PRC LAWS AND REGULATIONS

Our business operations are subject to extensive supervision and administration by the Chinese government. This section sets out: (i) the introductions of the Chinese governmental agencies with jurisdiction over our operation; and (ii) the overview of the laws, regulations and policies we must comply with.

REGULATORY AUTHORITIES

NMPA and Its Evaluation Center

China National Medical Products Administration (國家藥品監督管理局) (hereinafter referred to as "NMPA"), successor to the China Food and Drug Administration (國家食品藥品監督管理局) is the department in charge of the pharmaceutical industry of China. It is responsible for drawing up the laws and regulations related to pharmaceuticals and medical devices, making policy planning, formulating departmental regulations, organizing the development and issuance of pharmaceutical and medical device standards, classification and management systems, such as national formulary, and supervising the implementation.

The Center for Drug Evaluation (the "**CDE**") is the technical evaluation unit for drug registration with NMPA. It is mainly responsible for conducting technical evaluation on the drugs applying for registration and verifying the relevant drug registrations.

NHC

The National Health Commission (國家衛生健康委員會) (formerly known as the National Health and Family Planning Commission), (the "**NHC**"), is primary national regulator for public health and family planning management. It is primarily responsible for drafting national health policies, supervising and regulating public health, healthcare services, and health emergency systems, coordinating the reform of medical and health system, organizing the formulation of national drug policies and national essential medicine system, launching an early warning mechanism for the monitoring of the use and clinical comprehensive evaluation of medicine as well as the drug shortage, giving suggestions on the pricing policy of national essential medicine, and regulating the operation of medical institutions and practicing of medical personnel.

NIFDC

The National Institutes for Food and Drug Control (中國食品藥品檢定研究院) (the "**NIFDC**") is a public institution directly subordinate to NMPA and the statutory authority and supreme technical arbitration institution for inspecting the quality of pharmaceuticals and biological products. It is responsible for the approval and registration inspection, import inspection, supervision and inspection, safety evaluation of drugs, biological products, medical devices, foods, dietary supplements, cosmetics, laboratory animals and package materials and the batch release of biological products, the research, distribution and management of the national drug and medical device reference materials and bacterial and viral strains for production verification, as well as the relevant technical research.

In accordance with the Drug Registration Regulation (《藥品註冊管理辦法》) (the "**Drug Registration Regulation**"), the NIFDC shall undertake the drug registration inspection and other relevant work which are required for implementation of drug registration administration. Specifically, the NIFDC or a drug inspection institution designated by the NMPA shall undertake inspection for registration of the following drugs: innovative drugs; modified new drugs (except for traditional Chinese medicine); biological products, radioactive drugs and in-vitro diagnostic reagents subject to drug management; and other drugs stipulated by the NMPA.

China CDC

Under the leadership of National Health Commission, Chinese Center for Disease Control and Prevention (中國疾病預防控制中心) (the "**CDC**") exerts its function in technical guidance and support of public health. Focusing on the key tasks of national disease prevention and control, China CDC studies on the strategies and measures for disease prevention and control, organizing and implementing the work plan for various kinds of disease prevention and control. It takes care of management of public health services, including food safety, occupational safety, health related product safety, radiological health, environmental health, as well as women and children's health. China CDC forcefully carries out operational researches, and enhances technical instruction, training and quality controls in national disease prevention and control, as well as in public health service and plays the leading role nationwide in disease prevention and control, health emergency response and capacity building of public health information.

MOFCOM

Ministry of Commerce (商務部) (the "**MOFCOM**") is responsible for guiding and managing the foreign investment absorption in the country, drawing up the laws and regulations related to foreign investment, formulating the relevant rules, policies and reform schemes, organizing the implementation, supervising and inspecting the implementation status; participating in the formulation and joint issuance of Special Management 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)》) and Encouraging Foreign Investment Industries Catalogue (《鼓勵外商投資產業目錄》) with the National Development and Reform Commission; managing and guiding the foreign investment review, approval and filing works.

NDRC

National Development and Reform Commission (國家發展和改革委員會) (the "**NDRC**") is mainly responsible for participating in the formulation of health development policies, the establishment of technical reform investment projects, the macro guidance and management of the economic operation of pharmaceutical enterprises, and the supervision of the implementation of relevant policies and regulations. NDRC also regulate the price of drugs circulated in the market.

NHSA

National Healthcare Security Administration (國家醫療保障局) (the "**NHSA**") is mainly responsible for formulating and organizing the implementation of policies, plans and standards for medical insurance, maternity insurance, medical aid and other medical security systems, organizing the formulation and adjustment of prices and charging standards for drugs and medical services, and formulating and supervising the implementation of the bidding and procurement policies for drugs and medical consumables.

REGULATORY PROVISIONS

Laws and Regulations Related to Drugs

Introduction

In 2017, the drug regulatory system entered a new and significant period of reform. In October 2017, the General Office of the State Council and the General Office of the Central Committee of the China Communist Party jointly issued the Opinions on Deepening the Reform of the Evaluation and Approval System to Encourage Innovation in 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 "**the Innovation Opinion**") to encourage, among others, the reform of clinical trial management and acceleration of the review and approval for drugs and medical devices marketing.

To implement the regulatory reform introduced by the Innovation Opinion, the National People's Congress, or the NPC and the NMPA has been revising the fundamental laws, regulations and rules regulating pharmaceutical products and the industry, which include the framework law known as the PRC Drug Administration Law (《中華人民共和國藥品管理法》), or the Drug Administration Law. The Drug Administration Law was promulgated by the Standing Committee of the NPC, or the SCNPC, on September 20, 1984 and latest amended on August 26, 2019 and took effect as of December 1, 2019. The State Council issued the Regulations for Implementation of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》), which was promulgated on August 4, 2002 and latest amended on March 2, 2019, to further implement the Drug Administration Law. The NMPA also has its own set of regulations for the Drug Administration Law, and the primary one governing clinical trial applications, marketing approval, and post-approval amendment and renewal is known as the Drug Registration Regulation (《藥品註冊管理辦法》), which was latest amended by the NMPA on January 22, 2020 and effective from July 1, 2020.

