OVERVIEW

Our business in the PRC is subject to a large number of laws and regulations and extensive government supervision. This section sets out a summary of the major relevant laws, regulations, rules and policies which may have material impact on our business, particularly in relation to: (i) drugs; (ii) anti-unfair competition; (iii) production safety and liability; (iv) environmental protection; (v) intellectual property rights; (vi) foreign investment in the PRC; (vii) employment and social security and housing funds; (viii) taxation; and (ix) foreign exchange control.

LAWS AND REGULATIONS RELATING TO DRUGS

Regulatory Regime in the PRC

We operate our business in China through our PRC subsidiaries under a legal regime consisting of the National People's Congress of the PRC (the "**NPC**"), the Standing Committee of the National People's Congress of the PRC (the "**SCNPC**"), the State Council and several ministries and agencies under its authority including, among others, the NMPA and its local regulatory branches, the NHC, the NDRC.

According to the Institutional Reform Program of the State Council (《國務院機構改革方案》) promulgated by the NPC on March 17, 2018, the NMPA, formerly known as China's Food and Drug Administration, was established as a regulatory authority responsible for registration and supervision of pharmaceutical products, cosmetics and medical devices under the supervision of the SAMR, a newly established institution for supervising and administrating the market in China. The NHC performs multiple functions in relation to the administration of pharmaceutical products, including but not limited to formulating national health policies, coordinating to deepen the reform of the medical and health system, and organizing the formulation of a national essential drugs system. The NDRC is responsible for high-level guidance and administration of the health care industry, including establishing and monitoring the implementation of the pricing policy of drugs, and regulating the overall drug prices.

Reform of Medical and Healthcare System

Pursuant to the Opinions of the State Council on Deepening the Reform of the Medical and Healthcare System (《中共中央、國務院關於深化醫藥衛生體制改革的意見》) issued on March 17, 2009, the reform of the medical and healthcare system has been orderly conducted. The medical insurance system has been gradually improved and the basic medical mechanism has been consolidated and improved.

On October 25, 2016, the State Council introduced the Plan for Healthy China 2030 (《健康中國2030規劃綱要》), which proposes to (i) improve the system for collaborative innovation involving different aspects of policy, industry, education, research and practice, and promoting medical innovation, transformation and upgrading, (ii) research to establish an

examination and approval system based on clinical effects, and raise the examination and approval standards for drugs (medical devices), and (iii) accelerate the review and approval of innovative drugs (medical devices) and new drugs (medical devices) that are urgently needed in clinical practice.

According to the Notice of the Key Task of Deepening the Reform of Medical and Healthcare System in 2019 (《國務院辦公廳關於印發深化醫藥衛生體制改革2019年重點工作任務的通知》), issued by the General Office of the State Council in May 2019, accelerating and approving the registration of anticancer drugs, strengthening the work of cancer prevention, and unblocking the temporary import channels will continue to be the focus of the reform of the medical and healthcare system.

Laws and Regulations on Drug Research and Development

Drug Administration Law of the PRC

Pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the "**Drug Administration Law**"), last amended on August 26, 2019 and became effective on December 1, 2019, the PRC encourages the research and development of new drugs, and protects the legal rights and interests of citizens, legal persons and other organizations in the research and development of new drugs. The dossier on a new drug research and development, including the manufacturing method, quality standards, results of pharmacological and toxicological tests and the related data, documents and the samples, shall, in accordance with the regulations of NMPA be truthfully submitted to the competent authority for approval before the clinical trial is conducted. The NMPA shall, within 60 working days from the date on which the application for such 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. When a new drug has gone through the clinical trial and passed the evaluation, a drug registration certificate shall be issued upon approval by NMPA.

Drug Clinical Trial

According to the Provisions for Drug Registration (《藥品註冊管理辦法》) ("**Drug Registration Provisions**") which was lastly revised on January 22, 2020 and became effective on July 1, 2020, clinical trial of drugs shall be subject to approval, and bioequivalence test shall be filed; clinical trial of drugs shall comply with the Good Clinical Practice of Pharmaceutical Products (《藥物臨床試驗質量管理規範》) (the "**Good Clinical Practice**") and shall be carried out by drug clinical trial organizations which comply with the relevant provisions. Clinical trial of drugs shall consist of phases I, II, III and IV clinical trial as well as bioequivalence test. 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 clinical research. On September 6, 2013, the Announcement of the NMPA on Drug Clinical Trial Information Platform (《國家食品藥品監督管理總局關於

藥物臨床試驗信息平臺的公告》) providing that, instead of the aforementioned registration filed with the NMPA, all clinical trials approved by the NMPA and conducted in the PRC shall complete clinical trial registration and publish trial information through the Drug Clinical Trial Information Platform.

According to the Decision on Adjusting the Approval Procedures of the Administrative Approval Matters for Certain Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) issued by the NMPA, which took effect on May 1, 2017, the authority of the drug clinical trial approval decision is adjusted to the CDE in the name of the NMPA. The Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》) was promulgated by the NMPA on July 24, 2018, according to which, if the applicant does not receive any negative or questioning opinions from the CDE within 60 days after the application is accepted and the fees are paid, the applicant can carry out the clinical trials in accordance with the submitted trial protocol.

The institutions for non-clinical safety evaluation and study and clinical trial organizations shall respectively implement the Good Laboratory Practice for Non-Clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) which became effective on September 1, 2017, and Good Clinical Practice for Clinical Laboratory Studies (《藥物臨床試驗質量管理規範》) which was effective on September 1, 2003 and lastly revised on April 23, 2020 and became effective on July 1, 2020. If certain actions in the preclinical trial research and clinical research conducted for a clinical application trial, and/or in the application procedures for registration of medicines, are in violation of the relevant rules and regulations, the NMPA is authorized to handle such cases pursuant to the Measures regarding Non-compliance with Relevant Rules of Research and Application for Registration of Medicines (《藥品研究和申報註冊違規處理辦法(試行)》) promulgated on and effective from September 1, 1999.

On December 18, 2017, NMPA promulgated the Technical Guidelines for the Research and Evaluation of Cell Therapy Products (《細胞治療產品研究與評價技術指導原則(試行)》), which became effective on the same date, in order to propose the general technical requirements concerning the safety, effectiveness and quality control of cell therapy products. On March 13, 2018, the CDE promulgated the Key Considerations in Applying for Clinical Trials of Cell Therapy Products for Pharmaceutical Research and Application Data (《細胞治療產品申請臨床試驗藥學研究和申報資料的考慮要點》) to encourage the innovation of cell therapy products in view of the urgent need of clinical drug use. On the basis of the Technical Guiding Principles for Cell Therapy Products, on October 18, 2019, the CDE promulgated the Pharmaceutical Research Questions and Answers for Application of Cell Therapy Products for Clinical Trials (Issue One) (《細胞治療產品申報臨床試驗藥學研究問題與解答(第一期)》) to provide reference for applicants on the common problems in the review and communication of IND application data of cell therapy products.

Laws and Regulations on Drug Registration

Administrative Measures for Drug Registration

According to the currently effective Drug Registration Provisions, if all the regulatory requirements are satisfied, the NMPA will grant a new drug certificate and a drug approval number, assuming the applicant has a valid Pharmaceutical Manufacturing Permit (藥品生產許可證) and the requisite production conditions for the new medicine have been met. All pharmaceutical products that are produced in China must bear drug approval numbers issued by the NMPA, with the exception of certain Chinese herbs and Chinese herbal medicines in soluble form. Drug manufacturing enterprises must obtain the drug approval numbers before manufacturing any drug. A drug approval number issued by the NMPA is valid for five years and the applicant shall apply for renewal six months prior to its expiration date. Application for drug registration includes application for new drugs, application for generic drugs, application for imported drugs, application for supplementary drugs and its re-registration application. A new drug application refers to an application for registration of a drug that has not yet been marketed for sale in China. In addition, the registration of drugs that change the dosage form of the marketed drugs, change the route of administration, and increase the new indications shall be reported in accordance with the application procedures for new drugs. The NMPA then determines whether to approve the application according to the comprehensive evaluation opinion provided by the CDE. According to the Drug Registration Provisions, drug registration is regulated according to Chinese medicine, chemical medicine and biological products. As compared to the current effective version, the Drug Registration Provisions provides detailed procedural and substantive requirements for the key regulatory concepts established by the Drug Administration Law, confirms a number of reform actions that have been taken in the past years, including but not limited to: (i) the full implementation of MAH System and implied approval of the commencement of clinical trial; (ii) implementing associated review of drugs, excipients and packaging materials; and (iii) introducing four procedures for expedited registration of drugs, which are procedures for ground-breaking therapeutic drugs, procedures for conditional approval, procedures for prioritized reviews and approval, and procedures for special examination and approval.

