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 and 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 CFDA, was established as a regulatory authority responsible for registration and supervision of drugs, cosmetics and medical devices under the supervision of State Administration for Market Regulation (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 drugs, 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.

LAWS AND REGULATIONS IN RELATION TO DRUGS

Development of Drugs

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**") promulgated by the SCNPC, last amended on August 26, 2019 and became effective on December 1, 2019, and the Implementation Regulations of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》) promulgated by the State Council on August 4, 2002 and amended on February 6, 2016 and March 2, 2019, respectively, 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 specifications, results of pharmacological and toxicological tests and the related data, documents and the samples, shall, in accordance with the regulations of the 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 whether to approve it and then notify the clinical trial applicant. In case of a 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 related to the drug safety, effectiveness and quality controllability provided that the applicant is competent in quality management, risk control and liability compensation, a drug registration certificate shall be issued upon approval by the NMPA.

Drug Clinical Trial

Drug Clinical Trial Registration

According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) ("**Drug Registration Measures**") promulgated by the NMPA in July 2007 and became effective on October 1, 2007, 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 Drugs (《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 has completed filing pursuant to relevant provisions and 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 research clinical. On September 6, 2013, the Announcement of the CFDA on Drug Clinical Trial Registration and Information Publicity 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》) provides that, in addition to the aforementioned approval from 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 Registration and Information Publicity Platform. Specifically, the applicant shall complete the trial pre-registration within one month after obtaining the approval of the IND in order to obtain the trial's unique registration number and complete the registration of certain follow-up information before the first subject's enrollment in the trial and the first submission of publicity. If the first submission of publicity is not completed within one year after the approval of the IND, the applicant shall submit an explanation, and if the first submission of publicity is not completed within three years, the approval of the IND shall automatically be annuled.

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 was promulgated by the NMPA on March 17, 2017 and took effect on May 1, 2017, the authority of the drug clinical trial approval decision is adjusted to the Center for Drug Evaluation (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.

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

International Multi-Center Clinical Trials Regulations and Acceptance of Overseas Clinical Trial Data

According to the International Multi-Center Clinical Trial Guidelines (Trial) (《國際多中心藥物臨床試驗指南（試行）》), or the Multi-Center Clinical Trial Guidelines, promulgated by the NMPA on January 30, 2015 and effective from March 1, 2015, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicants plan to implement the International Multi-center clinical trials in the PRC, the applicants shall comply with relevant laws and regulations, such as the Drug Administration Law, the Implementation Regulations for the Drug Administration Law and the Administrative Measures for Drug Registration, execute the Good Clinical Practice, make reference to universal international principles such as the ICH-GCP, and comply with the laws and regulations of the countries involved in the International Multi-Center clinical trials. Where the applicants plan to use the data derived from the International Multi-Center clinical trials for approval of a drug registration in the PRC, it shall involve at least two countries, including China, and shall satisfy the requirements for clinical trials set forth in the Multi-Center Clinical Trial Guidelines and Drug Registration Measures and other related laws and regulations.

In October 2017, the NMPA issued the Decision on Adjustment of Matters Relating to Registration and Administration of Imported Drugs(《關於調整進口藥品註冊管理有關事項的決定》), pursuant to which, (i)for drugs subject to international multi-center clinical trial carried out in China, Phase I clinical trial shall be allowed to be carried out simultaneously, and the requirement that the clinical trial drug should be registered overseas or that the drug has entered into Phase II or Phase III clinical trial shall be removed, except for biological products for preventive purposes, (ii) following the completion of international multi-center clinical trial carried out in China, the applicant may directly apply for registration of market launch of the drugs, (iii) with respect to applications for clinical trial or market launch of imported innovative chemical drugs and therapeutic biological products, the marketing authorization in the country or region where the foreign drug manufacturer is located will not be required, and (iv) with respect to drug applications that have been accepted before the release of this Decision, if relevant requirements are met, importation permission can be granted if such applications request exemption of clinical trials for the imported drugs based on the data generated from international multi-center clinical trial.

According to the Technical Guiding Principles for the Acceptance of Overseas Clinical Trial Data of Drugs (《接受藥品境外臨床試驗數據的技術指導原則》) promulgated by the NMPA on July 6, 2018, the basic principles for accepting overseas clinical trial data include: (i) applicants shall ensure the authenticity, integrity, accuracy and traceability of overseas clinical trial data; (ii) the process of generating overseas clinical trial data shall comply with the relevant requirements of the GCP of International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH); (iii) applicants shall ensure the scientific design of overseas clinical trials, the compliance of clinical trial quality management system with the requirements, and the accuracy and integrity of statistical analysis of data; and (iv) to ensure that the clinical trial design and statistical analysis of the data are scientific and reasonable, for the drugs with simultaneous R&D in China and abroad and forthcoming clinical trials in China, the applicants may, prior to implementing key clinical trials, contact the CDE to ensure the compliance of their design with the essential technical requirements for drug registration in China.

Good Clinical Practice

The NMPA issued Good Clinical Practice which was effective on September 1, 2003, and the NMPA and the NHC promulgated the Regulations on the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》) on November 29, 2019 which became effective on December 1, 2019, to optimize the clinical trials and assign the responsibility of identifying the drug clinical trial institution to the NMPA and the NHC. The drug clinical trial institution should have an independent ethics committee that is responsible for the ethics review and examination of the clinical trial, and the clinical trial schemes are subject to review, examination and supervision. On April 23, 2020, NMPA and the NHC further revised the Good Clinical Practice which became effective on July 1, 2020, in order to further improve the quality of clinical trials and encourage innovation.

Registration of Drugs

According to the Drug Registration Measures, drug registration applications are divided into three different types, namely domestic new drug application, domestic generic drug application, and imported drug application. Drugs are classified as chemical drugs, biological products, traditional Chinese medicine or natural medicine. When Phases I, II and III of clinical trials have been completed, the applicant may apply to the NMPA for approval of a new drug 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 Measures, drug registration is regulated according to the classification into Chinese medicine, chemical medicine and biological products. Where overseas research materials and data are used in an application to support drug registration, its source, research institutes or laboratory criteria, quality system requirements and other management criteria shall comply with the general principles of the ICH, and comply with the relevant requirements with regard to the drug registration. The NMPA shall establish a system to expedite drug registration, and support drug innovation guided by clinical value. Where an application for drug registration satisfies the criteria, the applicant may apply for breakthrough therapy drug, conditional approval, prioritized/special review and approval. Drug registration inspection for overseas-manufactured drug shall be implemented by port drug inspection agencies organized by the National Institutes for Food and Drug Control (中國食品藥品檢定研究院, the "**NIFDC**"), and for application for registration of overseas-manufactured drug, where an applicant applies for drug registration inspection prior to acceptance of the application for drug registration, it shall request for random sampling pursuant to the provisions, and deliver the samples, materials required for inspection and standard substances to the NIFDC.

The Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices (《關於改革藥品醫療器械審評審批制度的意見》)(the "**Reform Opinions**"), promulgated by the State Council on August 9, 2015, established a framework for reforming the evaluation and approval system for drugs and medical devices. The Reform Opinions indicated enhancing the standard of approval for drug registration and accelerating the evaluation and approval process for innovative drugs as well as improving the approval of drug clinical trials.

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 Measures and under which, Category 1 drugs refer to new drugs that have not been marketed anywhere in the world, which is eligible for special review or fast track approval by the NMPA. Category 5 drugs are drugs which have already been marketed abroad but are not yet approved in China. Category 1 drugs and Category 5 drugs can be registered through the domestic new drug application and imported drug application procedures under the Drug Registration Measures, respectively.

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 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 prioritized evaluation and approval procedure.

In order to accelerate the marketing of clinically urgent drugs with outstanding clinical value in China, the CDE promulgated the Clinical Technical Guidelines for Conditional Approval of Drugs (Tentative) (《藥品附條件批准上市技術指導原則（試行）》) on November 19, 2020 which became effective on the same day. Such guidelines apply to traditional Chinese medicine, chemical drugs and biological products that are not listed for sales in China. According to such guidelines, during the period of drug clinical trials, a drug may be applied for conditional approval if it meets the following conditions: (i) for the treatment of seriously life-threatening diseases with no existing effective treatment available, as well as medicines urgently needed for public health, whose clinical trials have shown efficacy and whose clinical value can be predicted; (ii) vaccines that are urgently needed in response to major public health emergencies or other vaccines that are identified as being urgently needed by the NHC, and whose benefits are assessed to outweigh the risks. The quality of clinical trial data to support conditional approval for marketing of the drugs shall comply with the requirements and standards of ICH and relevant domestic technical guidelines. After a drug is conditionally approved for marketing, such drug may be marketed for treatment, but its drug Marketing Authorization Holder shall complete the new or ongoing drug clinical trials within the prescribed time frame in accordance with the specific conditions attached to the drug registration certificate of such drug, and then apply to the CDE for regular approval for marketing in the form of supplementary application.

According to the Special Examination and Approval of Registration of New Drugs (《新藥註冊特殊審批管理規定》) 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: (i) 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; (ii) 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; (iii) the new drugs are for treating AIDS, malignant tumors and orphan diseases, etc., and have obvious advantages in clinic treatment; or (iv) the new drugs are for treating diseases with no effective methods of treatment. The applicant may file for special examination and approval at the clinical trial application stage if the drug candidate falls within items (i) or (ii), and can only file for special examination and approval at the stage of filing for production if the drug candidates fall within items (iii) or (iv).

The Marketing Authorization Holder System

The Reform Opinions provides a pilot plan for the marketing authorization holder system, or the MAH system. The Circular on the Matters Relating to Promotion of the Pilot Program for the

Drug Marketing Authorization Holder System (《關於推進藥品上市許可持有人制度試點工作有關事項的通知》), or the MAH Circular, promulgated by the NMPA on August 15, 2017, clarified the legal liability of the marketing authorization holder, who is responsible for managing the whole manufacturing and marketing chain and the whole life cycle of drugs and assumes the full legal liability for non-clinical drug study, clinical trials, manufacturing, marketing and distribution and adverse drug reaction monitoring. The Decision on Extending the Pilot Period of Authorizing the State Council to Carry out the Pilot Program for the Drug Marketing Authorization Holder System in Some Regions (《關於延長授權國務院在部分地方開展藥品上市許可持有人制度試點期限的決定》), which was promulgated by SCNPC on October 26, 2018 and became effective on November 5, 2018, extended the term of the MAH system to November 5, 2019.

According to the Drug Administration Law, the State implements a drug MAH system for drug administration. Drug marketing authorization holder (the "**MAH**") shall mean enterprises or drug research and development institutes which have obtained a drug registration certificate. The MAH may engage in drug manufacturing on their own or may entrust a drug manufacturing enterprise to manufacture, and may sell the drugs for which they have obtained a drug registration certificate on their own or entrust a drug operation enterprise to sell in accordance with relevant regulations. In addition, upon approval by the NMPA, the MAH may transfer its drug marketing authorization, and such transferee shall possess the quality management, risk control and liability compensation competence to ensure drug safety, effectiveness and quality controllability, and perform the obligations of the MAH. The MAH shall be responsible pursuant to the law for drug safety, effectiveness and quality controllability throughout the drug research and development, production, management and use process including but not limited to: (i) the MAH shall establish a drug quality assurance system and assign special personnel to independently take charge of drug quality control; (ii) the MAH shall periodically review the quality management system of the entrusted pharmaceutical manufacturing enterprise and pharmaceutical operation enterprise, if any, and supervise their continuous quality assurance and control capabilities; and (iii) the MAH shall establish and implement a drug tracking system, provide tracking information pursuant to the provisions and ensure drug traceability, etc.

Consistency Evaluation for the Quality and Efficacy of Generic Drugs

The consistency evaluation for the quality and efficacy is only applicable to generic drugs. For the generic drugs which had been market-approved, the consistency evaluation shall be conducted in accordance with relevant regulations during a specified period of time. According to the Reform Plan for Registration Category of Chemical Medicine (《化學藥品註冊分類改革工作方案》) issued by the NMPA in March 2016, generic drugs shall be approved for registration according to the principle of consistency quality and efficacy with the original drugs. 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>的有關事項的公告》) promulgated in May 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.

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, for generic drugs, including essential drug varieties, approved for marketing before the implementation of the new registration 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 three years in principle. 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.

Importation of Drugs

Pursuant to the Administrative Measures on the Import of Drugs (《藥品進口管理辦法》) which became effective on 1 January 2004 and amended on 24 August 2012, the Imported Drug License (進口藥品註冊證) or Import Drug Approval shall be obtained prior to performing the import filing and port inspection procedures.

According to the Notice on Matters Concerning Imported Drugs' Compliance with the Chinese Pharmacopoeia (《關於進口藥品符合<中華人民共和國藥典>有關事宜的通知》) promulgated by NMPA on February 16, 2016, all drugs to be imported must meet the relevant requirements set forth in the Chinese Pharmacopoeia (《中華人民共和國藥典》). Drugs to be imported shall be inspected at ports in accordance with the relevant requirements prescribed in the Chinese Pharmacopoeia and those failing to meet the said requirements are not allowed to be imported.