Clinical Trials Approval

Before registering a new drug, a sponsor shall complete clinical trials according to the Drug Registration Regulation. To start the clinical trial, a sponsor needs to apply for clinical trial approval first, and the Administrative Regulations of Quality of Drug Clinical Practice (《藥物臨床試驗質量管理規範》), or the DCP, has been promulgated to further promote the research into good practice for clinical trials of drugs and enhance the quality thereof. The DCP was promulgated by NMPA on August 6, 2003 and latest amended by NMPA and NHC which came into effect on July 1, 2020. All clinical trials conducted in China for new drug registration purposes must be approved and conducted at pharmaceutical clinical trial institutions filed according to the Regulations on the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》) promulgated by NMPA and NHC on November 29, 2019.

According to the Announcement of Several Policies on the Evaluation and Examination for Drug Registration (《關於藥品註冊審評審批若干政策的公告》) promulgated by NMPA on November 11, 2015, an umbrella approval would be issued by NMPA for all phases (typically three) of a new drug clinical trial, instead of approvals phase by phase. Provided by the Announcement of the Adjustment of Procedures of the Evaluation and Examination for Drug Clinical Trial (《關於調整藥物臨床試驗審評審批程序的公告》) issued by NMPA on July 24, 2018, applicants could proceed with their clinical trials if they have not received any denial or query from the CDE within 60 business days after the application has been accepted and the relevant application fees have been paid. The newly revised Drug Administration

Law further confirms that the CDE under the State Council shall, within 60 working days from the date on which the application for a clinical trial is accepted, decide on whether to approve it and then notify the clinical trial applicant. In the case of failure to notify the applicant within the prescribed time limit, it shall be deemed as approved. On May 22, 2017, NMPA issued the Announcement of the Opinions on Handling Issues Related to Verification of Drug Clinical Trial Data (《關於藥物臨床試驗數據核查有關問題處理意見的公告》), according to which, if the clinical trial data is incomplete, ill-formed and insufficient to prove the safety and efficacy of the drug, the registration application of the drug will be rejected.

Drug Clinical Trial Registration

Pursuant to the Drug Registration Regulation, upon obtaining the clinical trial approval and before commencing a clinical trial, the sponsor shall register the scheme of the clinical trial and other information on the Drug Clinical Trial Registration and Information Platform for clinical trials of drugs. During the clinical trial of drugs, the sponsor shall update registration information continuously, and register information on the outcome of the clinical trial of drugs upon completion of the clinical trial of drugs. The registration information shall be published on the platform and the sponsor shall be responsible for the veracity of such information. More details are provided in the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) released by the NMPA on September 6, 2013, providing that for all clinical trials approved by the NMPA and conducted in China shall be published through the Drug Clinical Trial Registration and Information Platform. The applicant shall complete trial pre-registration within one month after obtaining the clinical trial approval to obtain the trial's unique registration number and shall complete certain follow-up information and first submission for publication before the first subject's enrollment in the trial. If the foregoing first time of publication has not been submitted within one year after obtaining the clinical trial approval, the applicant shall submit an explanation, and if the procedure is not completed within three years, the clinical trial approval shall automatically be annulled.

Clinical Trial Process and Good Clinical Practices

Pursuant to the Drug Registration Regulation, drug clinical trials in China shall go through four phases. 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. The NMPA requires that the different phases of clinical trials in China shall receive ethics committee approval respectively and comply with the relevant requirements of quality management standards for clinical trial of drugs in PRC. The sponsor shall submit safety update reports on the CDE website regularly during the research and development period. The sponsor shall promptly report to the CDE regarding suspicious and unexpected serious adverse reaction and other potential serious safety risks arising in the course of the clinical trial. Based on the severity of the safety risks, the sponsor may be required to adopt measures to strengthen risk control, and may be required to suspend or terminate the clinical trial of drugs where necessary.

According to the DCP, the sponsor shall provide investigators and the clinical trial institution with legal and economic insurance or guarantee relating to the clinical trial, and ensure that such insurance or guarantee is appropriate to the nature and degree of risks of the clinical trial, excluding the damages caused by the negligence of investigators or the clinical trial institution. Pursuant to the Innovation Opinion, the accreditation of the institutions for drug clinical trials shall be subject to record-filing administration. The conduct of clinical trials must adhere to the DCP, and the protocols must be approved

by the ethics committees. Pursuant to the newly amended Drug Administration Law and the Regulations on the Administration of Drug Clinical Trial Institution (《藥物臨床試驗機構管理規定》) jointly promulgated by NMPA and NHC on November 29, 2019 and effective from December 1, 2019, drug clinical trial institutions shall be subject to filing administration. Entities that only conduct analysis of biological samples related to clinical trials of drugs are not required perform filing procedures.

Human Genetic Resources Approval and Registration

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, if 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. On October 26, 2017, the Ministry of Science and Technology issued the Announcement 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》), which simplified the approval for utilizing human genetic resources for the purpose of obtaining the marketing license of a drug in the PRC.

On May 28, 2019, the State Council of PRC issued the Administrative Regulations on Human Genetic Resources (《人類遺傳資源管理條例》) (the "**Human Genetic Resource Regulation**"), which became effective on July 1, 2019. According to the Human Genetic Resource Regulation, human genetic resource includes human genetic resource materials and information. Human genetic resource materials refer to organs, tissues, cells and other genetic materials containing human genome, genes and other genetic materials. Human genetic resource information refers to information, such as data, generated by human genetic resources materials. The Human Genetic Resource Regulation formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities, under which, a new filing system (as opposed to the advance approval approach originally in place) is put in place for clinical trials utilizing China's human genetic resources in order to obtain market license at clinical institutions without involving the export of human genetic resources materials outside of China. Foreign organizations, individuals and institutions established or actually controlled by foreign organizations and individuals are not allowed to collect or preserve human genetic resources in China or provide human genetic resources abroad.

