal of hazardous wastes and the permit for operation of the collection of hazardous wastes in light of the ways of business operation. Application for a new permit for the comprehensive operation of the collection, storage and disposal of hazardous wastes should meet the requirements of environmental protection technicians, transportation tools, packaging tools, storage facilities, pollution prevention facilities, and technology and techniques and the validity period for such permit is five years. The Measures also stipulate that, under any of the following circumstances, the operating entity of hazardous wastes shall reapply for the permit for operation of hazardous wastes in light of the former application procedures: changing ways of operation of hazardous wastes, adding new varieties of hazardous wastes, newly establishing or rebuilding or expanding the construction of the former operation facilities of hazardous wastes, or managing hazardous wastes exceeding the originally permitted annual treatment capacity by 20% or more. No entity without permit for operation shall undertake any business activity of collection, storage, and disposal of hazardous wastes or undertake such activities not in accordance with the provisions of the permit for operation. An operating entity of hazardous wastes shall set up register for the management of hazardous wastes, which shall specify such matters according to the facts as the classes and sources of the hazardous wastes having been collected, stored or disposed, the direction the hazardous wastes have gone to, and whether there is any accident.

Pursuant to the Measures for the Management of Hazardous Waste Transfer (《危險廢物轉移管理辦法》) issued by the Ministry of Ecology and Environment, Ministry of Public Security, Ministry of Transport in November 2021 and became effective in January 2022. An entity that produces hazardous wastes shall work out a plan for managing hazardous wastes in accordance with the relevant provisions issued by the state; and keep a hazardous waste management journal, faithfully recording relevant information, and report the types, production, destination, storage, treatment and other relevant information to the local ecology and environment department through the National Hazardous Waste Information Management System. The transferor of hazardous waste shall perform the following obligations: (1) verify the qualification and technical capacity of the carrier or the recipient, sign a written contract according to law, and stipulate the pollution prevention requirements and relevant responsibilities for the transportation, storage, utilization and disposal of hazardous waste in the contract; (2) make a hazardous waste management plan to clarify the type, weight (quantity), flow direction and other information of the hazardous waste to be transferred; (3) establish a hazardous waste management account, measure and weigh the transferred hazardous waste, and faithfully record and properly keep the type, weight (quantity), receiver and other relevant information of the transferred hazardous waste; (4) fill in the hazardous waste transfer form and operate accordingly, truthfully fill in the information of the transferor, carrier and receiver in the hazardous waste transfer form, the type, weight (quantity), hazardous characteristics and other information of the transferred hazardous waste, as well as the preventive measures for environmental emergencies; (5) timely verify the storage, utilization or disposal of relevant hazardous wastes by the recipient.

Pursuant to the Notice of the NDRC, the MEP, Ministry of Health, the MOF and Ministry of Construction on Implementing the Charging System for Hazardous Waste Disposal to Promote the Industrialisation of Hazardous Waste Disposal (《關於實行危險廢物處置收費制度促進危險廢物處置產業化的通知》) issued in November 2003 and became effective on the same day, hazardous wastes refer to the wastes which are listed in the National Catalogue of Hazardous Wastes or identified as hazardous wastes according to the national hazardous wastes identification standard and method, including industrial hazardous wastes, medical wastes and other hazardous wastes of social origin. The units producing and commissioning other entities to dispose of hazardous wastes, shall pay the disposal fee of hazardous wastes according to relevant regulation. The specific principles and measures for charging fees for the disposal of hazardous waste shall be formulated by the competent price departments of provinces, autonomous regions and municipalities directly under the Central Government of the PRC. The specific fee rates for charging fees for the disposal of hazardous wastes shall be formulated by the price departments of the people's governments of cities divided into districts in consultation with the relevant departments, submitted to the people's governments of cities for approval and implementation, and submitted to the price departments at the provincial level for the record.