The Drug Administration Law stipulates that drugs shall be imported from the ports where drug imports are approved, and the drug-importing enterprise shall file record with the local branch of the NMPA at the port. The local branch of the General Administration of Customs shall proceed with customs clearance procedures on the basis of the drug import clearance document issued by the local branch of the NMPA at the port. The ports where drug imports are approved shall be jointly proposed by the NMPA and the General Administration of Customs, and subject to approval by the State Council.

Distribution of Drugs

Drug Operation Permit

According to the Drug Administration Law, the Provisions for Supervision of Drug Distribution (《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 engagement of a wholesale pharmaceutical distribution of a company requires the approval of the provincial medicine administrative authorities. Upon approval, the authority will grant a Drug Operation Permit (藥品經營許可證) in respect of the wholesale drugs distribution company. The grant of such permit is subject to an inspection of the operator's facilities, warehouse, hygiene environment, quality control systems, personnel (including of whether pharmacists and other professionals have the relevant qualifications) and equipment. Under the Measures on the Administration of Drug Operation Permit (《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 Drug Operation Permit is valid for five years. Each holder of the Drug Operation Permit must apply for an extension of its permit six months prior to expiration, and extensions are granted only after a reexamination of the permit holder by the authority which issued the permit.

In addition, where any MAH or drug operation enterprises engage in the online drug sales, such activities shall be conducted in compliance with the relevant provisions of the Drug Administration Law. Drugs subject to the special administration by the State, such as vaccines, blood products, anesthesia and psychiatric drugs, medical use poisons, radioactive drugs, drug precursor chemicals etc., shall not be sold online.

As of the Latest Practicable Date, of all the products we sold, only Zadaxin was provided on the GTP platform, which is not subject to the special administration by the State.

As of the Latest Practicable Date, SciClone Jiangsu had obtained a Drug Operation Permit for its wholesale operation of drugs, which is currently valid till January 18, 2026. According to the Drug Administration Law and Measures on the Administration of Drug Operation Permit, SciClone Jiangsu shall apply for renewal within 6 months before the expiration of the validity term of its Drug Operation Permit, and the competent authority shall conduct reexamination in accordance with the relevant regulations, among others, including: (i) employ pharmacists or other pharmacy technicians who obtain qualifications pursuant to the laws; (ii) have business premises, equipment, warehousing facilities and hygiene environment corresponding to their drug business; and (iii) have the quality management setup or staff corresponding to their drug business. We will submit our renewal application within the required timeframe and as of the Latest Practicable Date, we did not expect any obstacles to satisfy the required conditions for the renewal of our Drug Operation Permit.

Good Supply Practices

According to the Good Supply Practice for Drugs (《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.

As of the Latest Practicable Date, SciClone Jiangsu had obtained a certificate of Good Supply Practice for drugs, which is currently valid till August 1, 2021. According to the Drug Administration Law, the Good Supply Practice certificate is cancelled and the drug operation enterprise shall comply with Good Supply Practice, establish and improve the pharmaceutical quality management system to ensure that the whole process of pharmaceutical business continuously satisfies the statutory requirements.

Two-invoice System

In order to further optimize the order of purchasing and selling drugs 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 "two-invoice System" will be fully implemented in the PRC. According to the Notice of Publishing Opinions on Implementing Two-invoice 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》) which was issued on December 26, 2016, the "two-invoice system" refers to the system under which the value added invoices are allowed to be issued twice aggregately in the process of the distribution, one value added invoice to be issued from pharmaceutical manufacturers to pharmaceutical distributors and the other value added invoice to be issued from pharmaceutical distributors to medical institutions. The domestic general agent within the territory of the PRC for overseas drugs can be deemed as a pharmaceutical manufacturer under the "two-invoice system", provided that only one such general agent is permitted within the territory of the PRC. 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 in terms of which one value added invoice is to be issued, but during such process, only one value added invoice is allowed to be issued at most. The pharmaceutical manufacturers and pharmaceutical distributors that failed to comply with the requirements of the "two-invoice system", may be cancelled the qualifications for bidding, winning bids and distribution and included in the bad record of drug purchases.

Advertising of Drugs

On October 26, 2018, the SCNPC promulgated the Advertising Law of the PRC (amended in 2018) (《中華人民共和國廣告法(2018年修正)》), according to which certain contents such as statement on cure rate or efficiency shall not be included in advertisement of drugs. On December 24, 2019, the SAMR promulgated the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food, and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) which came into effect on March 1, 2020, stipulates that the advertisements for drugs shall not be released without being reviewed and the contents of a drug advertisement shall be based on the contents of the registration certificate or filing certificate approved by the drug administrations, the contents of a drug advertisement shall be based on the drug instructions approved by the NMPA.

Drug Purchase by Hospitals

Centralized Tender Process

The implementation of the centralized tender process. According to the Notice on the Trial Implementation of the Centralized Tender with Respect to Drug Purchases by Medical Institutions (《關于印發醫療機構藥品集中招標采購試點工作若干規定的通知》) promulgated and effective on July 7, 2000, and 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》) which

was promulgated and became effective on July 23, 2001, in principle, any drugs included in the NRDL and any drugs with relatively common clinical application and large clinical usage are required to be purchased by the public hospitals and other public medical institutions through centralized tender process. Further, pursuant to 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》) which was promulgated and took effect on January 17, 2009, and 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》) which was promulgated and became effective on July 7, 2010, (i) any public hospitals and public 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 tender process through a centralized procurement platform, and (ii) the scope of drugs to be purchased through centralized tender process was expanded, except for (a) certain drugs under the State's special administration, and (b) the Class II psychotropic drugs and medical radiopharmaceuticals, medical toxicity drugs, raw materials, Chinese herbal medicines and Chinese herbal slices, all the drugs used by the public hospitals and public medical institutions must be included into the scope of centralized tender process. In addition, 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 took 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 drug centralized procurement platform.

Mechanism and selection criteria for a drug to be eligible and enlisted in the centralized tender process. In general, the public hospitals should submit the procurement plan and budget to the provincial procurement agency, specific to the generic name (通用名), dosage form and specifications. The provincial procurement agency should summarize the procurement plans and budget and reasonably compile a drug procurement catalog of the hospitals within its own administration region, taking into consideration of several factors such as the principle of common clinical necessity, appropriate dosage form specifications, and convenient packaging and use. According to 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》), the narcotic drugs and Class I psychotropic drugs under the State's special management are not included in the drug procurement catalog, and the Class II psychotropic drugs and medical radiopharmaceuticals, medical toxicity drugs, raw materials, Chinese herbal medicines and Chinese herbal slices may not be included in the drug procurement catalog. The drugs used by the public hospitals and public medical institutions other than those mentioned above must be included in the scope of the drug procurement catalog.