In March 2016, the NMPA 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 outlined the reclassifications of drug applications under the Drug Registration Provisions and under which, Category I drugs refer to new drugs that have not been marketed anywhere in the world. Improved new drugs that are not marketed anywhere in the world fall into Category II. Generic drugs, that have equivalent quality and efficacy to the originator's drugs have been marketed abroad but not yet in China, fall into Category III. Generic drugs, that have equivalent quality and efficacy to the originator's drugs and have been marketed in China, fall into Category IV. Category V drugs are drugs which have already been marketed abroad, but are not yet approved in China. Category I drugs and Category V drugs can be registered through the domestic new drug application and imported drug application procedures under the Drug Registration Provisions, respectively. On June 29, 2020, the NMPA issued the Circular on Publication of Registration Category of Chemical Drugs and the Requirements of the Filling Materials (《國家藥監局關於發佈化學藥品註冊分類及申報資料要求的通告》) which became effective on July 1, 2020 and further updates and specifies the registration categories of chemical drugs.

On December 21, 2017, the Opinions on Encouraging the Prioritized Evaluation and Approval for Drug Innovations (《關於鼓勵藥品創新實行優先審評審批的意見》) was promulgated by the NMPA and further replaced by the Announcement on the Release of Three Documents including the Procedures for the Evaluation of Breakthrough Therapeutic Drugs (Trial) (《關於發佈<突破性治療藥物審評工作程序(試行)>等三個文件的公告》) issued by the NMPA on July 7, 2020, the three documents are namely the Procedures for the Evaluation of Breakthrough Therapeutic Drugs (Trial) (《突破性治療藥物審評工作程序(試行)》), Procedures for the Evaluation and Approval of the Listing Application for Conditional Approval of Drugs (Trial) (《藥品附條件批准上市申請審評審批工作程序(試行)》) and Procedures for Prioritized Evaluation and Approval for Drug Marketing (Trial) (《藥品上市許可優先審評審批工作程序(試行)》), among others, which allow the applicant to apply for the breakthrough therapy drug procedure during the phase I and II clinical trials and normally no later than the commencement of phase III clinical trials for the innovative or improved drugs etc. which are used for the prevention and treatment of diseases that seriously endanger life or seriously affect quality of life and there is no effective means of prevention and treatment or there is sufficient evidence to show a significant clinical advantage over the existing treatments. In addition, when applying for the marketing license of a drug, for the drugs with obvious clinical value, the applicant can apply for the prior evaluation and approval procedure.

According to the Special Examination and Approval of Registration of New Drugs (《新藥註冊特殊審批管理規定》) (the "**Special Examination and Approval Provisions**") which was promulgated and implemented on January 7, 2009 by the NMPA, the NMPA conducts special examination and approval for new drug registration applications when: (1) the effective constituent of drug extracted from plants, animals, minerals, etc. as well as the preparations thereof have never been marketed in China, and the material medicines and the preparations thereof are newly discovered; (2) the chemical raw material medicines as well as the preparations thereof and the biological product have not been approved for marketing in China and abroad; (3) the new drugs are for treating AIDS, malignant tumors and orphan diseases, etc., and have obvious advantages in clinic treatment; or (4) the new drugs are for treating diseases with no effective methods of treatment. The Special Examination and Approval Provisions further provide that the applicant may file for special examination and approval at the clinical trial application stage if the drug candidate falls within items (1) or (2), and if the drug candidates fall within items (3) or (4), the application for special examination and approval cannot be made until filing for production.

Registration of Generic Drugs

According to the Drug Registration Provisions, the applicants which apply for registration of generic drugs shall be manufacturer of the same drugs. The applicant's drugs shall also be within the manufacturing scope specified in the Pharmaceutical Manufacturing Permit. Furthermore, clinical trials are required to be conducted in accordance with the Drug Registration Provisions. According to the Circular on Implementation of Record-filing Management of Bioequivalence Trials of Chemical Drug (《關於化學藥生物等效性試驗實行備案管理的公告》), the management of bioequivalence trials of chemical drug has been changed from examination and approval to record-filing. After completion of clinical trials, applicants for registration of generic drugs should submit materials of the respective clinical trials to the CDE. With reference to the technical review opinions, the NMPA will either grant a drug approval number or issue a disapproval notice.

Pursuant to the Opinions on Conducting the Consistency Evaluation for the Quality and Efficacy of Generic Drugs issued by the General Office of the State Council (《國務院辦公廳關於開展仿製藥質量和療效一致性評價的意見》) promulgated on February 6, 2016 and the Opinions of Relevant Matters Concerning Implementing the Opinions on Conducting the Consistency Evaluation for the Quality and Efficacy of Generic Drugs issued by the NMPA (《關於落實<國務院辦公廳關於開展仿製藥質量和療效一致性評價的意見>的有關事項的意見》) promulgated in March 2016, generic drugs approved for marketing before the implementation of the new registration classification of chemical drugs, including domestic generic drugs, imported generic drugs and the indigenous varieties of the original developed drugs, shall carry out consistency evaluation. In principle, the consistency evaluation should be completed before the end of 2018 for the oral solid preparations of generic chemicals approved for sale before October 1, 2007 listed in the National Essential Drug List (2012 version) (《國家基本藥物目錄(2012年版)》). For any other generic drugs approved for marketing before the implementation of the new classification of registration of chemical drugs, after a drug produced by a pharmaceutical enterprise passes the consistency evaluation, other pharmaceutical enterprises shall complete the consistency evaluation for their identical drugs within three years in principle; no registration will be granted in case of failure to do so as required within the prescribed time limit.

Pursuant to the Circular on Relevant Matters Concerning Consistency Evaluation for Quality and Curative Effect of Generic Drugs (《關於仿製藥質量和療效一致性評價有關事項的公告》) further promulgated by NMPA on December 28, 2018, the time limit for evaluation of the varieties included in the National Essential Drug List (2018 version) will no longer be set uniformly. For generic drugs, including essential drug varieties, approved for marketing before the implementation of new registration and classification of chemical drugs, after the first variety has passed the consistency evaluation, the same variety of other drug manufacturers should complete the consistency evaluation within 3 years in principle. If it is not completed within the time limit, the enterprise may apply to the local provincial drug regulatory authority for an extension of the evaluation if it is deemed to be clinically necessary and in short supply in the market. After research and identification organised by the provincial drug regulatory department as well as the health administrative department, an appropriate extension may be granted. If the registration is not completed within the prescribed time limit, it shall not be re-registered.

On May 12, 2020, NMPA promulgated the Circular on Conducting the Consistency Evaluation for the Quality and Efficacy of Generic Drugs of Chemical Injections (《國家藥監局關於開展化學藥品注射劑仿製藥質量和療效一致性評價工作的公告》), according to which, for the generic drugs of chemical injections that have been marketed, consistency evaluation should be carried out for the varieties that have not been approved according to the principle of consistency quality and efficacy with the original drugs. The Drug Marketing Authorization Holder shall select the reference preparations according to the catalogue of reference preparations for generic drugs issued by the NMPA, and carry out the consistency evaluation and R&D application.

Laws and Regulations on Drug Manufacturing

Pharmaceutical Manufacturing Permit

Pursuant to the Drug Administration Law and the Implementing Regulations of the Drug Administration Law of the PRC (《藥品管理法實施條例》) (the "**Drug Administration Implementing Regulations**"), a drug manufacturing enterprise is required to obtain a Pharmaceutical Manufacturing Permit (藥品生產許可證) from the relevant provincial drug administration authority of the PRC. The grant of such permit 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. Pursuant to the Drug Administration Implementing Regulations and the Measures on the Supervision and Administration of the Manufacture of Drugs (《藥品生產監督管理辦法》) amended on November 17, 2017 and January 22, 2020 and became effective on July 1, 2020 (the "**Drug Manufacture Supervision Measures**"), the drug manufacturing license is valid for five years and the drug manufacturing enterprises shall apply to the original authority that issued such license for renewal six months prior to its expiration date. Where the market authorization holder consents to the production of pharmaceutical preparations, the market authorization holder shall apply to the provincial department of the NMPA for a Pharmaceutical Manufacturing Permit and subject it to the inspection and other administrative supervision by government agencies.

Good Manufacturing Practices

The Good Manufacturing Practice for Drugs (2010 revised edition) (《藥品生產質量管理規範》), which was effective on March 1, 2011, comprises a set of detailed standard guidelines governing the manufacture of drugs, which includes quality management, organization and personnel, plant and facilities, equipment, materials and products, confirmation and verification, production management, quality control and quality assurance, commissioned production and commissioned inspection, product shipping and recall, self-inspection, etc.

According to the Drug Administration Law, the requirement of obtaining a Good Manufacturing Practice Certificate is cancelled and the pharmaceutical manufacturing company shall comply with Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》), establish and improve upon a drug manufacturing quality management system, ensure the whole drug manufacturing process continuously comply with statutory requirements.

Laws and Regulations on Drug Distribution

Pharmaceutical Operation Certificate

According to the Drug Administration Law, the Drug Administration 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 issued by the NMPA on January 31, 2007 and came into effect on May 1, 2007, detailed provisions are imposed on aspects such as

the purchase, sale, transportation and storage of medicines. The establishment of a wholesale pharmaceutical distribution company requires the approval of the provincial medicine administrative authorities. Upon approval, the authority will grant a Pharmaceutical Operation Certificate (藥品經營許可證) in respect of the wholesale pharmaceutical product distribution company.