New Drug Application and Approval

According to the Drug Registration Regulation, an applicant shall, upon completion of studies including pharmacy, pharmacology and toxicology and clinical trial of drugs which support the registration of drug marketing, determination of quality standards, verification of commercial scale manufacturing process, and preparation to undergo examination and inspection for drug registration, submit an application for drug marketing authorization, and submit the relevant research materials in accordance with the submission requirements. The CDE shall organize pharmacist, medical and other technical personnel to comprehensively review the application regarding the safety, effectiveness and quality control of the drug. Where the application is cleared by the comprehensive review, the drug shall be approved for marketing and a drug registration certificate shall be issued.

In accordance with Drug Registration Regulation, during drug clinical trials, applications for conditional approval may be submitted for drugs falling under any of the following circumstances: (1) the drugs are used for treatment of diseases that seriously endanger life and have no effective measure of treatment, and the data of drug clinical trials can prove the efficacy and forecast the clinical value of the drugs; (2) the drugs are urgently needed for public health, and the data of drug clinical trials can prove the efficacy and forecast the clinical value of the drugs; or (3) vaccines are urgently needed to deal with major public health emergencies or other vaccines which the NHC deems to be urgently needed, and it is assessed that the benefits thereof outweigh the risks therein.

An applicant that applies for conditional approval shall communicate with the CDE about the conditions for marketing with conditional approval and the research work to be completed after marketing, among others, and submit an application for marketing authorization after making confirmation through communication. If it is reviewed that the requirements for conditional approval are satisfied, the drug registration certificate shall indicate the validity period of the conditional approval drug registration certificate, the research work to be completed after marketing, time limit for completion, and other relevant matters.

With respect to drugs with conditional approval, MAHs shall take corresponding risk management measures after the drugs are marketed, complete drug clinical trials and relevant research as required within the specified time limit, and submit an application in the form of a supplementary application. If any further research is required during approval of an application for vaccine registration, the vaccine holder shall complete the research within the specified time limit.

Under the Drug Registration Regulation, drugs are classified into Chinese medicine, chemical medicine, biological products and others. Biological products are further divided in 3 categories in the Registration Classification and Application Documents Requirements of Biological Products (《生物製品註冊分類及申報資料要求》) (the "**Registration Category**"), which was promulgated by the NMPA on June 29, 2020 and replaced the previous version issued in 2007. Pursuant to the Registration Category, Category I therapeutic biological products or vaccines refer to those have not been marketed in the PRC or abroad. Category II therapeutic biological products or vaccines refer to improved ones which, compared with the existing products marked in the PRC or abroad, could improve the safety, effectiveness and quality controllability, and have obvious advantages. Category III therapeutic biological products or vaccines refer to those have been marketed in the PRC or abroad.

Pursuant to the newly amended Drug Administration Law, an applicant who has obtained a drug registration certificate shall be recognized as a drug marketing authorization holder, responsible for non-clinical laboratory studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of the Drug Administration Law. The drug marketing authorization holder may engage in manufacturing or distribution on their own or to entrust a licensed third party. At the time of application for drug marketing authorization, the applicant and the manufacturing enterprise shall have held the corresponding Pharmaceutical Manufacturing Permit.

Biosimilars Application and Approval

Biosimilars refer to therapeutic biological products that are similar to approved and registered reference drugs in terms of quality, safety and efficacy. In accordance with the Announcement of the CFDA on Promulgating the Guiding Principles for the Research and Development and Evaluation

Techniques concerning biosimilars (《國家食品藥品監督管理總局關於發佈生物類似藥研發與評價技術指導原則的通告》) on 28 February 2015, biosimilars shall be declared according to the application procedures for new drugs. Application materials for therapeutic biological products shall be submitted following specific requirements in the Guidelines for the R&D and Evaluation of Biosimilar Drugs (for Trial Implementation) (《生物類似藥研發與評價技術指導原則(試行)》) (the "**Guiding Principles**").

In February 2015, the CFDA released the Guiding Principles, which outline the regulatory framework for biosimilars in China and provide the basic principles for the evaluation and management of biosimilars. It sets forth the definition of biosimilars and reference drugs, the requirements in relation to the selection of reference drugs, the basic principles for the technical review, the criteria for comparability, and the conditions under which extrapolations of indications would be permissible. According to the Guiding Principles, a biosimilar drug should in principle have the same amino acid sequence as the reference drug, and the R&D and evaluation of biosimilars should be carried out in accordance with basic principles (i.e. comparison principle, dose-escalation principle, consistency principle and equivalence principle) and should cover pharmaceutical, non-clinical and clinical research and evaluation. The Guiding Principles set out provisions for the expansion of indications of biosimilars. When similarities are proved in comparative trials, the indications of biosimilars may be expanded to include other indications of reference drugs. The expanded indications shall be those with same pathological mechanisms and/or receptors and the same action mechanisms and targets. In comparative trials, appropriate indications shall be selected and subsequent evaluation shall be made on the safety and immunogenicity of the expanded indications. The expansion of indications shall be considered according to product features on case basis. However, caution shall be taken in expanding indications for groups with combined medication, patients with different combined diseases and different recommended dosage.

With respect to the application and approval process for imported biosimilars developed overseas, according to the PRC Drug Administration Law (《中華人民共和國藥品管理法》), the importation of biosimilars which have been approved overseas shall be examined by the drug regulatory authority of the State Council. Import approval shall be granted only after the examination confirms that the drugs comply with quality standards and are safe for use. A Registration Certificate for Imported Drugs shall then be issued. According to the Drug Registration Regulation (《藥品註冊管理辦法》), the application for registration of drugs produced overseas shall be filed in accordance with the requirements for the detailed classification and the corresponding application materials. In order to cooperate with the implementation of the Drug Registration Regulation, the NMPA formulated the Registration Category, and the Registration Classification of Biological Products part came into effect on July 1, 2020 while the Requirements for Application Materials part came into effect on October 1, 2020. According to the Registration Category, the biosimilars are classified as category 3.3.

On February 10, 2021, the NMPA issued the Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars (《生物類似藥相似性評價和適應症外推技術指導原則》) (the "**Technical Guidelines**") to further standardize the development and evaluation of biosimilars, which came into effect on the same day. According to the Technical Guidelines, the similarity evaluation of biosimilars should be carried out comprehensively from the perspective of pharmaceutical, non-clinical and clinical studies to determine the overall similarity. And the similarity evaluation should be carried out on different stages of biopharmaceutical studies.