Evaluation and approval procedures for the centralized tender process. The centralized tender process is in principle conducted once every year in the relevant province or city in China. The eligible pharmaceutical enterprises may choose whether to participate in the centralized tender process. The bids are assessed by a committee consisted of pharmaceutical and medical experts who will be randomly selected from a database of experts approved by the relevant government authorities. The committee members assess the bids based on a number of factors, including but not limited to, bid price, product quality, clinical effectiveness, product safety, qualifications and reputation, after-sale services and innovation. The drugs that have won in the centralized tender process may be purchased by public hospitals and public medical institutions funded by the governmental or state-owned enterprises (including state-controlled enterprises) in the relevant region, unless otherwise prescribed by the relevant rules and regulations.

The relationship with the NEDL and NRDL. The provincial drug procurement agency will take the NEDL and NRDL into consideration when formulating the scope of the drug procurement catalog. The provincial medical insurance departments should include the drugs covered in the NRDL in the scope of the provincial centralized tender process in due course pursuant to the Notice of Issuance of NRDL (《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》).

The impact of the centralized tender process. If the drug of an enterprise is selected during the centralized tender process, such drug can be sold in public hospitals and public medical institutions at the bid price, while the public hospitals and public medical institutions will not procure the drug if such drug is not selected, unless otherwise prescribed by the relevant rules and regulations. Further, the doctors at the public hospitals and public medical institutions can prescribe the drugs not selected in the centralized tender process for patients in compliance with prescription regulations and the patients may still purchase such drugs with the prescriptions obtained from the doctors in other channels, such as pharmacies.

The Volume-based Procurement in "4+7 Cities" and Wider Areas

To reform the medical and healthcare system and improve the mechanism for setting drug prices, the State carried out the volume-based procurement.

First, 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 program for the volume-based procurement and 31 drug varieties were included in the catalog of purchased species as set forth in such paper. The pilot program will be carried out in 11 cities, including Beijing, Tianjin, Shanghai, Chongqing and 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采購和使用試點方案的通知》), which provides the detailed measures in the implementation of the volume-based procurement in the 4+7 Cities.

Second, on September 1, 2019, the Joint Procurement Office published 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)》), which required relevant regions to form an alliance to carry out the volume-based procurement of cross-regional alliances and 25 drug varieties were included in the catalog of purchased species as set forth in such document. In addition to the 4+7 Cities in the alliance area, 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). On September 25, 2019, 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》) was promulgated, which aimed at promoting the model of volume-based procurement in the above pilot program in the 4+7 Cities to be expanded nationwide.

Third, according to the Documents on National Centralized Drug Procurement (GYYD2019-2) (《全國藥品集中採購文件(GY-YD2019-2)》) published by the Joint Procurement Office on December 29, 2019 and the subsequent 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》) which was promulgated on January 13, 2020, the areas for the volume-based procurement expanded nationwide to launch the second batch of the volume-based procurement, and 33 drug varieties were included in the catalog of purchased species as set forth in the Documents on National Centralized Drug Procurement (GYYD2019-2) (《全國藥品集中採購文件(GY-YD2019-2)》).

Fourth, on July 29, 2020, 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)》) to launch the third batch of the volume-based procurement, and according to which, 56 drug varieties were included in the catalog of purchased species. Fifth, on December 25, 2020, the Joint Procurement Office issued the Notice on the Collection of Information on the Fourth Batch of Drugs Related to the Volume-based Procurement (《關於開展第四批國家組織藥品集中採購相關藥品信息收集工作的通知》) to launch the fourth batch of the volume-based procurement, and according to which, 90 drug varieties with different specifications were included in the catalog of purchased species. On January 15, 2021, the Joint Procurement Office issued the Documents on National Centralized Drug Procurement (GY-YD2021-1) (《全國藥品集中採購文件 (GY-YD2021-1)》) to carry out the fourth batch of the volume-based procurement, and 45 drug varieties were included in the catalog of purchased species as set forth in the Documents on National Centralized Drug Procurement (GY-YD2021-1)(《全國藥品集中採購文件 (GY-YD2021-1)》).

Mechanism and selection criteria for a drug to be eligible and enlisted in the volume-based procurement. The drug varieties for the volume-based procurement are selected by the Joint Procurement Office from the drugs with generic names (通用名) corresponding to the generic drugs that have been evaluated for quality and efficacy consistency (including generic drugs approved according to the classification of new chemical registrations). The factors, such as clinical efficacy of the drugs, adverse reactions, the stability of drug batches, the adequacy of competition and other factors will be considered in the selection. As for the corresponding innovative drugs (原研药) under the same generic name, if they have obtained the drug registration approval and been marketed in the PRC in accordance with laws, such innovative drugs can be declared by the eligible enterprises, at their option, to participate in the volume-based procurement. As of the Latest Practicable Date, no explicit laws or regulations stipulated that there is a fixed time interval to select the drug varieties and launch the next batch of volume-based procurement.

The procedure of the volume-based procurement. The eligible enterprises prepare the declaration materials and submit to the Joint Procurement Office, and after the disclosure of declared information, the enterprises and the drugs to be selected and the supply area will be determined and announced by the Joint Procurement Office. After the results of the proposed selection are announced without objection from the public, the Joint Procurement Office will issue a notice of the successful selection.

The relationship with the centralized tender process, NEDL and NRDL. (i) As market-oriented pricing mechanisms for drugs, in the context of the volume-based procurement, the eligible pharmaceutical enterprises may choose whether to participate in the volume-based procurement, and the catalogue of candidate drugs involved in the volume-based procurement are formulated by the State. While in the context of the centralized tender process, the pharmaceutical enterprises shall take part in the centralized tender process so that they are able to sell the drugs to the public hospitals and public medical institutions unless otherwise provided by the laws, and the public hospitals and public medical institutions shall work out a procurement plan and specify the type and quantity of drugs needed and to be purchased within a specified time period, and the provincial competent authority shall summarize the procurement plan and budget reported by the public medical institutions, and reasonably formulate the drug procurement list of the public hospitals and public medical institutions within its administrative region according to the relevant laws and regulations. Further, the relevant public hospitals and public medical institutions shall give priority to the drugs selected through the volume-based procurement and ensure the completion of the agreed procurement volume, on the basis of which, for the remaining volume needed to be purchased, the relevant public hospitals and public medical institutions can procure the same variety of other drugs at a suitable price through the provincial centralized tender process pursuant to the relevant rules and regulations. (ii) According to the Notice on Several Policies and Measures to Further Deepen the Reform of the Medical and Health System by Taking the Centralized Procurement and Use of Drugs as the Breakthrough Point (《關於以藥品集中採購和使用為突破口進一步深化醫藥衛生體制改革若干政策措施的通知》) promulgated in November 2019, priority will be given to essential drugs that have passed the quality and efficacy evaluation of generic drugs to be included in the scope of volume-based procurement. (iii) Pursuant to the Interim Measures for the Administration of Drugs Covered by Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》), subject to the prior expert evaluation, eligible drugs selected for the volume-based procurement can be directly included in the NRDL.