Under the Measures for the Administration of Pharmaceutical Operation Certificate (《藥品經營許可證管理辦法》) promulgated on February 4, 2004 and became effective from April 1, 2004 and amended on November 17, 2017 by the NMPA, a Pharmaceutical Operation Certificate is valid for five years. Each holder of the Pharmaceutical Operation Certificate must apply for an extension of its permit six months prior to expiration.

Good Supply Practices

According to the Good Supply Practice for Pharmaceutical Products (《藥品經營質量管理規範》) (the "**Good Supply Practice**") promulgated by NMPA on July 13, 2016, drug distributors shall strictly implement the Good Supply Practice. Enterprises shall take effective measures for quality control at such stages as procurement, storage, sales and transportation of drugs to ensure the quality of drugs and shall develop a drug traceability system as per relevant requirements of the state to realize the traceability of drugs. In addition, the NMPA revised the Guidelines for On-site Inspection of Drug Operation and Quality Management Specifications (《藥品經營質量管理規範現場檢查指導原則》) in 2016, in order to further regulate the organization of the supervision and inspection of drug distributors.

Regulations for Administration of Affairs Concerning Laboratory Animals

Pursuant to Regulations for Administration of Affairs Concerning Laboratory Animals (《實驗動物管理條例》) approved by the State Council on October 31, 1988 and revised for the third time on March 1, 2017, the Administrative Measures on Good Practice of Laboratory Animals (《實驗動物質量管理辦法》) promulgated and implemented on December 11, 1997, and the Administrative Measures on the Certificate for Laboratory Animals (Trial) (《實驗動物許可證管理辦法(試行)》) promulgated and implemented on January 1, 2002, performing experimentation on animals requires a License for Use of Laboratory Animals (實驗動物使用許可證).

Pharmaceutical Directions and Labels of Pharmaceutical Products

According to the Measures for the Administration of the Pharmaceutical Directions and Labels of Drugs (《藥品説明書和標籤管理規定》) effective on June 1, 2006, the pharmaceutical directions and labels of drugs should be reviewed and approved by the NMPA. A pharmaceutical directions should include the important scientific data concerning drug safety and efficacy in order to direct the safe and rational use of drugs. The inner label of a drug should bear such information as the drug's common name, indication or function, strength, dose and usage, production date, batch number, expiry date and drug manufacturer, and the outer label of a drug should indicate such information as the drug's name, ingredients, character, specifications, description of the drug's indications and contraindications, precautions, dosage, date of production, product batch number, valid term, approval number, manufacturing enterprise and any adverse reactions.

Advertisements of Drugs

On October 26, 2018, the SCNPC promulgated the Advertising Law of the PRC (《中華人民共和國廣告法》) (as amended in 2018), according to which certain contents shall not be included in advertisement of drugs, such as an assertion or guarantee on the efficacy or the safety, stating a cure rate or effective rate.

The SAMR promulgated the Interim Measures for the Administration of the Examination and Administration of Drugs, Medical Devices, Health Foods, and Formula Foods 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》) on December 24, 2019, which came into effect from March 1, 2020. The contents of a drug advertisement shall be based on the drug instructions approved by the drug administrations under the State Council. Where a drug advertisement involves drug name, indications or major functions, pharmacological effects, etc., it shall not go beyond the scope of instructions. The validity period of the advertisement approval number for drugs, medical devices, health food and formula food for special medical purposes shall be consistent with the shortest validity period of the product registration certificate, filing certificate or production license. If no valid period is prescribed in the product registration certificate, filing certificate or production license, the valid period of the advertisement approval number shall be two years.

Pharmaceutical Product Export

According to the Approval by NMPA on Certain Issues of Pharmaceutical Products Export (《國家藥品監督管理局關於藥品出口有關問題的批覆》), promulgated and effective on September 20, 1999, whether the enterprise can obtain the right to operate import and export business and the qualification shall be approved by relevant foreign trade authority. The pharmaceutical products export shall mainly comply with the requirements of the importing country, so long as there is no special requirement by the importation country, the pharmaceutical supervisory and administrative departments support the export in principal based on the national policy of encouraging exports. However, under the Drug Administration Law, the export licenses issued by the relevant NMPA are required for the export of narcotics and psychotropic substances falling within the restricted scope prescribed by the State.

On November 9, 2018, the NMPA promulgated Regulations on the Administration of Certificates of Export Sales of Pharmaceuticals (《藥品出口銷售證明管理規定》), according to which, where a drug manufacturer applies for a Drug Export Sales Certificate (藥品出口銷售證明), it shall submit an application form for a drug export sales certificate to the local drug regulatory department at the provincial level. The term of validity of the Drug Export Sales Certificate (藥品出口銷售證明) shall not exceed 2 years, and shall not exceed the term of validity of all the certificates in the application materials, and a new application shall be made before the expiry of the period of validity.

Drug Recalls

According to the Measures on Drug Recall (《藥品召回管理辦法》) effective from December 10, 2007, a drug manufacturer should establish and improve its recall system by collecting relevant information about drug safety and making an investigation and evaluation with respect to the drugs with potential safety hazards. If there are any potential safety hazards that endanger human health and life safety in respect of any drugs sold in PRC, such manufacturer must start the drug recall procedures. Where a drug is recalled, the drug operating units and users should assist such manufacturer to satisfy its recall obligations by communicating the drug recall information and any feedback, controlling and recovering such drugs according to the recall plan.

MAJOR REGULATORY REFORMS IN THE PHARMACEUTICAL INDUSTRY

In order to deepen the reform of the medical and health care systems and improve the drug pricing mechanism, the State has implemented a series of measures and schemes, such as the mechanism of the national medical insurance program which related to the National Reimbursement Drug List ("**NRDL**") updated from time to time, and the centralized drug procurement scheme which commenced from provincial level and expand to a nationwide level. Further, the first batch of National Key Drug List for Monitoring and Prescription Control was newly issued in 2019 for the purpose of strengthening the overall management of the clinical application of drugs and standardizing the prescribing behavior of doctors. Meanwhile, the State implemented the Dual Invoicing System to further optimize the order of purchasing and selling drugs and reduce distribution steps.

National Essential Drug List

On August 18, 2009, Ministry of Health and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the National Essential Drug List (《國家基本藥物目錄管理辦法(暫行)》) (the "**Measures on Essential Drugs**") which became effective on the same day, and was amended on February 13, 2015, and the Guidelines on the Implementation of the National List of Essential Drugs System (《關於建立國家基本藥物制度的實施意見》) (the "**Essential Drugs Guidelines**"), which aim to promote the sale of essential medicines sold to consumers at fair prices in the PRC and ensure that the general public in the PRC has equal access to the drugs contained in the National Essential Drug List. The National Health Commission and National Administration of Traditional Chinese Medicine promulgated the National Essential Drug List (《國家基本藥物目錄》) on September 30, 2018 which became effective on November 1, 2018.

According to these regulations, basic healthcare institutions funded by government, which primarily include county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed in the National Essential Drug List. The drugs listed in National Essential Drug List shall be purchased by centralized tender process and shall be subject to the price control by the NDRC. Remedial drugs in the National Essential Drug List are all listed in the Medical Insurance Catalog and the entire amount of the purchase price of such drugs is entitled to reimbursement.

National Medical Insurance Program

The national medical insurance program was adopted pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program (《關於建立城鎮職工基本醫療保險制度的決定》) issued by the State Council on December 14, 1998, under which all employers in urban cities are required to enroll their employees in the Urban Employee Basic Medical Insurance Program and the insurance premium is jointly contributed by the employers and employees. Pursuant to the Opinions on the Establishment of the New Rural Cooperative Medical System (《關於建立新型農村合作醫療制度意見的通知》) forwarded by the General Office of the State Council on January 16, 2003, China launched the New Rural Cooperative Medical System to provide medical insurance for rural residents in selected areas which has spread to the whole nation thereafter. The State Council promulgated the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance (《國務院關於開展城鎮居民基本醫療保險試點的指導意見》) on July 10, 2007, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. In 2015, the PRC government announced the Outline for the Planning of the National Medical and Health Service System (2015-2020) (《全國醫療衛生服務體系規劃綱要(2015-2020年)》) which aims to establish a basic medical and health care system that covers both rural and urban citizens by 2020.

The Notice Regarding the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《關於印發城鎮職工基本醫療保險用藥範圍管理暫行辦法的通知》) issued on May 12, 1999, provides that a pharmaceutical product listed in the NRDL must be clinically needed, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements: (1) it is set forth in the Pharmacopeia (the prevailing version) of the PRC; (2) it meets the standards promulgated by the NMPA; and (3) if imported, it is approved by the NMPA for import. Except for the abovementioned drugs that have been included in the NRDL, the Announcement on the Release of the Work Plan for the Adjustment of the National Medical Insurance Drug Catalogue in 2019 (《關於公佈<2019年國家醫保藥品目錄調整工作方案>的公告》) promulgated by the National Healthcare Security Administration (國家醫療保障局) on April 17, 2019, stipulates that the exclusive patent drugs with higher price or greater influence on the medical insurance fund shall be admitted into the NRDL through negotiation. According to the Notification on the Inclusion of Drugs under Negotiation in Part B of the Drugs Catalogue for the National Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance in 2019 (《關於將2019年談判藥品納入<國家基本醫療保險、工傷保險和生育保險藥品目錄>乙類範圍的通知》) promulgated on November 22, 2019, the negotiation drugs are an important part of the NRDL and the provincial medical security, human resources and social security departments shall promptly include the negotiated drugs into the payment scope of an provincial basic medical insurance, industrial injury insurance and maternity insurance funds in accordance with the relevant regulations, and implement such negotiated drugs in parallel from January 1, 2020.