Regulations on Intellectual Property Rights

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

Patents

According to the Patent Law of the PRC (《中華人民共和國專利法》) promulgated by the Standing Committee of the NPC in March 1984, as amended in September 1992, August 2000 and December 2008, October 2020 and came into effect in June 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 in June 2001 and as amended in December 2002 and January 2010, 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, 10 years for a utility model patent and 15 years for a design patent (10 years for a design patent filed on or before May 31, 2021), 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 of the PRC, 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, according to the Patent Law of the PRC, 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. The Patent Law of the PRC also sets forth the provisions for patent term extension and patent term adjustment.

Patent Transfer and License

Patent transfer (patent assignment) and patent license are two different ways of transferring or granting rights of a patent.

Patent assignment refers to the transfer of ownership of a patent from one party (assignor) to another (assignee). The party who receives the assignment (assignee) becomes the new owner of the patent, has the entire right to enforce it and collect any damages for infringement. In countries like China, patent assignment needs to be recorded with the patent office and announced to public, before it takes effect.

On the other hand, patent license grants permission to another party (licensee) to use a patent, but ownership of the patent remains with the original owner (licensor). The licensee is allowed to use the patent subject to the terms of the license agreement, which may specify limitations on territory, field, scope and/or duration of use. In Mainland China, the recordal of a patent license agreement is not mandatory.

Patent Enforcement

Unauthorized use of patents without consent from owners of patents, forgery of the patents belonging to other persons, or engagement in other patent infringement acts, will subject the infringers to infringement liability. Serious offences such as forgery of patents may be subject to criminal penalties.

A patent owner, or an interested party who believes the patent is being infringed, may either file a civil legal suit or file an administrative complaint with the relevant patent administration authority. A PRC court may issue a preliminary injunction upon the patent holder's or an interested party's request before instituting any legal proceedings or during the proceedings. Damages for infringement are calculated as the loss suffered by the patent holder arising from the infringement or the benefit gained by the infringer from the infringement. If it is difficult to ascertain damages in this manner, damages may be determined by using a reasonable multiple of the license fee under a contractual license. If willful patent infringement is found with serious circumstances, the damages may be increased to an amount between one and five times the amount determined as per the aforementioned calculation method. Statutory damages may be awarded in the circumstances where the damages cannot be determined by the above-mentioned calculation standards. The damage calculation methods shall be applied in the aforementioned order.

Trade Secrets

According to the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》), promulgated by the Standing Committee of the NPC in September 1993, and amended in November 2017 and April 2019 respectively, 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: (1) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (2) disclosing, using or permitting others to use the trade secrets obtained illegally under item (1) above; (3) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (4) instigating, inducing or assisting others to violate confidentiality obligation or to violate a rights holder's requirements on keeping confidentiality of trade secrets, disclosing, using or permitting others to use the trade secrets of the rights holder. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of

others, the third party may be deemed to have committed a misappropriation of the others' trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties.

Trademarks

According to the Trademark Law of the PRC (《中華人民共和國商標法》) promulgated by the Standing Committee of the NPC in August 1982, and amended in February 1993, October 2001, August 2013 and April 2019 respectively, the period of validity for a registered trademark is ten years, commencing from the date of registration. The registrant shall go through the formalities for renewal within twelve months prior to the expiry date of the trademark if continued use is intended. Where the registrant fails to do so, a grace period of six months may be granted. The validity period for each renewal of registration is ten 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 the law.

Domain Names

Domain names are protected under the Administrative Measures on the Internet Domain Names (《互聯網域名管理辦法》) promulgated by the Ministry of Industry and Information Technology in August 2017, and came into effect in November 2017, and the Implementing Rules of China ccTLD Registration (《國家頂級域名註冊實施細則》) issued by China Internet Network Information Center on June 18, 2019, which became effective on the same day. 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.