Drug Manufacturing

According to the Drug Administration Law and Administrative Measures on Supervision of Pharmaceutical Manufacturing (《藥品生產監督管理辦法》) which was promulgated by the NMPA on December 11, 2002 and last amended on January 22, 2020 and effective on July 1, 2020, all facilities that manufacture drugs in China must apply for a Pharmaceutical Manufacturing Permit which are issued by the drug supervision and administration department of the province, autonomous region or municipality directly under the central government where it is domiciled. The Pharmaceutical Manufacturing Permit is valid for five years and shall be renewed six months before the expiry date. The drug marketing authorization holder who entrusts another party to produce preparations shall meet the requirements as specified in Administrative Measures on Supervision of Pharmaceutical Manufacturing, sign an entrustment agreement and a quality agreement with a qualified drug producer, and submit the relevant agreements and the application materials of the actual production site to provincial drug administrative departments where the drug marketing authorization holder is located to apply for the drug production license. When an application for marketing authorization is submitted, the applicant and the manufacturer shall have obtained the corresponding Pharmaceutical Manufacturing Permit.

Drug Operation

As required by Drug Administration Law and Administrative Measures for Drug Business Permits (《藥品經營許可證管理辦法》) which was promulgated by the NMPA on February 4, 2004 and amended on November 17, 2017, operation of drug business, including drug wholesale and drug retail, is prohibited without a Drug Business Permit. A Drug Business Permit shall state the validity period and the scope of business and be subject to review and reissuance upon expiry of the validity period. Drug business operators shall comply with the drug operation quality management norms, establish and improve their business operation quality management system, and ensure that the whole drug business process continuously comply with statutory requirements.

In China, governmental pricing controls on drugs (other than narcotic and certain psychiatric drugs) have been lifted since May 2015 when the Opinions on Advancing Drug Price Reform (《推進藥品價格改革意見》) came into effect. Instead of direct governmental controls, the government exercises control over the drugs through establishing a centralized tender process or centralized procurement mechanism, revising the National Reimbursement Drug List or provincial medical insurance drug catalogs and strengthening regulation of medical and pricing practices. Also, according to the Opinions on the Reform of Review and Approval System for Drugs and Medical Devices (《關於改革藥品醫療器械審評審批制度的意見》) promulgated by the State Council in August 2015, enterprises which apply for the registration of new drugs should promise that the prices of their products on the PRC market should not be higher than the comparable market prices in original countries or the surrounding area of the PRC.

According to the Interim Measures for the Administration of Use of Drugs Covered by the Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》), western drugs and Chinese drugs in the national Drug Catalog are divided into "drugs of Category A" and "drugs of Category B". "Drugs of Category A" are drugs which are necessary for clinical treatment, are widely used, have a definite effect, and have a lower price or treatment cost among similar drugs. "Drugs of Category B" are drugs which may be selected for clinical treatment, have definite effect, and have a slightly higher price or treatment cost than "drugs of Category A" among similar drugs. The expenses for "drugs of Category A" used by the insured shall be paid according to the payment standards and sharing measures stipulated for basic medical insurance, while those for "drugs of Category B" shall be first paid by the insured in a certain

percentage, and then paid according to the sharing measures stipulated for basic medical insurance. The percentage of expenses paid by individuals for "drugs of Category B" is determined by the provincial or pooling region's healthcare security administrative department.

Laws and Regulations Related to Vaccines

Vaccine Policies

The Laws on Prevention and Treatment of Infectious Diseases (《中華人民共和國傳染病防治法》), issued in February 1989 and amended in August 2004 and June 2013, stipulates that a planned prophylactic vaccination system is performed in the PRC. The health administration department under the State Council and such departments under the people's governments of provinces, autonomous regions, and municipalities directly under the central government shall, in accordance with the requirements of prevention and control of infectious diseases, draw up plans for prophylactic vaccination against infectious diseases and coordinate efforts for their implementation. Vaccines used for prophylactic vaccination shall conform to the quality standards of the PRC.

According to the Vaccine Administration Law of the PRC (《中華人民共和國疫苗管理法》) (the "**Vaccine Administration Law**"), which was promulgated by the SCNPC on June 29, 2019 and came into effect on December 1, 2019, the State applies the most stringent management system for vaccines, and adheres to the principles of safety first, risk management, whole-process control, scientific supervision and social co-governance. Also, a National Immunization Program system is applied in the PRC, under which the government would provide vaccines under the immunization program to the residents free of charge.

According to Biosecurity Law of the PRC (《中華人民共和國生物安全法》) (the "**Biosecurity Law**"), which was promulgated by the SCNPC on October 17, 2020 and came into effective on April 15, 2021, organizations engaged in biotechnology research and development shall comply with the national safety administration norms for biotechnology research and development. The high- or medium-risk biotechnology research and development activities shall be carried out by corporate bodies lawfully established within the territory of China and shall be approved or filed for record in accordance with the law. The corporate bodies engaged in high- or medium-risk biotechnology research and development activities shall conduct risk assessment, formulate risk prevention and control plans and emergency plans for biosafety incidents, and reduce the risks in the implementation of the research and development activities. The clinical research of new biomedical technologies shall pass the ethical review and be conducted in the medical institutions with corresponding qualifications; the operation of human clinical research shall be conducted by the professional medical workers with corresponding qualifications.

Vaccine Administration

On January 15, 2017, the General Office of State Council issued Opinions on Further Enhancing Administration of Circulation and Vaccination of Vaccines (《關於進一步加強疫苗流通和預防接種管理工作的意見》) (the "**Vaccine Opinion**") among others, to improve the work mechanism for the management of vaccines and promote the independent R&D and quality improvement of vaccines. On June 29, 2019, the SCNPC released the Vaccine Administration Law, which requires the most stringent management system for vaccines, and at the same time, supports the basic research and applied research on vaccines, promotes the development and innovation of vaccines, including the development, production and reserve of vaccines for the prevention and control of serious diseases in the national

strategy. Entities and individuals engaged in vaccine development, production, circulation and vaccination shall abide by the laws, regulations, rules, standards and specifications, ensure that the information during the whole process is true, accurate, complete and traceable, assume responsibilities in accordance with the law and accept social supervision.