The impact of the volume-based procurement. Under the volume-based procurement, the public hospitals and public medical institutions procure the bid-winning drugs with priority, and the doctors shall give priority to prescribe the bid-winning drugs so as to satisfy the required quantity commitment. As a result, the sales volume of the bid-winning drugs will significantly increase in the short run, which enables such drugs to gain a substantial market share despite the erosion effect of the average selling price potentially resulted from price-based competitive bidding. However, the bidding mechanism in the volume-based procurement could result in significant price decline of the bid-winning drugs. For the risks related to the volume-based procurement, please refer to the section headed "Risk Factors — We may experience difficulties in our sales efforts as a result of pricing regulations or other policies such as the volume-based procurement that are intended to reduce healthcare costs, which could subject us to pricing and volume pressures and adversely affect our operations, revenue and profitability." in this prospectus. Further, the doctors at the public hospitals and public medical institutions can prescribe the drugs not selected in the volume-based procurement for patients in compliance with prescription regulations and the patients may still purchase such drugs with the prescriptions obtained from the doctors in other channels, such as pharmacies.

REFORM OF MEDICAL AND HEALTHCARE SYSTEM

In order to deepen the reform of the medical and healthcare 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 is related to the NRDL and updated from time to time, and the centralized drug procurement scheme which commenced from provincial level and expanded to a nationwide level. Further, the first batch of National Key Drug List for Monitoring and Prescription Control (Chemical and Biological Products) 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 Two-invoice System to further optimize the order of purchasing and selling drugs and reduce distribution steps.

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" 規划綱要》), 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.

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

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

LAWS AND REGULATIONS IN RELATION TO THE COVERAGE AND REIMBURSEMENT

Coverage of the 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 (《國務院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 addition, on January 3, 2016, the Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents (《國務院關於整合城鄉居民基本醫療保險制度的意見》) issued by the State Council required the integration of the urban resident basic medical insurance and the new rural cooperative medical care system and the establishment of a unified basic medical insurance system, which will cover all urban and rural residents other than the persons who shall participate in the basic medical insurance for urban employees. Rural migrant workers and persons in flexible employment arrangements shall participate in the basic medical insurance for urban employees, and those who have difficulties can join the basic medical insurance for urban and rural residents in accordance with local regulations.

Medical Insurance Catalogue

Participants of the national medical insurance program and their employers, if any, are required to contribute to the payment of insurance premium on monthly basis. Program participants are eligible for full or partial reimbursement of the cost of medicines included in the NRDL which sets forth the payment standard for drugs under the basic medical insurance, work-related injury insurance and maternity insurance funds. The Notice Regarding the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Drugs for Urban Employee (《關于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 drug listed in the Medical Insurance Catalog (now known as NRDL) must be clinically needed, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements: (i) it is listed in the Chinese Pharmacopeia (the prevailing version) of the PRC; (ii) it meets the standards promulgated by the NMPA; and (iii) if imported, it is approved by the NMPA for import.

The Ministry of Human Resources and Social Security of the PRC (the "**MOHRSS**", according to the institutional reform, the functions with respect to change the NRDL have been transferred to the National Healthcare Security Administration of the PRC, the "**NHSA**") , 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.

Mechanism and selection criteria for a drug to be eligible and enlisted in the NRDL. According to the Interim Measures for the Administration of Drugs Covered by Basic Medical Insurance(《基本醫療保險用藥管理暫行辦法》), the drugs included in the NRDL shall be chemical drugs, biological products, proprietary Chinese medicines (ethnic drugs) and Chinese herbal slices processed according to national standards that have been approved by the NMPA and have obtained the drug registration certificate, and shall meet the basic conditions of clinical necessity, safety, effectiveness and reasonable price.

Evaluation and approval procedures for a drug to be eligible and enlisted in the NRDL. The agency of NHSA organizes experts to evaluate all drugs that meet the conditions for adjustment of the NRDL for the current year and propose the alteration of the NRDL, if applicable. The agency of NHSA shall organize experts to carry out drug negotiations or access bidding in accordance with the provisions, among which, the exclusive drugs enter the negotiation stage, while non-exclusive drugs enter the bidding stage. If negotiations or access bidding are successful, the drugs shall be included in the NRDL or the limited payment scope of which will be adjusted; if the negotiations or access bidding are unsuccessful, the drugs shall not be included in or removed from the NRDL, or the limited payment scope of which shall not be adjusted. The NHSA is responsible for determining and promulgating the NRDL and announcing the results of adjustment.

Provincial governments are required to include all Part A medicines listed in 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, on August 20, 2019, the MHRSS and the NHSA amended the NRDL, which became effective on January 1, 2020. It regulates that all localities shall strictly implement the drug catalogue and are not allowed to make a catalogue by themselves or add drugs in the catalogue, or adjust the limited payment scope of drugs in the catalogue. For those drugs that were already added to Part B of the provincial catalogue in accordance with the previous NRDL, the drugs shall be gradually removed within 3 years. On December 25, 2020, the NHSA and MOHRSS promulgated the Notice of Issuance of Drugs Catalogue for the National Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (2020) (《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(2020年)>的通知》), which will take effect on March 1, 2021 and simultaneously replace the current effective version of NRDL. According to this Notice, the new NRDL consists of 2,800 drugs in total, among which, 119 drugs were newly included into the scope of NRDL, and 29 drugs mainly with low clinical value and can be easily replaced or that its drug registration approval had been withdrawn by the NMPA were removed from the List. The Notice repeats to stress that the localities shall strictly implement the NRDL and promote the uniformity of drug use.

Patients purchasing medicines included in Part A of the NRDL are entitled to reimbursement of the entire amount of the purchase price through the basic medical insurance program. Patients purchasing medicines included in Part B of the NRDL are required to pay a certain percentage of the purchase price and obtain reimbursement for the remainder of the purchase price through the basic medical insurance program. 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.

The NHSA promulgated 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》) on April 17, 2019, stipulating 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 by the NHSA and the MOHRSS on November 22, 2019, the negotiation drugs are the 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 provincial basic medical insurance, industrial injury insurance and maternity insurance funds in accordance with the relevant regulations, and implement such negotiated drugs in parallel with regular admitted drugs from January 1, 2020. On December 16, 2019, the NHSA and NHC issued the Notice on the Landing of Drugs in National Medical Insurance Negotiations in 2019 (《關於做好2019年國家醫保談判藥品落地工作的通知》), in order to further implement the work of online purchasing and payment of negotiated drugs and promote the negotiated drugs to be used in the designated medical institutions in a timely manner.