Regulations on Cybersecurity

On December 28, 2021, the Cyberspace Administration of China (the "**CAC**"), jointly with 12 other governmental authorities, promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the "**MCR**"), which became effective on February 15, 2022. Pursuant to Article 2 of the MCR, critical information infrastructure operators purchasing internet products and services and online platform operators engaging in data processing activities, which affect or may affect national security, will be subject to cybersecurity review. As of the Latest Practicable Date: (i) we had not been determined or identified as a critical information infrastructure operator by any governmental authorities; (ii) we believe that we had not engaged in any data processing activities that affect or may affect national security; and (iii) we had not been involved in any investigations on cybersecurity review made by CAC, and

had not received any inquiry, notice, warning or sanctions in this regard. Based on the foregoing, our PRC Legal Advisors are of the view that it is unlikely that we would be determined or identified as a critical information infrastructure operator as long as there is no material change to the Company's current business and we have no obligation to proactively apply for cybersecurity review under the MCR.

On November 14, 2021, CAC promulgated the Regulation on the Administration of Cyber Data Security (Draft for Comments) (《網絡數據安全管理條例(徵求意見稿)》) (the "**Draft Cyber Data Security Regulation**"). Pursuant to Article 2 and Article 73 of the Draft Cyber Data Security Regulation, the Draft Cyber Data Security Regulation applies to data processing activities by utilizing the internet as well as cyber data security supervision and management activities within the PRC. "Cyber data" refer to any information that is electronically recorded, whereas "data processing activities" refer to activities such as data collection, storage, usage, processing, transmission, provision, disclosure and deletion. In general, any company which is engaged in data processing activities through the internet within the PRC will be subject to the Draft Cyber Data Security Regulation. As advised by our PRC Legal Advisors, by collecting, storing and otherwise processing certain information via internet in connection with our business operation, the Company would be subject to relevant requirements under the Draft Cyber Data Security Regulation in terms of personal data protection, cyber security management, assessment and report and other applicable aspects, assuming that such regulation is implemented in the current form. In addition, Article 13 of the Draft Cyber Data Security Regulation stipulates that data processors must apply for cybersecurity review when carrying out activities including (i) seeking to be listed in Hong Kong that affect or may affect national security and (ii) other data processing activities that affect or may affect national security. Given that the Draft Cyber Data Security Regulation was still in the draft form for comments and had not come into force as of the Latest Practicable Date, the applicability of various requirements under the Draft Cyber Data Security Regulation is still subject to further official guidance and applicable implementation rules.

REGULATIONS RELATING TO THE LEASING OF PROPERTY

Pursuant to the Administrative Measures for the Leasing of Commodity Housing (商品房屋租賃管理辦法) issued by the Ministry of Housing and Urban-Rural Development of the PRC (中華人民共和國住房和城鄉建設部) on December 1, 2010 and coming into force on February 1, 2011, within 30 days after the execution of the housing lease contract, parties to the leasing of housing shall handle the registration and filing procedure of the leasing of housing at the departments in charge of construction (real estate) of the governments in the municipality directly under the Central Government, city and county where the leased housing is located. Parties to the leasing of housing may entrust in writing another party to handle the registration and filing procedure of the leasing. In the event that parties to the leasing of housing fail to handle the registration and filing procedure of the leasing of housing, the department in charge of construction (real estate) of the people's government in the municipality directly under the Central Government, the cities or the counties shall order rectification within a time limit. If

rectification is not made by an individual within the time limit, a fine of less than RMB1,000 shall be imposed. If rectification is not made by an entity within the time limit, a fine of more than RMB1,000 but less than RMB10,000 shall be imposed.

Pursuant to the Law of the People's Republic of China on Administration of Urban Real Estate (中華人民共和國城市房地產管理法) issued by the SCNPC on August 26, 2019 and became effective on January 1, 2020, Where the owner of a building leases, with a profit-making objective, buildings on State-owned land for which the land use right is granted to the owner of the building by way of allocation, the gains on land included in the rental shall be turned over to the State.

Regulations on Product Liability

In addition to the strict drug approval process, certain PRC laws have been promulgated to protect the rights of consumers and to strengthen the control of medical products in the PRC. According to the Civil Code of the PRC (《中華人民共和國民法典》), promulgated by the NPC in May 2020 and came into effect in January 2021 manufacturers shall assume tort liability where the defects in relevant products cause damage to others. Sellers shall assume tort liability where the defects in relevant products causing damage to others are attributable to the sellers. The aggrieved party may claim for compensation from the manufacturer or the seller of the relevant product in which the defects have caused damage.