Pursuant to the Vaccine Administration Law, vaccine marketing authorization holders shall establish an electronic vaccine traceability system, which is connected with the national electronic vaccine traceability collaboration platform to realize the traceability and verifiability of the smallest packaging units of vaccines in the whole process of production, circulation and vaccination. In addition, vaccine marketing authorization holders are required to purchase compulsory liability insurance for their vaccines. Where an inoculated person suffers any damage due to vaccine quality problems, the insurance company shall pay compensation within the limit of liability insured.

Development and Registration of Vaccines

On October 14, 2005, the NMPA promulgated the Notice on Issuing Six Technical Guidelines including the Technical Guidelines on Preclinical Study of Preventive Vaccines (《關於印發〈預防用疫苗臨床前研究技術指導原則〉等6個技術指導原則的通知》), which specified the requirements on preclinical research, change of production process, quality control in clinical stages of vaccine to ensure its safety and efficacy.

According to the Vaccine Administration Law, clinical trials of vaccines shall not be conducted without obtaining the approval of the drug administrative department under the State Council. Clinical trials of vaccines shall be conducted or organized for implementation by Grade III medical institutions that meet the conditions prescribed by the drug administrative department under the State Council and the competent health department under the State Council, or by disease prevention and control institutions at or above the provincial level.

A vaccine to be marketed within the territory of China shall be approved by the drug administrative department under the State Council and obtain a drug registration certificate; when applying for registration of a vaccine, an applicant shall provide true, sufficient and reliable data, information and samples. With respect to the vaccines urgently needed for disease prevention and control as well as the innovative vaccines, the drug administrative department under the State Council shall prioritize their evaluation and approval.

According to the Vaccine Administration Law, for vaccines urgently needed for disease prevention and control as well as the innovative vaccines, the NMPA shall prioritize the evaluation and approval work. With respect to a vaccine urgently needed for responding to a major public health emergency or any other vaccines urgently needed as determined by the health department under the State Council, if the benefits outweigh the risks upon assessment, the drug administrative department under the State Council may conditionally approve the vaccine registration application.

According to the Drug Registration Regulation, before the applicant submits an application for drug marketing authorization, it shall communicate with the CDE and, upon communication and confirmation, submit the application for drug marketing authorization and simultaneously submit an application for prioritized review and approval. Upon included in the procedures for prioritized review and approval, the sponsors could enjoy, among others, a shortened review period for drug marketing authorization within 130 days.

Production and Batch Release of Vaccines

According to the Vaccine Administration Law, whoever engages in vaccine production activities shall, in addition to meeting the conditions for engaging in drug production activities as prescribed in the Drug Administration Law, also meet the following conditions: (1) Having moderate scale and sufficient capacity reserves; (2) Having systems, facilities and equipment for ensuring bio-safety; and (3) Meeting the needs of disease prevention and control. A vaccine marketing authorization holder shall have the capacity for production of vaccines. If it is really necessary to entrust the production of vaccines in excess of its capacity, the vaccine marketing authorization holder shall obtain the approval of the drug administrative department under the State Council. When it accepts the entrustment to produce vaccines, it shall abide by the provisions of the Vaccine Administration Law and the relevant provisions of the State, so as to guarantee the quality of vaccines.

The State adopts a batch release system for vaccines. Each batch of vaccines shall, before being sold or imported, be examined and inspected according to the relevant technical requirements by the batch release institution designated by the drug administrative department under the State Council. If the requirements are met, a batch release certificate shall be issued; otherwise, a notice on rejecting batch release shall be issued. According to the Measures for Administration of Batch Release of Biological Products (《生物製品批簽發管理辦法》) issued on December 13, 2002 and latest amended on December 11, 2020 and effective on March 1, 2021, the vaccine products with marketing approval shall be subject to document review and sample inspection by the drug batch release institution designated by NMPA and pass the biological product batch release approval before the marketing and sales of each batch of products. Vaccines that are urgently needed for infectious disease prevention and control or for emergencies shall be exempted from the biological product batch release approval upon approval by the NMPA.

According to Notice on further strengthening supervision of vaccine quality and safety (關於進一步加強疫苗質量安全監管工作的通知) which was promulgated by the NMPA on December 31, 2010 and came into effective on the same day, approval of new production of already marketed vaccine products is strictly controlled, which further improve the quality standards of products on the market. Strict quality standards will be applied to vaccines produced by multiple companies, and vaccines produced with outdated production methods, preservatives and excipients with safety risks will be phased out.

Circulation of Vaccines

According to the Vaccine Opinion, vaccines should be procured online on the provincial public resource trading platform in accordance with the principles of transparency, competition, and fair trade.

According to the Vaccine Administration Law, the competent health department under the State Council shall, in concert with the finance department under the State Council and other departments, organize centralized bidding or unified negotiation to form and publish the bid-winning price or transaction price of vaccines under the National Immunization Programs, and all provinces, autonomous regions and municipalities directly under the central government shall implement centralized procurement for such vaccines. The procurement of vaccines under other immunization programs other than those under the National Immunization Program and vaccines not under any immunization program shall be organized by provinces, autonomous regions and municipalities directly under the central government through provincial public resources trading platforms.

According to the Vaccine Administration Law, the price of vaccines shall be set reasonably and independently by the vaccine marketing authorization holder according to law. The price level, price difference rate and profit rate of vaccines shall be kept within a reasonable range. A vaccine marketing authorization holder shall, as agreed upon in the procurement contract, supply vaccines to the disease prevention and control institution. A vaccine marketing authorization holder shall, as agreed upon in the procurement contract, deliver vaccines to the disease prevention and control institution or the inoculation entity designated thereby. The vaccine marketing authorization holder and disease prevention and control institution that distribute vaccines themselves shall have the conditions for cold chain storage and transport of vaccines or may entrust eligible vaccine distribution entities to distribute vaccines. A vaccine marketing authorization holder shall, in accordance with the provisions, set up true, accurate and complete sales records, and preserve them for inspection for at least five years after expiry of the validity of the vaccines.