In general, such policies will have favorable impacts on the drugs included in the NRDL.

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》) which became effective on the same day, and 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》), which aim to promote 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 NEDL. NHC and National Administration of Traditional Chinese Medicine promulgated the National Essential Drug List(2018 Version) (《國家基本藥物目錄(2018年版)》) on September 30, 2018 which became effective on November 1, 2018. To further improve the selection, production, circulation, use, payment, monitoring and other aspects of the policy of essential drugs, the Opinions of the General Office of the State Council on Improving the National Essential Drug System (《國務院辦公廳關於完善國家基本藥物制度的意見》) (the "**Opinions**") was promulgated on September 13, 2018, in which the State insists on the dominant position of essential drugs, specifies the proportion of essential drugs used in public medical institutions on a province-by-province basis, and continuously increases the amount of essential drugs used in medical institutions.

According to these regulations, basic healthcare institutions funded by the 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 NEDL.

Mechanism and selection criteria for a drug to be eligible and enlisted in the NEDL. The selection of national essential drugs should be in accordance with the principles of necessity for prevention and treatment, safety and effectiveness, reasonable price, easy to use and clinical preference, and in combination with the characteristics of drug use in China and with reference to international experience, to reasonably determine the variety (dosage form) and quantity and to meet the main clinical needs of common diseases, chronic diseases, emergency rescue as well as taking into account the needs of children and other special populations and public health prevention and treatment drugs. The following drugs are not included in the selection of the NEDL: (a) containing national endangered wildlife medicinal materials; (b) mainly used for tonic health effects and prone to abuse; (c) non-clinical treatment preferred; (d) due to serious adverse reactions, the NMPA clearly suspends the production, sale or use of; (e) contrary to national laws and regulations, or does not meet the ethical requirements; and (f) other cases specified by the National Working Committee on Essential Drugs (國家基本藥物工作委員會).

Evaluation and approval procedures for a drug to be eligible and enlisted in the NEDL. The National Working Committee on Essential Drugs establishes an advisory expert group and an review expert group. The advisory expert group conducts technical evaluation of the drugs included in the selection range, makes selection comments and forms an alternative catalog, and the review expert group reviews and votes on the alternative catalog to form the draft of the NEDL. After the final review by the National Working Committee on Essential Drugs, the NEDL will be issued by the NHC.

The relationship with NRDL. When adjusting the NRDL, the medical insurance department will prioritize to include the eligible therapeutic drugs listed in the NEDL into the scope of NRDL or adjust the scope of Part A and/or Part B.

In general, the policies mentioned above will have favorable impacts on the drugs included in the NEDL. As of the Latest Practicable Date, only Holoxan(和樂生), Mesna(美司鈉) and Endoxan（安道生） which we sell were listed in the NEDL.

Price Controls

Pursuant to the Notice on Issuing the Opinion on Promoting Pharmaceutical Pricing 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 drugs (other than narcotic drugs and certain psychiatric drugs) were lifted from June 1, 2015. After price controls were lifted, trading prices of drugs are mainly determined by market competition. Instead of direct government price controls which were historically used in the PRC but abolished in June 2015, 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.

The Circular of the NHSA on Issuing the Opinions on Effectively Carrying out Drug Price Administration at Present (《國家醫療保障局關於印發<關於做好當前藥品價格管理工作的意見>的通知》) was promulgated by NHSA in November 2019, which expounds on works from four aspects, including getting aligned with and improving the existing drug price policies, establishing and improving a normalized mechanism of drug price regulation, effectively carrying out price tendering and procurement related to safeguarding the supply and stabilizing the prices of drugs in short supply, as well as strengthening the organization of regulatory authorities and enhancing their administration.

The General Office of the State Council promulgated the Guidelines of the General Office of the State Council on Promoting the Reform of the Supervision System of Medical Security Fund (《國務院辦公廳關於推進醫療保障基金監管制度體系改革的指導意見》) on June 30, 2020 which became effective on the same day, according to which, the State will continue to improve the market-oriented drug price formation mechanism, and improve the linkage mechanism between medical insurance payment and bidding and procurement prices. In addition, the State will strengthen supervision and inspection of the quality of accounting information in the pharmaceutical industry, and deepen special efforts against the inflated drug prices. On August 28, 2020, the NHSA further promulgated the Guiding Opinions on Establishment of the Credit Evaluation System for Drug Prices and Procurement by Bidding (《關於建立醫藥價格和招採信用評價制度的指導意見》) which came to effect on the same day, and pursuant to which, a catalogue of dishonest matters involving drug prices and procurement by bidding (醫藥價格和招採失信事項目錄清單) is established by the NHSA and subject to dynamic adjustment.

REGULATIONS AND POLICIES IN RELATION TO THE INTERNET MEDICAL SERVICES

The State Council issued the Guiding Opinions on Vigorously Advancing the "Internet Plus" Action (《國務院關於積極推進"互聯網+"行動的指導意見》) on July 1, 2015, which, among others, encourages the internet enterprises to cooperate with medical institutions in establishing online medical information platforms, and strengthen the integration of regional healthcare service resources.

In April 2018, the General Office of the State Council promulgated the Opinions on the Promoting the "Internet Plus Health Care" Development (《關於促進"互聯網+醫療健康"發展的意見》), encouraging the medical institutions to use the internet and other information technologies to expand the space and content of medical services, and to build an integrated online and offline medical service model covering pre-treatment, in-treatment and post-treatment. On July 17, 2018, Administrative Measures on Internet Diagnosis and Treatment (Trial) (《互聯網診療管理辦法(試行)》), Administrative Measures for Internet Hospitals (Trial) (《互聯網醫院管理辦法(試行)》) and Management Standards for Promote Medical Services (Trial) (《遠程醫療服務管理規範(試行)》) were promulgated by NHC and National Administration of Traditional Chinese Medicine. According to the above measures, the development of Internet hospitals supported by the physical medical institutions and online subsequent visits for some common diseases and chronic diseases by the doctors shall be permitted. After reviewing documents of the medical records and profiles of patients, doctors shall be allowed to prescribe online for some common diseases and chronic diseases.

As of the Latest Practicable Date, we did not engage in any activities relating to Internet hospitals, Internet diagnosis and treatment, or providing any remote medical services.

LAWS AND REGULATIONS IN RELATION 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 (《中國人民共和國反不正當競爭法》) ("**Anti-Unfair Competition Law**"), which was most recently amended on April 23, 2019, 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.

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》) ("**Prohibition Commercial Bribery Provisions**"), which was promulgated by State Administration for Industry & Commerce of the PRC 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 (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》) ("**Regulations on the Establishment of Adverse Records**") enforced on March 1, 2014 by the National Health Family Planning Commission, the enterprises manufacturing and operating drugs, medical equipment and medical supplies, and the agencies as well as individuals thereof, which bribe the employee(s) of the medical and health institutions procuring and using their drugs, medical equipment or medical supplies with property or other benefits, shall be included into the Adverse Records of Commercial Bribery if they satisfy any of the circumstances as described in the Regulations on the Establishment of Adverse Records.