According to the Notice Regarding the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《關於印發城鎮職工基本醫療保險用藥範圍管理暫行辦法的通知》), the PRC Ministry of Labor and Social Security, together with other government authorities, has the power to determine the medicines included in the NRDL, which is divided into two parts, Part A and Part B. Provincial governments are required to include all Part A medicines listed on the NRDL in their provincial catalogue, but have the discretion to adjust upwards or downwards by no more than 15% from the number of Part B medicines listed in the NRDL. As a result, the contents of Part B of the provincial catalogue may differ from region to region in the PRC. However, such aforementioned mechanism has been changed since the issuance of the Notice of MHRSS and the NHSA on the Issuance of the NRDL (《國家醫保局、人力資源社會保障部關於印發<國家基本醫療保險、工傷保險和生育保險藥品目錄>的通知》) on August 20, 2019 which became effective on January 1, 2020. Such Notice regulates that all localities shall strictly implement the NRDL and are not allowed to make a catalogue or add drugs in the NRDL, or adjust the limited payment scope of drugs in the NRDL. For those drugs that were already added to Part B of the provincial catalogue in accordance with the previous provincial catalog, the drugs shall be gradually removed within 3 years. During the process, all provinces should give priority to the adjustment of the payment scope of the drugs included in the First Batch of National Key Drug List for Monitoring and Prescription Control (Chemical and Biological Products) or such list which may be dynamically adjusted by the NHC and the National Administration of Traditional Chinese Medicine (國家中醫藥管理局).

Patients purchasing medicines included in Part A of the NRDL are entitled to reimbursement in accordance with the regulations in respect of basic medical insurance. Patients purchasing medicines included in Part B of the NRDL are required to pay a certain percentage of the purchase price and the remainder of the purchase price shall be reimbursed in accordance with the regulations in respect of basic medical insurance. The percentage of reimbursement for Part B medicines is stipulated by local authorities and in result may differs from region to region in the PRC.

In principal, the NRDL shall be adjusted every two years, and the drug list of all provinces, autonomous regions and municipalities directly under the Central Government shall be adjusted accordingly. However, in practice, the NRDL was formulated and adjusted from time to time in the year of 2000, 2004, 2009, 2017 and 2019, respectively, and was not strictly updated within the time limit specified above. On July 30, 2020, the NHSA issued Interim Measures for the Administration of Drug Use in Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) which became effective on September 1, 2020, stipulating that the dynamic adjustment mechanism will be established and the NRDL shall be adjusted once a year in principle.

National Key Drug List for Monitoring and Prescription Control

On June 11, 2019, the NHC and National Administration of Traditional Chinese Medicine (國家中醫藥管理局) jointly issued the Notice on the Issuance of the First Batch of National Key Drug List for Monitoring and Prescription Control (Chemical and Biological Products) (《關於印發第一批國家重點監控合理用藥藥品目錄(化藥和生物製品)的通知》)(the "**Control List**"), aiming to strengthen the overall management of the clinical application of drugs in the Control List, further standardize the prescribing behavior of doctors, formulate the drug use guidelines or technical specifications for the drugs included in the Control List and clearly stipulate the conditions and principles of clinical application. Relevant laws and regulations shall be strictly implemented by the physicians for chemical drugs and biological products which are not included in the Control List. According to the indications, guidelines for the diagnosis and treatment of diseases stipulated in the drug instructions and the corresponding prescription permission, the drug varieties, route of administration and dosage shall be rationally selected and prescribed. As for traditional Chinese medicines, doctors of traditional Chinese medicine should prescribe traditional Chinese medicines according to the relevant laws and regulations, and in accordance with the basic principle of dialectical treatment of traditional Chinese medicines. There are 20 kinds of drugs included in the Control List and the NHC will work with the National Administration of Traditional Chinese Medicine together to dynamically adjust the Control list.

The formulation basis of the Control List is the Opinions on Strengthening the Performance Appraisal of Tertiary Public Hospitals (《關於加強三級公立醫院績效考核工作的意見》) promulgated by the General Office of the State Council on January 16, 2019 and the relevant PRC regulations. Pursuant to the relevant PRC regulations, the national key drug list for monitoring and prescription control shall be formulated in the following ways: firstly, the provincial health administration department shall organize the secondary or higher medical institutions within its jurisdiction to order their key monitored drugs by the common name and according to the annual amount of money used from the most to least, and report to the provincial health administration department; secondly, the provincial health administration department summarizes the key monitored drugs reported by medical institutions within its jurisdiction and reports the information of the top 20 drugs to the NHC under the common name and in order of the total amount of money used from the most to least; and then the NHC shall, on the basis of the information reported by the provinces, draw up and publish the national key drug list for monitoring and prescription control; finally, on the basis of the Control List published by the NHC, the provincial health administration departments shall formulate the catalogue of key drug list for monitoring and prescription control in their respective provinces.

Price Controls

Pursuant to the Notice on Issuing the Opinion on Promoting Pharmaceutical Price Reform (《關於印發推進藥品價格改革意見的通知》) promulgated on May 4, 2015, government price controls on pharmaceutical products (other than narcotic drugs and certain psychiatric drugs) were lifted on June 1, 2015. After price controls were lifted, prices of pharmaceutical products are mainly determined by market competition. Instead of direct governmental price controls, the government will regulate prices mainly by establishing a centralized procurement mechanism, revising medical insurance reimbursement standards and strengthening regulation of medical and pricing practices. Please see the PRC laws and regulations related to the centralized procurement mechanism in the "Tender Process" and the relevant PRC laws and regulations related to revising medical insurance reimbursement standards in "National Medical Insurance Program" of Regulatory Overview.

Dual Invoicing System

In order to further optimize the order of purchasing and selling pharmaceutical products and reduce circulation steps, as required at the executive meeting of the State Council dated April 6, 2016 and under the 2016 List of Major Tasks in Furtherance of the Healthcare and Pharmaceutical Reforms (《深化醫藥衛生體制改革2016年重點工作任務》) issued by the General Office of the State Council on April 21, 2016, the "dual invoicing system" will be fully implemented in the PRC. According to the Notice of Publishing Opinions on Implementing Dual Invoicing System in Drug Procurement Among Public Medical Institutions (For Trial Implementation) (《印發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)的通知》) ("**Dual Invoicing System Notice**") which was issued on December 26, 2016, the "dual invoicing system" refers to the system that requires one invoice to be issued from pharmaceutical manufacturers to pharmaceutical distributors and the other invoice to be issued from pharmaceutical distributors to medical institutions. The wholly-owned or holding commercial company (only one commercial company is permitted in the whole country) or the domestic general agent for overseas drugs (only one domestic agent is permitted in the whole country) established by a pharmaceutical manufacturer or a group enterprise integrating science, industry and trade may be regarded as a manufacturer. The allocation of drugs between a pharmaceutical distribution group enterprise and its wholly-owned (holding) subsidiaries or among its wholly-owned (holding) subsidiaries may not be regarded as a process for which an invoice should be issued, but one invoice is allowed to be issued at most. According to the Dual Invoicing System Notice and the Several Opinions of the General Office of the State Council on Further Reforming and Improving the Policies on 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》) issued on January 24, 2017, dual invoicing system will be promoted in pilot provinces (autonomous regions and municipalities directly under the Central Government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis, while other regions are encouraged to implement such system, so that such system can be promoted in full swing nationwide in 2018.

Tender Process

Drug Purchases by Hospitals

According to the Opinion on the Guidance of the Reform of Urban Medical and Health Care System (《關於城鎮醫藥衛生體制改革的指導意見》) promulgated and took into effect on February 16, 2000 and the Opinion on the Implementation of Classification Management of Urban Medical Institutions (《關於城鎮醫療機構分類管理的實施意見》) promulgated on July 18, 2000 and became effective on September 1, 2000, a non-profit-making medical institution is established to provide services to the general public, with its revenue used for maintaining and developing such institution, while a profit-making medical institution is established by investors for the purpose of investment return. Any non-profit-making medical institutions must implement a collective tender system in respect of any drug purchases and any profit-making medical institutions is not mandatorily required to implement such a system according to relevant PRC laws and regulations.

According to the Notice on the Trial Implementation of the Centralized Tender with Respect to Drug Purchases by Medical Institutions (《關於印發醫療機構藥品集中招標採購試點工作若干規定的通知》) which was promulgated and effective on July 7, 2000, the Notice on the Further Standardizing of the Centralized Tender with respect to Drug Purchases By Medical Institutions (《關於進一步做好醫療機構藥品集中招標採購工作的通知》) promulgated and became effective on August 8, 2001 and the Opinions concerning Further Regulating Purchase of Medicines by Medical Institutions through Centralized Tendering (《關於進一步規範醫療機構藥品集中採購工作的意見》) promulgated and took into effect on January 17, 2009, any non-profit-making medical institutions established and/or controlled by any government at a county level or above must implement the centralized tendering in respect of purchase of the drugs contained in the Medicines List for National Basic Medical Insurance and the drugs with relatively large clinical usage.