With regard to storage and transportation of vaccines, the present Notice for Distributing Regulations on Administration of Vaccine Storage and Transportation (2017 Edition) (《疫苗儲存和運輸管理規範(2017年版)》), which promulgated by the NMPA and NHC on December 15, 2017 and effective on the same day, requires that, among others, vaccine production enterprises shall be equipped with full-time staff for vaccine management, establish a management system for vaccine storage and transport, maintain cold chain facilities and equipment for storage and transport of vaccines to ensure the quality of vaccines, and must store and transport vaccines in light of the instructions for use of vaccines, the vaccination work rules and other relevant requirements on temperature for storage and transport of vaccines.

Laws and Regulations Related to Foreign Investment

Since January 1, 2020, the Foreign Investment Law of the People's Republic of China (《中華人民共和國外商投資法》) (the "**Foreign Investment Law**") promulgated by the National People's Congress has come into effect. The Law of the People's Republic of China on Sino-Foreign Equity Joint Ventures and the Law of the People's Republic of China on Wholly Foreign-Owned and Law of the People's Republic of China on Sino-Foreign Cooperative Joint Ventures were abolished at the same time. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors. While the organization form, institutional framework and standard of conduct of foreign-invested enterprises shall be subject to the provisions of the Company Law of the PRC and other laws. The PRC government will implement the management system of pre-entry national treatment and the Negative List for foreign investment abolished the original approval and filing administration system for the establishment and change of foreign-invested enterprises. Pre-entry national treatment refers to the treatment accorded to foreign investors and their investments at the stage of investment entry which is no less favorable than the treatment accorded to domestic investors and their investments. Negative List refers to a special administrative measure for the entry of foreign investment in specific sectors as imposed by the PRC. The PRC accords national treatment to foreign investment outside of the Negative List. The current Negative List is the Special Management Measures (the "**Negative List**") for the Access of Foreign Investment (2021 Revision) (《外商投資准入特別管理措施(負面清單)(2021年版)》) issued by the NDRC and the MOFCOM on December 27, 2021, and came into effect on January 1, 2022 which lists the special management measures for foreign investment access for industries regulated by the Negative List, such as equity requirements and senior management requirements. In the current implementation of the negative list, the vaccine industry is not explicitly listed as a negative regulatory object.

While strengthening investment promotion and protection, the Foreign Investment Law further regulates foreign investment management and proposes the establishment of a foreign investment information reporting system that replaces the original foreign investment enterprise approval and filing system of the Ministry of Commerce. The foreign investment information reporting is subject to the Foreign Investment Information Reporting Method (《外商投資信息報告辦法》) jointly developed by the MOFCOM and the SAMR, which came into effect on January 1, 2020. According to the Foreign Investment Information Reporting Method, foreign investors who directly or indirectly carry out investment activities in China shall submit investment information to the competent commercial department through the enterprise registration system and the National Enterprise Credit Information Publicity System and the reporting methods include initial reports, change reports, cancelation reports, and annual reports.

Laws and Regulations Related to Product Liability

Pursuant to the Product Quality Law (《中華人民共和國產品質量法》) promulgated on February 22, 1993 and amended on July 8, 2000, August 27, 2009 and December 29, 2018 respectively by SCNPC, Seller shall be responsible for the repair, replacement or return of the product sold if (1) the product sold does not possess the properties for use that it should possess, and no prior and clear indication is given of such a situation; (2) the product sold does not conform to the applied product standard as carried on the product or its packaging; or (3) the product sold does not conform to the quality indicated by such means as a product description or physical sample. If a consumer incurs losses as a result of purchased product, the seller shall compensate for such losses.

Pursuant to the PRC Civil Code (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and coming into effect on January 1, 2021, where a patient suffers damage due to defects in drugs, he may seek compensation from the drug marketing authorization holder or also from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution, after it has made the compensation, shall have the right to recover the compensation from the liable drug marketing authorization holder.

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 on October 31, 1993 and was amended on August 27, 2009 and October 25, 2013 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the amendments made on October 25, 2013, all business operators must pay high attention to protecting customers' personal information and must strictly keep confidential any consumer information they obtain during their business operations.

Laws and Regulations Related to Environmental Protection and Fire Prevention

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 on December 26, 1989, came into effect on the same day and last amended on April 24, 2014, 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. Meanwhile, local environment protection authorities may formulate local standards which are more rigorous than the national standards, in which case, the concerned enterprises must comply with both the national standards and the local standards.

Environmental Impact Appraisal

According to 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 on November 29, 1998, amended on July 16, 2017 and became effective on October 1, 2017, 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. As to a construction project, for which an environmental impact report or the environmental impact statement is required, the construction employer shall, before the commencement of construction, submit the environmental impact report or the environmental impact statement to the relevant authority at the environmental protection administrative department for approval. If the environmental impact assessment documents of the construction project have not been examined or approved upon examination by the approval authority in accordance with the law, the construction employer shall not commence the construction.

According to the Environmental Impact Appraisal Law of PRC (《中華人民共和國環境影響評價法》), which was promulgated by the SCNPC on October 28, 2002, amended on July 2, 2016 and December 29, 2018, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the seriousness of effect that may be exerted on the environment.

Pollutant Discharge Licensing

Pursuant to the Administrative Measures for Pollutant Discharge Licensing (for Trial Implementation) (《排污許可管理辦法(試行)》) promulgated on January 10, 2018 and partially revised on August 22, 2019 by the Ministry of Ecology and Environment, or the MEE, enterprises and public institutions as well as other producers and operators included in the Catalog of Classified Administration of Pollutant Discharge License for Stationary Pollution Sources shall apply for and obtain a pollutant discharge license within a prescribed time limit. Any enterprise that fails to obtain a pollutant discharge license as required shall not discharge pollutants.