LAWS AND REGULATIONS IN RELATION TO CUSTOMS

According to the Customs Law of the PRC (《中華人民共和國海關法》) which was passed by the SCNPC on January 22, 1987 and last amended on November 4, 2017, a consignee or consignor of import or export goods or a customs clearing enterprise shall be subject to registration by customs in accordance with PRC laws and regulations, prior to handling customs declaration procedures. Customs clearing personnel shall obtain the occupational qualifications for customs clearances in accordance with law.

According to the Provisions of the Administration of Registration of Customs Clearance Entities (《中華人民共和國海關報關單位註冊登記管理規定》), which was promulgated by the General Administration of Customs on March 13, 2014, became effective as of March 13, 2014 and was amended on December 20, 2017 and May 29, 2018 respectively, registration of customs clearance entities shall be divided into the registration of customs clearance enterprises and the registration of consignees or consignors of imported or exported goods. A customs clearance enterprise shall not go through the clearance procedures at the customs unless it has been approved by the relevant competent authority directly under the General Administration of Customs or the authorized affiliated customs. A consignee or consignor of imported or exported goods may directly go to the local customs for the registration.

LAWS AND REGULATIONS IN RELATION TO PRODUCT QUALITY LIABILITY

The Product Quality Law of the PRC (《中華人民共和國產品質量法》) promulgated by the SCNPC on February 22, 1993 and last amended on December 29, 2018, is the principal governing law relating to the supervision and administration of product quality, which clarified liabilities of the manufactures and sellers. A seller shall pay compensation if it fails to identify the manufacturer and the supplier of the defective product. A person who is injured or whose property is damaged by the defects in the product may claim for compensation from the manufacturer or the seller.

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 became effective on January 1, 2021, according to which, a manufacture or a commercial seller is subject to liability for harm to persons or property caused by the product defects. The injured shall be entitled to raise a claim for compensation against the manufacture or the commercial seller. In the case that the product defects are caused by the faults of the manufacture, after compensating the injured, the commercial seller shall be entitled to claim for compensation against the manufacture.

LAWS AND REGULATIONS IN RELATION 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 by the SCNPC 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 commencing from the date of registration and the registered trademarks can be 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 revised in September 1992 and August 2000, amended on December 27, 2008 and became effective on October 1, 2009 and further amended on October 17, 2020 which will be effective on June 1, 2021 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 effective from February 1, 2010, there are three types of patents in the PRC: invention patents, utility model patents and design patents. The protection period of a patent right for invention patents shall be 20 years and the protection period of a patent right for utility model patents and design patents 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. 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 on 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 IN RELATION TO FOREIGN INVESTMENT IN THE PRC

The Foreign Investment Law of the PRC (《中華人民共和國外商投資法》), promulgated by the NPC on March 15, 2019, has come into effect on January 1, 2020 and has replaced the previous major laws and regulations governing foreign investment in the PRC, including the Sino-foreign Equity Joint Ventures Enterprises Law (《中華人民共和國中外合資經營企業法》), the Sino-foreign Co-operative Enterprises Law(《中華人民共和國中外合作經營企業法》), the Wholly Foreign-invested Enterprise Law(《中華人民共和國外資企業法》), and together with their implementation rules and ancillary regulations. Pursuant to Foreign Investment Law, the existing foreign invested enterprises established prior to the effective of the Foreign Investment Law may keep their corporate

organization forms for five years after the effectiveness of the Foreign Investment Law before such existing foreign invested enterprises change their organization forms, organization structures, and their activities of foreign-invested enterprises in accordance with the Company Law of the PRC (《中華人民共和國公司法》), the Partnership Enterprise Law (《中華人民共和國合伙企業法》) and other applicable laws. According to the Foreign Investment Law, "foreign-invested enterprises" refers to enterprises that are wholly or partly invested by foreign investors and registered within Mainland China under the PRC laws; "foreign investment" refers to any foreign investor's direct or indirect investment in Mainland China, including: (i) establishing foreign-invested enterprises in Mainland China either individually or jointly with other investors; (ii) obtaining stock shares, stock equity, property shares, other similar interests of Chinese domestic enterprises; (iii) investing in new projects in Mainland China either individually or jointly with other investors; and (iv) making investment through other means provided by laws, administrative regulations, or provisions of the State Council.

Investments conducted by foreign investors in the PRC are subject to the Catalogue of Industries on Encouraged Foreign Investment (2020 Version) (《鼓勵外商投資產業目錄(2020年版)》) and the Negative List which were jointly issued by the NDRC, and the MOFCOM. The Negative List currently in force was amended in 2020 and became effective on July 23, 2020, which further reduces the restrictions on foreign investment.

On December 26, 2019 the State Council issued Implementation Regulations for the Foreign Investment Law (《外商投資法實施條例》) (the " **Implementation Rules**") which came into effect on January 1, 2020. According to the Implementation Rules, in the event of any discrepancy between the Foreign Investment Law, the Implementation Rules and relevant provisions on foreign investment promulgated prior to January 1, 2020, the Foreign Investment Law and the Implementation Rules shall prevail. The Implementation Rules also sets forth that foreign investors that invest in sectors on the Negative List in which foreign investment is restricted shall comply with special management measures with respect to shareholding, senior management personnel and other matters in the Negative List.

On December 30, 2019, the MOFCOM and the SAMR jointly promulgated the Measures on Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which took effect on January 1, 2020 and has replaced the Interim Measures for the Administration of Record-filling on the Establishment 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 or foreign-invested enterprises 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）.

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 special purpose vehicle, 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 IN RELATION TO LABOR AND SOCIAL SECURITY

According to 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, 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, labor contracts in written form shall be executed to establish labor relationships between employers and employees. In addition, wages cannot be lower than local minimum wage. The employers must establish a system for labor safety and sanitation, strictly abide by State rules and standards, provide education regarding labor safety

and sanitation to its employees, provide employees with labor safety and sanitation conditions and necessary protection materials in compliance with State rules, and carry out regular health examinations for employees engaged in work involving occupational hazards.

According to the Law on Social Insurance (《中華人民共和國社會保險法》), which was promulgated by the SCNPC on October 28, 2010 and came into effect on July 1, 2011, and was amended on December 29, 2018, the Provisional Regulations on the Collection and Payment of Social Insurance Premium (《社會保險費征繳暫行條例》), which was promulgated by the State Council on January 22, 1999 and amended on March 24, 2019, and the Regulations on the Administration of Housing Provident Fund (《住房公積金管理條例》), which was promulgated by the State Council on April 3, 1999 and came into effective on the same date, and was amended on March 24, 2002 and March 24, 2019, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance, maternity insurance and to housing provident funds. Any employer who fails to contribute may be fined and ordered to make good the deficit within a stipulated time limit.