The Good Practice of Medical Institutions with respect to Centralized Procurement of Drugs (《醫療機構藥品集中採購工作規範》) promulgated and was effective on July 7, 2010, stipulating that any non-profit-making medical institutions established by the government at the county level or above or state-owned enterprises (including state-holding enterprises) must participate in the centralized procurement of medical institutions through a non-profit-making centralized procurement platform. The centralized procurement management authority at provincial (municipal or district) level is responsible for compiling the catalog of drugs for centralized procurement by medical institutions within its own administrative region, and narcotic drugs and first class psychoactive drugs with respect to which the special administration is carried out by the state are not included in such catalog for centralized procurement; second class psychoactive drugs, radioactive pharmaceuticals, toxic drugs for medical use, crude drugs, traditional Chinese medicinal materials and traditional Chinese medicine decoction pieces may be excluded from such catalog for centralized procurement.

According to the Guidance Opinion of the General Office of the State Council on the Improvement of the Drug Centralized Procurement Work of Public Hospitals (《國務院辦公廳關於完善公立醫院藥品集中採購工作的指導意見》) promulgated and came into effect on February 9, 2015, the centralized procurement work of public hospitals will be improved through the purchase of drugs by classification. All drugs used by public hospitals (with the exception of traditional Chinese medicine decoction pieces) should be procured through a provincial centralized pharmaceutical procurement platform. The provincial procurement agency should work out a summary of the procurement plans and budget submitted by hospitals and compile reasonably a drug procurement catalog of the hospitals within its own administration region, listing by classification the drugs to be procured through bids, negotiations, direct purchases by hospitals or to be manufactured by appointed pharmaceutical manufacturers.

The Centralized volume-based drug Procurement in "4+7 Cities" and Wider Areas

In order to deepen the reform of the medical and health care system and improve the mechanism for setting drug prices, the State carried out to organize drug centralized procurement.

First, the State launched the trials for the centralized volume-based drug procurement in 11 cities in November 2018. On November 15, 2018, the Joint Procurement Office published the Papers on Drug Centralized Procurement in "4+7 Cities" (《4+7城市藥品集中採購文件》), which launched the national pilot scheme for centralized volume-based drug procurement in the public medical institutions. The pilot scheme will be carried out in 11 cities, including Beijing, Tianjin, Shanghai, Chongqing, Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xi'an (the "**4+7 Cities**"). On January 1, 2019, the General Office of the State Council also published the Notice of Issuing Pilot Program of the Centralized Procurement and Use of Drugs Organized by the State (《國務院辦公廳關於印發國家組織藥品集中採購和使用試點方案的通知》), which provides the detailed measures in the implementation of the national pilot scheme for centralized volume-based drug procurement in the 4+7 Cities.

Second, on the basis of the centralized volume-based drug procurement implemented by 4+7 cities and provinces, the State organizes relevant regions to form an alliance to carry out the centralized volume-based drug procurement of cross-regional alliances in September 2019. The Document for Centralized Drug Procurement in the Alliance Area (GY-YD2019-1) (《聯盟地區藥品集中採購文件(GY-YD2019-1)》) was issued by the Joint Procurement Office (聯合採購辦公室) on September 1, 2019. The alliance area included the provinces of Shanxi, Inner Mongolia, Liaoning, Jilin, Heilongjiang, Jiangsu, Zhejiang, Anhui, Jiangxi, Shandong, Henan, Hubei, Hunan, Guangdong, Guangxi, Hainan, Sichuan, Guizhou, Yunnan, Xizang, Shaanxi, Gansu, Qinghai, Ningxia and Xinjiang (including Xinjiang Production and Construction Army Unit), except the 4+7 cities in the alliance area.

Third, the State promoted the centralized volume-based drug procurement nationwide in December 2019. According to the Implementing Opinions on Expanding the Pilot Program for Conducting Centralized Procurement and Use of Drugs by the State to Wider Areas (《關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見》) promulgated and came into effect on September 25, 2019, together with the Documents on National Centralized Drug Procurement (GY-YD2019-2) (《全國藥品集中採購文件(GY-YD2019-2)》) issued by the Joint Procurement Office on December 29, 2019 to launch the second batch of state organized centralized volume-based drug procurement, the model of centralized procurement with target quantity in the pilot program for conducting centralized procurement and use of drugs by the State will be promoted nationwide and all manufacturers of drugs within the scope of centralized procurement marketed in Mainland China, with the approval of the medical products administration, may participate in the pilot program.

The drug being offered for tender must belong to one of the following categories: (1) an originator drug or reference preparations used for consistency evaluation designated by NMPA; (2) a generic drug that has passed the consistency evaluation; (3) a generic drug approved for registration; or (4) a drug included in the Catalogue of the Drugs Marketed in China. The tenderer must also ensure that its annual production and sales capacity can satisfy the intended minimum quantity requirement. Public hospitals must prioritize their drug purchasing from the successful bidder during the procurement cycle, calculated from the execution date of the successful bid result, until the quantity commitment has been satisfied. If the quantity commitment is satisfied, the excess is still procured at the selected price until the expiration of the procurement cycle.

The NHSA, the NHC, the NMPA, the Ministry of Industry and Information Technology(工業和信息化部) and the Logistics Support Department of the Central Military Commission(中央軍委後勤保障部) promulgated the Notice on the Commencement of the Second Batch of State Organized Centralized Drug Procurement and Use (《關於開展第二批國家組織藥品集中採購和使用工作的通知》) on January 13, 2020 which became effective on the same date. The second batch of national organization of centralized procurement and use of drugs will no longer be carried out in selected areas, and the national organization for the centralized procurement and use of drug varieties is selected from the generic drugs with generic names that have passed the consistency evaluation for the quality and efficacy of generic drugs, including generic drugs which had been approved for marketing according to the new registration classification of chemical drugs. This Notice expands the range of drugs to be centrally procured and used by state organizations, focusing on the selection of more competitive varieties. Considering the clinical efficacy, adverse reactions, the stability of the drug batches and other factors, the specific selection indicators shall be determined by the joint procurement office (聯合採購辦公室).

In order to comprehensively deepen the reform and establish a standardized and normalized mode of centralized volume-based drug procurement and use, the Joint Procurement Office issued the Documents on National Centralized Drug Procurement (GY-YD2020-1) (《全國藥品集中採購文件(GY-YD2020-1)》) on July 29, 2020 and launched the third batch of State organizations for the centralized volume-based drug procurement.

For centralized procurement drugs within the scope of the NRDL, the centralized procurement price shall be regarded as the payment standard of medical insurance. In principle, the medical insurance fund shall be settled pursuant to the same payment standard for the original researched drugs, reference preparations and generic drugs which passed the consistency evaluation for the quality and efficacy of generic drugs under the same generic name.

LAWS AND REGULATIONS RELATING TO ANTI-UNFAIR COMPETITION

Since early 1990s, the legislative authorities at different levels in China have promulgated certain laws and regulations in respect of commercial bribery. According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) (the "**Anti-Unfair Competition Law**"), which was passed by the SCNPC on September 2, 1993, became effective as of December 1, 1993 and was most recently amended on April 23, 2019, unfair competition refers to that the operator disrupts the market competition order and damages the legitimate rights and interests of other operators or consumers in violation of the provisions of the Anti-unfair Competition Law in the production and operating activities. Pursuant to the Anti-unfair Competition Law, operators shall abide by the principle of voluntariness, equality, impartiality, integrity, and adhere to laws and business ethics during market transactions. Operators in violation of the Anti-unfair Competition Law shall bear corresponding civil, administrative or criminal liabilities depending on the specific circumstances.

On June 26, 2019, the SAMR promulgated the Interim Provisions on Prohibiting Monopoly Agreement(《禁止壟斷協議暫行規定》) and Interim Provisions on Prohibiting Abuse of Dominant Market Positions (《禁止濫用市場支配地位行為暫行規定》) which became effective on September 1, 2019, according to which, "monopoly agreement" means an agreement, a decision, or any other act in concert to exclude or restrict competition. The SAMR shall be responsible for the anti-monopoly law enforcement work against monopoly agreements and the anti-monopoly law enforcement work against abuse of dominant market positions. Business operators and their transaction counterparties are prohibited from concluding the following monopoly agreements in respect of prices of the commodities: (i) fix the price level, price change range, profit level or discount, handling fee etc. for resale of commodities to a third party; (ii) restrict the minimum price for resale of commodities to a third party, or restrict the minimum price for resale of commodities through restricting price change range, profit level or discount, handling fee or other fees; or (iii) fix the price for resale of commodities or restrict minimum price of resale of commodities through other methods. Without legitimate reasons, business operators with dominant market position are prohibited from adding other unreasonable transaction conditions for their transactions, such as add unreasonable restrictions on sales regions, sales targets, after-sale service and others.