According to the Catalog of Classified Administration of Pollutant Discharge License for Stationary Pollution Sources (2019 Version) (《固定污染源排污許可分類管理名錄(2019年版)》) issued by the MEE on December 20, 2019, key management, simplified management and registration management of pollutant discharge permits are implemented according to factors such as the amount of pollutants generated, the amount of emissions, the degree of impact on the environment, etc., and only pollutant discharge entities that implement registration management do not need to apply for a pollutant discharge permit.

The State Council issued the Regulation on Pollutant Discharge Permit Administration (《排污許可管理條例》) on January 24, 2021 to further enhance the pollutant discharge administration. The administration on pollutant discharge units are divided into key management and simplified management pursuant to the amount of pollutant caused and discharged and the impact on the environment. The review, decision and information disclosure of pollutant discharge licenses shall be handled through the national pollutant discharge license management information platform. The pollutant discharge license is valid for 5 years and the discharging units should apply for renewal 60 days before the expiry for continues pollutant discharge.

Acceptance Inspection on Environmental Protection Facilities

Interim Measures for Acceptance inspection of Environmental Protection upon Completion of Construction Projects (《建設項目竣工環境保護驗收暫行辦法》) also requires that upon completion of construction for which an environment impact report or environment impact statement is formulated, the constructor shall conduct acceptance inspection of the environmental protection facilities pursuant to the standards and procedures stipulated by the environmental protection administrative authorities of the State Council, formulate the acceptance inspection report, and announce the acceptance inspection report pursuant to the law except for circumstances where there is a need to keep confidentiality pursuant to the provisions of the State. Where the environmental protection facilities have not undergone acceptance inspection or do not pass acceptance inspection, the construction project shall not be put into production or use.

Fire Prevention Design and Acceptance

The Fire Prevention Law of the PRC (《中華人民共和國消防法》) ("**the Fire Prevention Law**"), was issued on April 29, 1998, then became effective on September 1, 1998 and latest amended on April 29, 2021. According to the Fire Prevention Law, for special construction projects stipulated by the housing and urban-rural development authority of the State Council, the developer shall submit the fire safety design documents to the housing and urban-rural development authority for examination, while for construction projects other than those stipulated as special development projects, the developer shall, at the time of applying for the construction permit or approval for work commencement report, provide the fire safety design drawings and technical materials which satisfy the construction needs. According to Interim Regulations on Administration of Examination and Acceptance of Fire Control Design of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) issued by the Ministry of Housing and Urban-Rural Development of the PRC 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.

Laws and Regulations Related to Intellectual Property

Patent

The Patent Law of the People's Republic of China (《中華人民共和國專利法》) (the "**Patent Law**") is revised by the SCNPC on October 17, 2020 and came into effect on June 1, 2021. According to the current Patent Law, when the invention or utility model patent is granted, unless otherwise stipulated in the Patent Law, without the approval of the patent owner, no entity or person shall implement the relevant patent, that is, manufacture, use, offer to sell, sell or import the patented products for business purpose, or use the patented method and use, offer to sell, sell or import the products directly obtained with the patented method. Implementing the patent without the approval of the patent owner constitutes the infringement of patent rights. Any dispute in connection with this shall be resolved by the relevant parties through negotiation. If the relevant parties refuse to negotiate or the negotiation fails, the patent owner or the relevant stakeholders may file a lawsuit in the people's court or turn to the patent administration authorities for handling.

Pursuant to the Rules for Implementation of the Patent Law of the People's Republic of China (《中華人民共和國專利法實施細則》), which was amended by the State Council on 9 January 2010 and became effective on 1 February 2010, where the entity to which a patent right is granted fails to agree with the inventor or the designer on, or to specify in its legitimately enacted company rules the way and amount of reward and remuneration specified in its rules and regulations established by law, the entity shall reward to the inventor or designer within 3 months from the announcement of granting the patent. The minimum reward for one invention patent shall not be less than RMB3,000; and the minimum reward for one utility model or design patent shall not be less than RMB1,000. The entity shall, after exploiting the patent for invention-creation within the term of the patent right, pay the inventor or designer remuneration at a percentage of not less than 2% each year from the profits generated from the exploitation of the invention or utility model patent, or at a percentage of not less than 0.2% from the profits gained from the exploitation of the design, or pay the inventor or creator a lump sum of remuneration by reference to the above percentages; where the entity to which a patent right is granted authorize other entity or individual to exploit its patent, it shall reward the inventor or designer at a percentage no less than 10% from the license and royalty fee.

Trademark

According to the Trademark Law of the People's Republic of China (《中華人民共和國商標法》) revised by the SCNPC on April 23, 2019 and taking effect on November 1, 2019 (the "**Trademark Law**"), the registered trademark has a validity period of 10 years starting from the registration date. The trademark registrant enjoys the exclusive right to use the trademark. Any dispute in connection with the activities the infringe the exclusive right to use a registered trademark set out in Article 57 of the Trademark Law shall be resolved by the relevant parties through negotiation. If the relevant parties refuse to negotiate or the negotiation fails, the trademark registrant or the relevant stakeholders may file a lawsuit in the people's court or turn to the industrial and commercial administrative department for handling.

Domain Names

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

Laws and Regulations Related to Employment and Social Securities

Employment

According to the Labor Law of the People's Republic of China (《中華人民共和國勞動法》) taking effect on January 1, 1995 and revised on December 29, 2018 and the Labor Contract Law of the People's Republic of China (《中華人民共和國勞動合同法》) taking effect on January 1, 2008 and revised on December 28, 2012, a labor contract shall be signed when the employer establishes labor relationship with the worker. The labor contracts shall be signed in written. When agreement is reached after negotiation, labor contracts, including fixed term labor contract, open term labor contract or labor contract based on the completion of work, shall be signed, and the salary shall be no less than the local minimum wage standard. The employer and the worker shall each fully perform its/his obligations in accordance with the labor contract.