LAWS AND REGULATIONS IN RELATION TO TAXATION

Enterprise Income Tax

According to 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 Enterprise Income Tax Law (《中華人民共和國企業所得税法實施條例》), which was promulgated by the State Council on December 6, 2007 and came into effect on January 1, 2008, and amended by the State Council on April 23, 2019 and came into effect on the same date, a uniform income tax rate of 25% will be applied to resident enterprises and non-resident enterprises that have established production and operation facilities in China. Besides enterprises established within the PRC, enterprises established in accordance with the laws of other judicial districts whose "de facto management bodies" are within the PRC are considered "resident enterprises" and subject to the uniform 25% enterprise income tax rate for their global income. A non-resident enterprise refers to an entity established under foreign law whose "de facto management bodies" are not within the PRC but which have an establishment or place of business in the PRC, or which do not have an establishment or place of business in the PRC but have income sourced within the PRC. An income tax rate of 10% will normally be applicable to dividends declared to or any other gains realized on the transfer of shares by non-PRC resident enterprise investors that do not have an establishment or place of business in the PRC, or that have such establishment or place of business but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends are derived from sources within the PRC.

According to the Arrangement for the Avoidance of Double Taxation and Tax Evasion between Mainland of China and Hong Kong (《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 the HKSAR on August 21, 2006, if the non-PRC parent company of a PRC enterprise is a Hong Kong resident which directly owns 25% or more of the equity interest pf the PRC foreign-invested enterprise which pays the dividends and interests, the 10% withholding tax rate applicable under the EIT Law may be lowered to 5% for dividends and 7% for interest payments if a Hong Kong resident enterprise is determined by the competent PRC tax authority to have satisfied the relevant conditions and requirements under such Double Tax Avoidance Arrangement and other applicable laws. However, according to the Notice on the Certain Issues with Respect to the Enforcement of Dividend Provisions in Tax Treaties (《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 State Administration of Taxation (the "**SAT**") on February 20, 2009 and came into effect on the same date, if the relevant PRC tax authorities determine, in their discretion, that a company benefits unjustifiably from such reduced income tax rate due to a transaction or arrangement that is primarily tax-driven, such PRC tax authorities may adjust the preferential tax treatment; and based on the Announcement of the Certain Issues with Respect to the "Beneficial Owner" in Tax Treaties (《國家税務總局關於税收協定中"受益所有人"有關問題的公告》), issued by the SAT on February 3, 2018 and effective on April 1, 2018, if an applicant's business activities do not constitute substantive business activities, it could result in the negative determination of the applicant's status as a "beneficial owner", and consequently, the applicant could be precluded from enjoying the above-mentioned reduced income tax rate of 5% under the Double Tax Avoidance Arrangement.

Value-added Tax

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.

The State Council approved, and the SAT and the MOF officially launched a pilot value-added tax reform program starting from January 1, 2012, or the Pilot Program, applicable to businesses in selected industries. Businesses in the Pilot Program would pay value-added tax instead of business tax. The Pilot Program was initiated in Shanghai, then further applied to ten additional regions such as Beijing and Guangdong province. On November 19, 2017, the State Council promulgated the Decisions on Abolishing the Provisional Regulations of the PRC on Business Tax and Amending the Provisional Regulations of the PRC on Value-added Tax (《關於廢止<中華人民共和國營業税暫行條例>和修改<中華人民共和國增值税暫行條例>關的決定》), according to which, all enterprises and individuals engaged in the sale of goods, the provision of processing, repair and replacement services, sales of services, intangible assets, real property and the importation of goods within the territory of the PRC are the taxpayers of value-added tax. The value-added tax rates generally applicable are simplified as 17%, 11%, 6% and 0%, and the value-added tax rate applicable to the small-scale taxpayers is 3%. According to the Notice of the MOF and the SAT on Adjusting Value added Tax Rates (《財政部、國家税務總局關於調整增值税税率的通知》) issued on April 4, 2018 and became effective on May 1, 2018, the deduction rates of 17% and 11% applicable to the taxpayers who have value added tax taxable sales activities or imported goods are adjusted to 16% and 10%, respectively. According to the Notice of the MOF, the SAT and the General Administration of Customs on Relevant Policies for Deepening Value Added Tax Reform (《關於深化增值税改革有關政策的公告》) issued on March 20, 2019 and became effective on April 1, 2019, the value added tax rate was reduced to 13% and 9%, respectively.

LAWS AND REGULATIONS IN RELATION TO FOREIGN EXCHANGE CONTROL

The Regulation on the Foreign Exchange Control of PRC (《中華人民共和國外匯管理條例》), which was 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, sets 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 Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》) which was promulgated by SAFE in February 2012, PRC citizens or non-PRC citizens residing in China for a continuous period of no less than one year (except for foreign diplomatic personnel in China and representatives of international organizations in China) who participate in any stock incentive plan of an overseas publicly listed company shall, through the domestic company to which the said company is affiliated, collectively entrust a domestic agency (may be the Chinese affiliate of the overseas publicly listed company which participates in stock incentive plan, or other domestic institutions qualified for asset trust business lawfully designated by such company) to handle foreign exchange registration, and entrust an overseas institution to handle issues like exercise of options, purchase and sale of corresponding stocks or equity, and transfer of corresponding funds. In addition, the domestic agency is required to amend the SAFE registration with respect to the stock incentive plan if there is any material change to the stock incentive plan.

The Circular on Relevant Issues Concerning Foreign Exchange Administration for PRC Residents to Engage in Overseas Investment and Financing and Inbound Investment via Special Purpose Vehicles (《國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》), which was promulgated by the SAFE on July 4, 2014 and came into effective on the same date, states that (i) a PRC resident, including a PRC resident natural person or a PRC legal person, shall register with the local branch of the SAFE before it contributes its assets or equity interest in domestic enterprises or offshore assets or interests 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 the Notice on Further Simplifying and Improving the Foreign Exchange Management Policies on Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) which was promulgated by SAFE on February 13, 2015 and 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 Method regarding the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》) (the "**Circular 19**"), promulgated on March 30, 2015 and last 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 willingness-based foreign exchange settlement of capital for foreign-invested enterprises is temporarily set at 100%. The 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 the Management Policies on the Settlement of Capital Projects (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) 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 in securities and other investments except for bank's principal-secured products, 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**"), according to which 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 provided that such investments do not violate the Negative List and the target investment projects are genuine and in compliance with laws.

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 funds, 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.