In February 1993, the Product Quality Law of the PRC (《中華人民共和國產品質量法》) (the "**Product Quality Law**") was promulgated to supplement the PRC Civil Law aiming to protect the legitimate rights and interests of the end-users and consumers and to strengthen the supervision and control of the quality of products. The Product Quality Law was last revised in December 2018. According to the revised Product Quality Law, manufacturers who produce defective products may be subject to civil or criminal liability and have their business licenses revoked.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》) was promulgated in October 1993, amended in October 2013, and came into effect in March 2014, to protect consumers' rights when they purchase or use goods and accept services. According to which, all business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the latest amendment, all business operators shall pay high attention to protect the customers' privacy and strictly keep it confidential any consumer information they obtain during the business operation. In addition, in extreme situations, pharmaceutical product manufacturers and operators may be subject to criminal liability if their goods or services lead to the death or injuries of customers or other third parties.

Regulations on Tort

According to the Civil Code of the PRC (《中華人民共和國民法典》), promulgated by the NPC in May 2020 and came into effect in January 2021, if damages to other persons are caused by defective products due to the fault of a third party, such as the parties providing transportation or warehousing, the producers and the sellers of the products have the right to recover their respective losses from such third parties. If defective products are identified after they have been put into circulation, the producers or the sellers shall take remedial measures such as issuance of a warning, recall of products, etc. in a timely manner. The producers or the sellers shall be liable under tort if they fail to take remedial measures in a timely manner or have not made efforts to take remedial measures, thus causing damages. If the products are produced or sold with known defects, causing deaths or severe adverse health issues, the infringed party has the right to claim punitive damages in addition to compensatory damages.

Regulations on Foreign Exchange and the Dividend Distribution

Foreign Exchange Control

According to the PRC Regulation for the Foreign Exchange (《中華人民共和國外匯管理條例》) promulgated by the State Council in January 1996, which was amended in January 1997 and August 2008, and the Regulation on the Administration of the Foreign Exchange Settlement, Sales and Payment (《結匯、售匯及付匯管理規定》) promulgated by the People's Bank of China in June 1996, foreign exchanges required for distribution of profits and payment of dividends may be purchased from designated foreign exchange banks in the PRC upon presentation of a board resolution authorizing distribution of profits or payment of dividends.

According to the Circular of State Administration of Foreign Exchange on Further Improving and Adjusting the Foreign Exchange Policies on 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》) and its appendix promulgated in November 2012 and amended in May 2015, October 2018 and December 2019 by the State Administration of Foreign Exchange (the "**SAFE**"), (1) the opening of and payment into foreign exchange accounts under direct investment accounts are no longer subject to approval by the SAFE; (2) reinvestment with legal income of foreign investors in China is no longer subject to approval by SAFE; (3) the procedures for capital verification and confirmation that foreign-funded enterprises need to go through are simplified; (4) purchase and external payment of foreign exchange under direct investment accounts are no longer subject to approval by SAFE; (5) domestic transfer of foreign exchange under direct investment account is no longer subject to approval by SAFE; and (6) the administration over the conversion of foreign exchange capital of foreign-invested enterprises is improved. Later, the SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) in February 2015, which was further amended in December 2019 and

prescribed that the bank instead of SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

The Provisions on the Administration of Foreign Exchange in Foreign Direct Investments by Foreign Investors (《外國投資者境內直接投資外匯管理規定》), which were promulgated by the SAFE in May 2013 and amended in October 2018 and December 2019, regulate and clarify the administration over foreign exchange administration in foreign direct investments.

According to the Circular on the Reform of the Management Method for 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 the SAFE in March 2015 and amended in December 2019, and the Circular on the Reform and Standardization of the Management Policy of the Settlement of Capital Projects (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) promulgated by the SAFE in June 2016, the settlement of foreign exchange by foreign invested enterprises shall be governed by the policy of foreign exchange settlement on a discretionary basis. However, the settlement of foreign exchange shall only be used for its own operation purposes within the business scope of the foreign invested enterprises and following the principles of authenticity.