Social Securities

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which issued by the SCNPC on October 28, 2010 and came into effect on July 1, 2011 and was newly revised on December 29, 2018, enterprises and institutions in the PRC shall provide their employees with welfare schemes covering basic pension insurance, unemployment insurance, maternity insurance, work-related injury insurance and basic medical insurance. The employer shall apply to the local social insurance agency for social insurance registration within 30 days from the date of its formation. And it shall, within 30 days from the date of employment, apply to the social insurance agency for social insurance registration for the employee. Any employer who violates the regulations above shall be ordered to make correction within a prescribed time limit; if the employer fails to rectify within the time limit, the employer and its directly liable person will be fined. If the employer fails to pay social insurance contributions on time and in full, the social insurance agency shall place an order with the employer demanding full payment within a prescribed period, and an overdue payment fine at the rate of 0.5‰ shall be levied as of the date of indebtedness. When the payment is not made at the expiry of the prescribed period, a fine above the overdue amount but less than its triple shall be demanded by the authoritative administrative department. Meanwhile, the Interim Regulation on the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) (issued by the State Council on January 22, 1999 and came into effect on the same day and was recently revised on March 24, 2019) prescribes the details concerning the social securities.

Housing Provident Fund

According to Regulations on Management of Housing Provident Fund (《住房公積金管理條例》) issued by the State Council on April 3, 1999 and revised and implemented on March 24, 2019, the enterprises shall fully pay the housing provident fund contribution for the employees on time, with the contribution ratio no less than 5% of the average monthly salary of the relevant employee in the previous year. The housing provident fund contribution paid by the employees and the employers shall be owned by the employees.

Laws and Regulations Related to Tax

Enterprise Income Tax

According to the Corporate Income Tax Law of the People's Republic of China (《中華人民共和國企業所得税法》), which was promulgated on March 16, 2007, came into effect on January 1, 2008 and amended by the SCNPC on February 24, 2017 and December 29, 2018, and Implementation Regulations for the Corporate Income Tax Law of the People's Republic of China (《中華人民共和國企業所得税法實施條例》), which was promulgated by the State Council on December 6, 2007 and came into effect on January 1, 2008, and amended by the State Council on April 23, 2019 and came into effect on the same date, all the domestic enterprises in China (including foreign-invested enterprises) shall be subject to enterprise income tax at the uniform tax rate of 25%, except for the high-tech enterprises certificated by the state, which will be subject to enterprise income tax at the reduced rate of 15%, or the qualified small low-profit enterprises, which will enjoy the reduced enterprise income tax rate of 20%.

Value-added Tax

The Provisional Regulations on Value-added Tax of the People's Republic of China (《中華人民共和國增值税暫行條例》), which was promulgated on December 13, 1993, came into effect on January 1, 1994, and last amended on November 19, 2017, and the Detailed Implementing Rules of the Provisional Regulations on Value-added Tax of the People's Republic of China (《中華人民共和國增值税暫行條例實施細則》), which was promulgated on December 25, 1993 and came into effective on the same date, and was amended on December 15, 2008 and October 28, 2011, came into effect on November 1, 2011 set out that all taxpayers selling goods or providing processing, repairing or replacement services, sales of services, intangible assets and immovable assets and importing goods in China shall pay a value-added tax. A tax rate of 17% shall be levied on general taxpayers selling goods and services, leasing of tangible movable assets or importing goods whereas the applicable rate for the export of goods by taxpayers shall be nil, unless otherwise stipulated. According to the Notice of the Ministry of Finance and the SAT on Adjusting Value added Tax Rates (《財政部、國家税務總局關於調整增值税税率的通知》) issued on April 4, 2018 and became effective on May 1, 2018, the deduction rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively. According to the Notice of the Ministry of Finance, the SAT and the General Administration of Customs on Relevant Policies for Deepening Value Added Tax Reform (《關於深化增值税改革有關政策的公告》) issued on March 20, 2019 and became effective on April 1, 2019, the VAT rate was reduced to 13% and 9%, respectively.

Laws and Regulations Related to Foreign Exchange

The Regulations on Foreign Exchange Control of the PRC (《中華人民共和國外匯管理條例》) issued by the State Council on January 29, 1996 and implemented on April 1, 1996, which was revised on January 14, 1997 and August 5, 2008 respectively, is the key foreign exchange control regulation in force, applicable to the foreign exchange income and payment and foreign exchange operation activities of the domestic institutions and domestic individuals in China and the foreign exchange payment and collection and foreign exchange operation activities of the overseas institutions and overseas individuals in China.

The Regulations on Foreign Exchange Settlement, Sale and Payment (《結匯、售匯及付匯管理規定》) issued by PBOC on June 20, 1996 and implemented on July 1, 1996 set out requirements on the foreign exchange settlement, purchase, payment, opening of foreign exchange account and external payment by the domestic institutions, individual citizens, foreign institutions in China and foreigners in China.

According to the Decision of the State Council on Canceling and Adjusting A Batch of Items Requiring Administrative Approval (《國務院關於取消和調整一批行政審批項目等事項的決定》) issued by the State Council on October 23, 2014, SAFE and its branches canceled the review and approval on the foreign exchange settlement for the repatriation of funds raised abroad under the overseas listed foreign capital stock account.

In addition, according to the Notice of SAFE on Relevant Issue Concerning the Administration of Foreign Exchange for Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》) issued by the SAFE on December 26, 2014, the domestic companies shall register the overseas listing with the foreign exchange control bureau located at its registered address in 15 working days after the completion of the overseas listing and issuance. The funds raised by the domestic companies through overseas listing may be repatriated to China or deposited overseas, provided that the intended use of the fund shall be consistent with the contents of the document and other public disclosure documents.

According to the Notice of SAFE on Reforming and Standardizing Capital Account Foreign Exchange Settlement Administration Policies (《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》) issued by SAFE on June 9, 2016, it has been specified clearly in the relevant policies that, for the capital account foreign exchange income subject to voluntary foreign exchange settlement (including the repatriation of the proceeds from overseas listing), the domestic institutions may conduct the foreign exchange settlement at the banks according to their operation needs. The proportion of the capital account foreign exchange income subject to voluntary foreign exchange settlement was tentatively set as 100%, provided that SAFE may adjust the aforesaid proportion according to the international payment balance status in good time.