According to the Interim Provisions on the Prohibition of Commercial Bribery (《國家工商行政管理局關於禁止商業賄賂行為的暫行規定》) (the "**Prohibition Commercial Bribery Provisions**"), which was promulgated by SAIC on November 15, 1996, commercial bribery refers to an act of offering money or property or using other means by an operator to the other entity or individual for the purposes of selling or buying goods, among which "other means"

refer to the means used to provide any types of benefits other than money or property, such as offering overseas or domestic travel. According to the Anti-Unfair Competition Law and the Prohibition Commercial Bribery Provisions, regulatory authorities may impose fines depending on the seriousness of the cases and if there is any illegal income, such income shall be confiscated.

Pursuant to the Regulations on the Establishment of Adverse Records with Respect to Commercial Briberies in the Medicine Purchase and Sales Industry (2013 revision) (《關於建立醫藥購銷領域商業賄賂不良記錄的規定(2013年修訂)》) enforced on March 1, 2014 by the NHFPC, where a manufacturer of drugs, medical devices and medical disposables, an enterprise, an agency or an individual offers staff of a medical institution any items of value or other benefits, the enterprise should be listed in the adverse records with respect to commercial bribery in the event of the following circumstances: (1) where the act has constituted a crime of bribery as determined by the ruling of a people's court, or where the circumstance of crime is not serious enough for the imposition of criminal punishment and criminal punishment is exempted as decided by the people's court in accordance with the Criminal Law; (2) where the circumstance of the crime of bribery is minor and the relevant people's procuratorate has decided not to lodge a prosecution; (3) where a discipline inspection and supervision authority has initiated a case of bribery and conducted investigation, and punishment has been imposed in accordance with the law; (4) where administrative penalties against the act of bribery have been imposed by, inter alia, the finance administration, the industrial and commercial administration, the NMPA; and (5) any other circumstances specified by laws, regulations and rules. If medical production and operation enterprises be listed into the Adverse Records of Commercial Briberies for the first time, their products shall not be purchased by public medical institutions, and medical and health institutions receiving financial subsidies in local province for two years since publication of the record, and public medical institution, and medical and health institutions receiving financial subsidies in other province shall lower their rating in bidding or purchasing process. If medical production and operation enterprises be listed into the Adverse Records of Commercial Bribery more than once in five years, their products shall not be purchased by public medical institutions, and medical and health institutions receiving financial subsidies nationwide for two years since publication of the record.

LAWS AND REGULATIONS RELATING TO PRODUCTION SAFETY AND LIABILITY

Production Safety Law of the PRC

Pursuant to the Production Safety Law of the PRC (《中華人民共和國安全生產法》) amended on August 31, 2014 and coming into effect on December 1, 2014, an enterprise shall (i) provide production safety conditions as stipulated in this law and other relevant laws, administrative regulations, national and industry standards, (ii) establish a comprehensive production safety accountability system and production safety rules, and (iii) develop production safety standards to ensure production safety. Any entity that fails to provide required production safety conditions is prohibited from engaging in production activities.

Some chemical materials needed for new drug research and development, such as toluene and hydrochloric acid, are hazardous chemicals. Pursuant to the Regulations on Safety Management of Hazardous Chemicals (《危險化學品安全管理條例》) which was effective on March 15, 2002 and amended on March 2, 2011 and December 7, 2013, respectively, the production, storage, use, operation, and transportation of hazardous chemicals must be in accordance with the safety management regulations. The hazardous chemical units shall oblige to satisfy the safety conditions required by laws and administrative regulations and state and industry standards, establish and improve safety management rules and post safety responsibility systems, and provide safety education and legal education and occupation technical training for employees. Employees should accept such education and training, and may begin working only after qualifying the relevant assessment.

Product Quality Law of the PRC

Pursuant to the Product Quality Law of the PRC (《中華人民共和國產品質量法》) was promulgated by the SCNPC on 22 February 1993, and lastly amended and came into effect on December 29, 2018, producers and sellers shall have their own proper regulations for the management of product quality, rigorously implementing post-oriented quality regulations, quality liabilities and relevant measures for their assessment. Producers and sellers are responsible for the product quality according to the provisions of the laws. Quality of products shall pass standard examinations and it is not allowed to pass off sub-standard products as standard ones. Producers or sellers shall be responsible for any compensation arising from their unlawful acts such as production or sales of defective, eliminated or ineffective products, faking the place of origin or quality marks, mixing or adulterating products or passing off imitations as genuine, substandard products as quality ones or non-conforming products as conforming. Proceeds from the sales may be confiscated, the business license may be revoked and penalties may be imposed. If the case is serious, criminal responsibilities shall be investigated. Producers or sellers shall be liable for any damage to any person or property due to the defects of products resulting from the default of the producers or sellers.

Tort Law of the PRC

Pursuant to the Tort Law of the PRC (《中華人民共和國侵權責任法》) promulgated on December 26, 2009 and coming into effect on July 1, 2010, a patient may make a claim against a medical institution or producer for any damage arising from defects of drugs. In respect of any claim made by a patient, the medical institution is entitled to make a claim against the producer after the settlement of the compensation paid to the patient. On May 28, 2020, the Civil Code of the PRC (《中華人民共和國民法典》) was adopted by the third session of the 13th NPC, which will become effective on January 1, 2021 and simultaneously replace the current effective Tort Law of the PRC, according to which, a patient may make a claim against the drug marketing authorization holder, a medical institution or producer for any damage arising from defects of drugs.

LAWS AND REGULATIONS RELATING TO ENVIRONMENTAL PROTECTION

Pursuant to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) promulgated on December 26, 1989 and became effective on the same day, last amended on April 24, 2014 and became effective on January 1, 2015, the waste discharge licensing system has been implemented in the PRC and entities that discharge medical sewage to water bodies directly or indirectly shall obtain a waste discharge license. Furthermore, installations for the prevention and control of pollution at a construction project must be designed, built and commissioned together with the principal part of the project.

Pursuant to the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》) promulgated on October 28, 2002, became effective on September 1, 2003 and last amended on December 29, 2018, the State 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 purpose. 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.

Regulations on Pollution Permit

Pursuant to the Administrative Measures on Pollutant Emission Permits (Trial) (《排污許可管理辦法(試行)》) which became effective on January 10, 2018 and amended on August 22, 2019, enterprises, institutions and other producers and operators (the "**pollutant discharge enterprises**") that have been included in the Classification Management List for Fixed Source Pollution Permits shall apply for and obtain a discharge permit in accordance with the prescribed time limit. The pollutant discharge enterprises that are not included in the Classification Management List do not need to apply for a pollutant discharge permit. The pollutant discharge enterprise shall hold a pollutant discharge permit in accordance with the law and discharge pollutants in accordance with the discharge permit.

Pursuant to the Notice of the General Office of the State Council on Issuing the Implementation Plan for the Control of Pollutant Release Permit System (《國務院辦公廳關於印發控制污染物排放許可制實施方案的通知》) and the Classification Management List for Fixed Source Pollution Permits (2019 Edition) (《固定污染源排污許可分類管理名錄(2019年版)》), the state implements a focused management and a simplification of emission permits based on the pollutant-discharging enterprises and other manufacturing businesses' amount of pollutants, emissions and the extent of environmental damage. The manufacturing of drug substance and manufacturing dose for chemical drugs are industries that shall obtain the discharge permit in accordance with the prescribed time limit. The Ministry of Environmental Protection shall be responsible for guiding the implementation and the supervision of the

National Sewage Permit System. The municipal environmental protection department shall be responsible for issuing the Pollutant Discharge Permit in the district where the pollutant-discharging enterprise is located.

LAWS AND REGULATIONS RELATING TO INTELLECTUAL PROPERTY RIGHTS

Trademark

Trademarks are protected by the Trademark Law of the PRC (《中華人民共和國商標法》) which was promulgated on August 23, 1982 and last amended on April 23, 2019 and took effect on November 1, 2019 as well as the Implementation Regulation of the PRC Trademark Law (《中華人民共和國商標法實施條例》) adopted by the State Council on August 3, 2002 and revised on April 29, 2014. In the PRC, registered trademarks include commodity trademarks, service trademarks, collective marks and certification marks. The Trademark Office of National Intellectual Property Administration handles trademark registrations and grants a term of 10 years to registered trademarks, renewable every 10 years where a registered trademark needs to be used after the expiration of its validity term.

Patent

According to the Patent Law of the PRC (《中華人民共和國專利法》), promulgated by the SCNPC on March 12, 1984 and further amended on September 4, 1992, August 25, 2000, December 27, 2008 and came into effect on October 1, 2009 and the Implementing 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 China Patent Bureau Council on January 19, 1985, and last amended on January 9, 2010 and came into effect on February 1, 2010, the term "invention-creations" refers to inventions, utility models and designs. The duration of a patent right for inventions shall be 20 years and the duration of a patent right for utility models and designs shall be 10 years, both commencing from the filing date.