According to the Notice of the State Administration of Foreign Exchange on Further Promoting the Convenience 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》) promulgated by SAFE in October 2019, non-investment Foreign Invested Enterprises may use capital to carry out domestic equity investment in accordance with the law under the premise of not violating the negative list and the projects invested are true and in compliance with laws and regulations.

According to the Notice of the 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》) promulgated by SAFE in April 2020, under the condition that the use of funds is genuine and compliant with current administrative provisions on use of income relating to capital account, enterprises are allowed to use income under capital account such as capital funds, foreign debts and overseas listings for domestic payment, without submission to the bank prior to each transaction of materials evidencing the veracity of such payment.

Dividend Distribution

The principal regulations governing distribution of dividends of wholly foreign-owned enterprise, or WFOE, include the PRC Company Law. Under these regulations, WFOEs in China may pay dividends only out of their accumulated profits, if any, determined in accordance with the PRC accounting standards and regulations. In addition, foreign investment enterprises in the PRC are required to allocate at least 10% of their accumulated profits each year, if any, to fund certain reserve funds unless these reserves have reached 50% of the registered capital of the enterprises. These reserves are not distributable as cash dividends.

The SAFE promulgated the Notice on Improving the Check of Authenticity and Compliance to Further Promote Foreign Exchange Control (《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》) in January 2017, which stipulates several capital control measures with respect to outbound remittance of profits from domestic entities to offshore entities, including the following: (1) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (2) domestic entities shall hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities shall make detailed explanations of 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.

Foreign Exchange Registration of Offshore Investment by PRC Residents

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

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

Employee Stock Incentive Plan

According to the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》) which was promulgated by SAFE in February 2012, PRC citizens or non-PRC citizens residing in China for a continuous period of no less than one year (except for foreign diplomatic personnel in China and representatives of international organizations in China) who participate in any stock incentive plan of an overseas publicly listed company shall, through

the domestic company to which the said company is affiliated, collectively entrust a domestic agency (may be the Chinese affiliate of the overseas publicly listed company which participates in stock incentive plan, or other domestic institutions qualified for asset trust business lawfully designated by such company) to handle foreign exchange registration, and entrust an overseas institution to handle issues like exercise of options, purchase and sale of corresponding stocks or equity, and transfer of corresponding funds. In addition, the domestic agency is required to amend the SAFE registration with respect to the stock incentive plan if there is any material change to the stock incentive plan. Moreover, the SAFE Circular 37 provides that PRC residents who participate in a share incentive plan of an overseas unlisted special purpose company may register with local branches of SAFE before exercising rights.

Regulations on Labor

Labor Law and Labor Contract Law

According to the PRC Labor Law (《中華人民共和國勞動法》), which was promulgated by the Standing Committee of the NPC in July 1994 and amended in August 2009 and December 2018 respectively, the PRC Labor Contract Law (《中華人民共和國勞動合同法》), which was promulgated by the Standing Committee of the NPC in June 2007 and amended in December 2012 and came into effect in July 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 in September 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.

Social Insurance and Housing Provident Funds

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which was promulgated by the Standing Committee of the NPC in October 2010 and came into effect in July 2011, and further amended in December 2018, and 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 in January 1999 and amended in March 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 in April 1999 and amended in March 2002 and March 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. Any employer who fails to contribute may be fined and ordered to make good the deficit within a stipulated time limit.

Regulations on Enterprise Income Tax

According to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得税法》) promulgated by the NPC in March 2007 and amended in February 2017 and December 2018, and the Implementation Rules of the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得税法實施條例》) promulgated by the State Council in December 2007 and amended in April 2019, other than a few exceptions, the income tax rate for both domestic enterprises and foreign-invested enterprises is 25%. Enterprises are classified as either "resident enterprises" or "non-resident enterprises". 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. 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. An income tax rate of 10% will normally be applicable to dividends declared to non-PRC resident enterprise investors that do not have an establishment or place of business in the PRC, or that have such establishment or place of business but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends are derived from sources within the PRC.