According to the Patent Law of the PRC, any entity or individual that seeks to exploit a patent owned by another party shall enter into a patent license contract with the patent owner concerned and pay patent royalties to the patent owner. The licensee does not have the right to allow any entity or individual not specified in the contract to exploit such patent. Pursuant to the Measures for the Filling of Patent Licensing Contracts (《專利實施許可合同備案辦法》) promulgated by the State Intellectual Property Office on June 27, 2011 and became effective on August 1, 2011, the State Intellectual Property Office shall be responsible for filing of patent licensing contracts nationwide and the parties concerned shall complete filing formalities within three months from the effective date of a patent licensing contract.

Domain Names

The Administrative Measures for Internet Domain Names (《互聯網域名管理辦法》), which was promulgated by the Ministry of Industry and Information Technology on August 24, 2017 and became effective on November 1, 2017, regulates the ".CN" and the ".zhongguo (in Chinese character)" shall be China's national top level domains. Any party that engages in internet information services shall use its domain name in compliance with laws and regulations and in line with relevant provisions of the telecommunications authority, but shall not use its domain name to commit any violation.

LAWS AND REGULATIONS RELATING TO FOREIGN INVESTMENT IN THE PRC

The Company Law of the People's Republic of China (《中華人民共和國公司法》), or the Company Law, which was promulgated on December 29, 1993 and came into effective on July 1, 1994, last amended on October 26, 2018 and came into effective on the same day, provides that companies established in China may take the form of limited liability company or joint stock company with limited liability. Each company has the status of a legal person and owns the assets itself. The Company Law applies to foreign-invested companies unless relevant laws provide otherwise.

The Catalogue of Industries for Encouraging Foreign Investment (2019 Version) (《鼓勵外商投資產業目錄(2019年版)》) (the "**Encouraging List 2019**") which was issued on June 30, 2019 and effective from July 30, 2019, and the Special Administrative Measures for the Access of Foreign Investment (Negative List) (2020 Version) (《外商投資准入特別管理措施(負面清單)(2020年版)》) (the "**Negative List 2020**") which was issued on June 23, 2020 and effective from July 23, 2020, further reduced restrictions on the foreign investment and replaced the Catalogue for the Guidance of Foreign Investment Industries (2017 Revision) (《外商投資產業指導目錄(2017年修訂)》) and the Special Administrative Measures for the Access of Foreign Investment (Negative List) (2019 Version) (《外商投資准入特別管理措施(負面清單)(2019年版)》). Industries that do not fall within the Negative List 2020 and the Encouraging List 2019 are industries permitted for foreign investment. According to the Negative List 2020, the human cell and gene diagnosis and therapy business remains as prohibited areas for foreign investment.

On March 15, 2019, the 2nd meeting of the 13th SCNPC approved the Foreign Investment Law of the People's Republic of China (《中華人民共和國外商投資法》) (the "**FIL**"), which became effective on January 1, 2020. According to the FIL, the "foreign investment" refers to investment activities carried out directly or indirectly by foreign natural persons, enterprises or other organizations (the "**Foreign Investors**"), including the following: (i) Foreign Investors establishing foreign-invested enterprises in China alone or collectively with other investors; (ii) Foreign Investors acquiring shares, equities, properties or other similar rights of Chinese domestic enterprises; (iii) Foreign Investors investing in new projects in China alone or collectively with other investors; and (iv) Foreign Investors investing through other ways prescribed by laws and regulations or the State Council. The State adopts the management system of pre-establishment national treatment and negative list for foreign investment. The

pre-establishment national treatment refers to granting to foreign investors and their investments, in the stage of investment access, the treatment no less favorable than that granted to domestic investors and their investments; the negative list refers to special administrative measures for access of foreign investment in specific fields as stipulated by the State. The State will give national treatment to foreign investments outside the negative list. The negative list will be released by or upon approval by the State Council. After the FIL came into effect, the FIL replaced the Law of the People's Republic of China on Sino-Foreign Equity Joint Ventures (《中華人民共和國中外合資經營企業法》), the Law of the People's Republic of China on Sino-Foreign Cooperative Joint Ventures (《中華人民共和國中外合作經營企業法》) and the Wholly Foreign-Owned Enterprise Law of the People's Republic of China (《中華人民共和國外資企業法》), became the legal foundation for foreign Investment in the PRC.

On December 26, 2019, the State Council promulgated the Implementing Rules of the Foreign Investment Law (《外商投資法實施條例》) (the "**Implementing Rules**"), which became effective on January 1, 2020 and replaced the Implementing Rules of the Laws on Sino-Foreign Equity Joint Ventures (《中外合資經營企業法實施條例》), the Implementing Rules of the Laws on Sino-Foreign Cooperative Joint Ventures (《中外合作經營企業法實施細則》) and the Implementing Rules of the Wholly Foreign-Owned Enterprise Law (《外資企業法實施細則》). The Implementation Rules restates certain principles of the FIL and further provides, among others, if a foreign-invested enterprise established prior to the effective date of the FIL fails to adjust its legal form or the governing structure to comply with the provisions of the Company Law or the PRC Partnership Enterprise Law, as applicable, and complete the amendment registration accordingly before January 1, 2025, the enterprise registration authority will not process other registration matters of such foreign-invested enterprise and publicize such non-compliance issues thereafter.

On December 30, 2019, the MOFCOM and the State Administration for Market Regulation jointly promulgated the Measures on Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which took effective on January 1, 2020 and replaced the Interim Measures for the Administration of Record-filing on the Incorporation and Changes in Foreign-invested Enterprises (《外商投資企業設立及變更備案管理暫行辦法》). Foreign investors carrying out investment activities in the PRC or foreign-invested enterprises directly or indirectly shall submit investment information to the commerce administrative authorities through the Enterprise Registration System (企業登記系統) and the National Enterprise Credit Information Publicity System (國家企業信用信息公示系統) pursuant to the Measures on Reporting of Foreign Investment Information.

The CSRC, the SAFE, the MOFCOM and three other PRC governmental and regulatory agencies promulgated the M&A Rules on August 8, 2006, as later amended on June 22, 2009, governing the mergers and acquisitions of domestic enterprises by foreign investors. The M&A Rules, among other things, require that if a domestic company, domestic enterprise, or a domestic individual, through an overseas company established or controlled by it/him/her, acquires a domestic company which is affiliated with it/him/her, an approval from the MOFCOM is required. The M&A Rules further requires that a SPV, that is controlled directly or indirectly by the PRC companies or individuals and that has been formed for overseas listing

purposes through acquisitions of PRC domestic interest held by such PRC companies or individuals, shall obtain the approval of CSRC prior to overseas listing and trading of such SPV's securities on an overseas stock exchange.

LAWS AND REGULATIONS RELATING TO EMPLOYMENT AND SOCIAL SECURITY AND HOUSING FUNDS

Labor Law of PRC

The Labor Law of PRC (《中華人民共和國勞動法》), which was promulgated by the SCNPC on July 5, 1994, came into effect on January 1, 1995, and was amended on August 27, 2009 and December 29, 2018, provides that an employer shall develop and improve its rules and regulations to safeguard the rights of its workers. Labor safety and health facilities must comply with relevant national standards. Workers engaged in special operations shall have received specialized training and obtained the pertinent qualifications.

Labor Contract Law of PRC and its Implementation Regulations

The Labor Contract Law of PRC (《中華人民共和國勞動合同法》), which was promulgated by the SCNPC on June 29, 2007, came into effect on January 1, 2008, and was amended on December 28, 2012, and came into effect on July 1, 2013, and the Implementation Regulations on Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》) which was promulgated and came into effect on September 18, 2008 by the State Council, regulate the relations of employer and the employee, and contain specific provisions involving the terms of the labor contract.

Regulations on Supervision over the Social Security and Housing Funds

According to the Provisional Regulations on the Collection and Payment of Social Insurance Premium (《社會保險費徵繳暫行條例》), the Regulations on Work Injury Insurance (《工傷保險條例》), the Regulations on Unemployment Insurance (《失業保險條例》) and the Trial Measures on Employee Maternity Insurance of Enterprises (《企業職工生育保險試行辦法》), enterprises in China must provide benefit plans for their employees, which include basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance. An enterprise must provide social insurance by processing social insurance registration with local social insurance agencies, and must pay or withhold relevant social insurance premiums for or on behalf of employees.

The Law on Social Insurance (《中華人民共和國社會保險法》), which was promulgated on October 28, 2010 and came into effect on July 1, 2011, and was amended on December 29, 2018 regulates basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance, and has elaborated in detail the legal obligations and liabilities of employers who do not comply with relevant laws and regulations on social insurance.

The Regulations on the Administration of Housing Provident Fund (《住房公積金管理條例》), which was promulgated on April 3, 1999 and came into effective on the same date, and was amended on March 24, 2002 and March 24, 2019, stipulates that housing provident fund contributions paid by an individual employee and housing provident fund contributions paid by his or her employer shall all belong to the individual employee.

LAWS AND REGULATIONS RELATING TO TAXATION

EIT

According to the Enterprise Income Tax Law of the People's Republic of China (《中華人民共和國企業所得税法》) (the "**EIT Law**"), 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 the Implementation Regulations on the EIT Law (《中華人民共和國企業所得税法實施條例》) (the "**EIT Regulations**"), 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, within the territory of China, enterprises and other organizations that obtain income shall be taxpayers of enterprise income tax and shall pay enterprise income tax in accordance with the PRC regulations. These enterprises are classified as either resident enterprises or non-resident enterprises. Resident enterprises refer to enterprises that are established in accordance with PRC laws, or that are established in accordance with the laws of foreign countries but whose actual or de facto control is administered from within the PRC. Where a non-resident enterprise has establishments or places within the territory of China, it shall pay enterprise income tax on income derived from sources within the territory of China and income derived from sources outside the territory of China but actually connected with its establishments or places in China. Under the EIT Law and EIT Regulations, a uniform corporate income tax rate of 25% is applicable. If non-resident enterprises have not established institutions or places in the PRC, or if they have established institutions or places in the PRC but there is no actual relationship between the relevant income derived in the PRC and the institutions or places set up by them, such non-resident enterprises shall pay enterprise income tax on its income originating in the PRC.

According to the EIT Law and the EIT Regulations, an enterprise certified as a high and new technology enterprise was subject to a preferential EIT rate of 15%. In accordance with the Measures for Administration of Recognition of High and New Technology Enterprise (《高新技術企業認定管理辦法》) effective from January 1, 2008 and amended on January 29, 2016, an enterprise certified as a high and new technology enterprise is subject to review by the relevant PRC authorities.

VAT

The Provisional Regulations on Value-added Tax (《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 (《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 State Administration of Taxation 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 State Administration of Taxation and the General Administration of Customs on Relevant Policies for Deepening Value Added Tax Reform (《關於深化增值税改革有關政策的公告》) issued on March 20, 2019 and became effective on April 1, 2019, the value added tax rate was reduced to 13% and 9%, respectively.

On November 16, 2011, the MOF and the STA promulgated the Trial Scheme for the Conversion of Business Tax to Value-added Tax (《營業税改徵增值税試點方案》), pursuant to the government launched gradual taxation reforms from January 1, 2012, where a value-added tax is imposed in lieu of business tax on a trial basis in regions and industries showing strong economic performance, such as transportation and certain modern service industries.

According to the Notice on Overall Implementation of the Pilot Program of Replacing Business Tax with Value-added Tax (《財政部、國家税務總局關於全面推開營業税改徵增值税試點的通知》), if the taxpayer of the pilot project has already enjoyed tax incentives of business tax according to relevant policies and regulations before the application of the pilot collection of value-added tax in lieu of business tax, he/she may, in the remaining period of tax incentives, enjoy tax incentives of value-added tax in accordance with the relevant provisions.

Withholding Tax and International Tax Treaties

According to the Arrangement on the Avoidance of Double Taxation and Tax Evasion between Main Land and Hong Kong Special Administrative Region (《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》) entered into between Mainland China and Hong Kong on August 21, 2006, dividends paid by a resident company of one Party to a resident of another Party may be taxed in that other Party. However, such dividends may also be taxed in accordance with the laws of the Party to which the company paying the dividends

is a resident. If the beneficial owner of the dividend is a resident of the other Party and the beneficial owner directly owns at least 25% of the capital of the company paying the dividend, the tax shall not exceed 5% of the total dividend.

The Notice on the Several Issues of the Implementation of Tax Treaty (《國家税務總局關於執行税收協定股息條款有關問題的通知》), which was promulgated by the STA on February 20, 2009 and came into effect on the same date, stipulates that if the taxpayer needs to pay tax in accordance with the provisions of the dividend provisions of the tax agreement, the relevant taxpayer or withholding agent should obtain and maintain the information supporting the implementation of the provisions of the dividend provisions of the tax agreement, and timely report or provide the information according to the requirements of the tax authorities in accordance with the relevant provisions.

According to the Administrative Measures on Non-resident Taxpayers to Enjoy the Treatment under Tax Treaties (《非居民納税人享受協定待遇管理辦法》) promulgated by the STA on October 14, 2019 and came into effect on January 1, 2020, where a non-resident taxpayer self-assesses and concludes that it satisfies the criteria for claiming treaty benefits, it may enjoy treaty benefits at the time of tax declaration or at the time of withholding through the withholding agent, simultaneously gather and retain the relevant materials for future inspection, and accept follow-up administration by the tax authorities.

The Announcement of the State Administration of Taxation on Issues Relating to "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》) (the "**Announcement of Beneficial Owner**") was issued by the STA on February 3, 2018 and came into effect on April 1, 2018. The Announcement of Beneficial Owner provided that the "beneficial owner" shall mean a person who has ownership and control over the income and the rights and property from which the income is derived. When an individual who is a resident of the treaty counterparty derive dividend income from China, the individual may be determined as a "beneficial owner." The Announcement of Beneficial Owner also specifies that if the business activities carried out by the applicant do not constitute substantive business activities, it will be treated unfavorably in determining whether an applicant has the status as a "beneficial owner."

LAWS AND REGULATIONS RELATING TO FOREIGN EXCHANGE CONTROL

The Regulations on the Control of Foreign Exchange of PRC (《中華人民共和國外匯管理條例》), which were promulgated by the State Council on January 29, 1996, came into effect on April 1, 1996, and amended on January 14, 1997 and August 5, 2008, set out that foreign exchange receipts of domestic institutions or individuals may be transferred to China or deposited abroad and that the SAFE shall specify the conditions for transfer to China or overseas and other requirements in accordance with the international receipts, payments status and requirements of foreign exchange control. Foreign exchange receipts for current account transactions may be retained or sold to financial institutions engaged in the settlement or sale of foreign exchange. Domestic institutions or individuals that make direct investments abroad, are engaged in the distribution, sale of valuable securities or derivative products overseas

should register according to SAFE regulations. Such institutions or individuals subject to prior approval or record-filing with relevant authorities shall complete the required approval or record-filing prior to foreign exchange registration. The exchange rate for RMB follows a managed floating exchange rate system based on market demand and supply.

According to the Notice on Issues Relating to Foreign Exchange Control on Fund-raising by Domestic Residents through Offshore Special Purpose Vehicles and Round-trip Investments (《國家外匯管理局關於境內居民通過境外特殊目的公司融資及返程投資外匯管理有關問題的通知》) (the "**SAFE Circular 75**") promulgated by SAFE on October 21, 2005, domestic resident natural persons or domestic resident legal persons are required to register with the competent local branch of SAFE before they establish or control any offshore special purpose vehicles for capital raising with the assets or equity interest of PRC domestic companies owned by them. SAFE Circular 37, which replaced the SAFE Circular 75, states that (i) a PRC resident, including a PRC resident natural person or a PRC legal person, shall register with the local branch of the SAFE before it contributes the assets of or its equity interest into a special purpose vehicle for the purpose of investment and financing and (ii) when the special purpose vehicle undergoes change of basic information, such as change in PRC resident natural person shareholder, name or operating period, or occurrence of a material event, such as change in share capital of a PRC resident natural person, performance of merger or split, the PRC resident shall register such change with the local branch of the SAFE in a timely manner.

According to SAFE Circular 13 which became effective on June 1, 2015, banks are required to review and carry out foreign exchange registration under offshore direct investment directly. The SAFE and its branches shall implement indirect supervision over foreign exchange registration of direct investment via the banks.

The Circular on Reforming the Management Approach regarding the Settlement of Foreign Capital of Foreign-invested Enterprise (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》) (the "**Circular 19**"), promulgated on March 5, 2018 and amended on December 30, 2019, allows foreign-invested enterprises to make equity investments by using RMB fund converted from foreign exchange capital. Under the Circular 19, the foreign exchange capital in the capital account of foreign-invested enterprises upon the confirmation of rights and interests of monetary contribution by the local foreign exchange bureau (or the book-entry registration of monetary contribution by the banks) can be settled at the banks based on the actual operation needs of the enterprises. The proportion of discretionary settlement of foreign exchange capital of foreign-invested enterprises is currently 100%. SAFE can adjust such proportion in due time based on the circumstances of the international balance of payments. However, Circular 19 and the Circular on Reforming and Regulating Policies on the Control over Foreign Exchange Settlement of Capital Accounts (《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》) continues to prohibit foreign-invested enterprises from, among other things, using RMB fund converted from its foreign exchange capitals for expenditure beyond its business scope, investment and financing (except for security investment or guarantee products issued by banks), providing loans to non-affiliated enterprises or constructing or purchasing real estate not for self-use.

On October 23, 2019, the SAFE released the Circular on Further Promoting Cross-border Trade and Investment Facilitation (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》) (the "**Circular 28**") which was implemented on the same date. Under Circular 28, besides foreign-invested enterprises engaged in investment business, non-investment foreign-invested enterprises are also permitted to make domestic equity investments with their capital funds under the condition that the negative list are not violated and the relevant domestic investment projects are true and compliant.

According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《關於優化外匯管理支持涉外業務發展的通知》) issued by the SAFE on April 10, 2020, eligible enterprises are allowed to make domestic payments by using their capital, foreign credits and the income under capital accounts of overseas listing, with no need to provide the evidentiary materials concerning authenticity of such capital for banks in advance, provided that their capital use shall be authentic and in line with provisions, and conform to the prevailing administrative regulations on the use of income under capital accounts. The concerned bank shall conduct spot checking in accordance with the relevant requirements.