According to the Arrangement Between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with Respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵税和防止偷漏税的安排》) (the "**Double Tax Avoidance Arrangement**") promulgated in August 2006 and came into effect in August 2006, 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 (《關於執行税收協定股息條款有關問題的通知》) which was promulgated by the State Taxation Administration in February 2009, 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 (《國家税務總局關於税收協定中"受益所有人"有關問題的公告》) which was promulgated by the State Taxation Administration in February 2018 and came into effect in April 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 the Double Tax Avoidance Arrangement.

Regulations on Overseas Listing

On 17 February 2023, the CSRC promulgated Trial Administrative Measures of the 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 "Overseas Listing Trial Measures") and relevant five guidelines, which became effective on 31 March 2023. The Overseas Listing Trial Measures will comprehensively improve and reform the existing regulatory regime for overseas offering and listing of PRC domestic companies' securities and will regulate both direct and indirect overseas offering and listing of PRC domestic companies' securities by adopting a filing-based regulatory regime.

Pursuant to the Overseas Listing Trial Measures, PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfil the filing procedure with the CSRC and report relevant information. The Overseas Listing Trial Measures provides that an overseas offering and listing is explicitly prohibited, if any of the following: (i) such securities offering and listing is explicitly prohibited by provisions in laws, administrative regulations and relevant state rules; (ii) the intended overseas securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with law; (iii) the domestic company intending to make the securities offering and listing, or its controlling shareholder(s) and the actual controller, have committed relevant crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the latest three years; (iv) the domestic company intending to make the securities offering and listing is currently under investigations for suspicion of criminal offenses or major violations of laws and regulations, and no conclusion has yet been made thereof; or (v) there are material ownership disputes over equity held by the domestic company's controlling shareholder(s) or by other shareholder(s) that are controlled by the controlling shareholder(s) and/or actual controller. As advised by our PRC Legal Advisor, our Company does not fall within any of the circumstances aforesaid which overseas offering and listing is explicitly prohibited.

The Overseas Listing Trial Measures also provides that if the issuer meets both the following criteria, the overseas securities offering and listing conducted by such issuer will be deemed as indirect overseas offering by PRC domestic companies: (i) 50% or more of any of the issuer's operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by domestic companies; and (ii) the main parts of the issuer's business activities are conducted in mainland China, or its main place(s) of business are located in mainland China, or the majority of senior management staff in charge of its business operations and management are PRC citizens or have their usual place(s) of residence located in mainland China. The determination of the indirect overseas issuance and listing of domestic enterprises follows the principle of "substance over form". If the relevant issuer does not fall under the two conditions as stated in the comment from the Stock Exchange above, but submits an application for issuance and listing in overseas markets according to the relevant regulations for non-domestic (or regional) issuers, and the disclosed risk factors are mainly related to domestic factors, securities companies and domestic lawyers of the issuer shall comprehensively verify and identify

whether the issuer falls within the scope of filing in accordance with the principle of "substance over form". Where an issuer submits an application for initial public offering to competent overseas regulators, such issuer must file with the CSRC within three business days after such application is submitted.

On the same day, the CSRC also held a press conference for the release of the Trial Measures and issued the Notice on Administration for the Filing of Overseas Offering and Listing by Domestic Companies (《關於境內企業境外發行上市備案管理安排的通知》), which, among others, clarifies that (1) on or prior to the effective date of the Overseas Listing Trial Measures, domestic companies that have already submitted valid applications for overseas securities offering and listing but have not obtained approval from overseas regulatory authorities or stock exchanges may reasonably arrange the timing for submitting their filing applications with the CSRC, and must complete the filing before the completion of their overseas securities offering and listing; (2) a six-month transition period will be granted to domestic companies which, prior to the effective date of the Overseas Listing Trial Measures, have already obtained the approval from overseas regulatory authorities or stock exchanges (such as the completion of hearing in the market of Hong Kong or the completion of registration in the market of the United States), but have not completed the indirect overseas listing if domestic companies fail to complete the overseas listing within such six-month transition period, they shall file with the CSRC according to the requirements.