We are subject to various laws and regulations of the PRC that are material to our operations and are discussed below.

LAWS AND REGULATIONS OF THE PRC

Laws and regulations of the PRC in relation to drug products

Bio-industry

To promote the development of bio-industry, the PRC government has promulgated a series of industry policies in recent years. The General Office of the State Council promulgated the Circular on Printing and Issuing Certain Policies for Promotion of Accelerated Development of Bio-industry (《關於印發促進生物產業加快發展若干政策的通知》) on June 2, 2009, clearly indicating that accelerating the development of bio-industry is a major initiative for China to grasp the strategic opportunity of the revolution of new science and technology and to build an innovation-oriented country in an all-round way in the new century. On October 9, 2010, the Guidance on the Acceleration of the Structural Adjustment of the Pharmaceutical Industry (《關於加快醫藥行業結構調整的指導意見》) was promulgated and it requests boosting the development and innovation of biological technologies and pharmaceutical agents and breakthroughs of technologies, including large-scale and high throughput gene cloning and protein expression, humanization of antibody, preparation of human antibody, new vaccine adjuvants and large-scale cell culturing and protein purification. On October 10, 2010, the State Council issued the Decision on Accelerating the Fostering and Development of Strategic Emerging Industries (《關於加快培育和發展戰略性新興產業的決定》), categorizing the bio-industry as a strategically developing emerging industry and calling for strong support to not only develop biotechnology-drived pharmaceuticals, new types of vaccines, diagnostic reagents, chemical drugs and a large variety of innovative pharmaceuticals used for the prevention and control of critical diseases, but also set higher standards for biomedical industry.

Innovation Encouragement

In March 2016, the General Office of the State Council promulgated the Guiding Opinions on Promoting the Sound Development of the Medical Industry (《關於促進醫藥產業健康發展的指導意見》), which aim to accelerate the development of innovative drugs and biological products with major clinical needs, to speed up the promotion of green and intelligent pharmaceutical production technologies, to strengthen scientific and efficient supervision, and to promote the development of industrial internationalization.

In May 2016, the General Office of the State Council promulgated the Pilot Plan for the Drug Marketing Authorization Holder Mechanism (《藥品上市許可持有人制度試點方案》), which provides a detailed pilot plan for the drug marketing authorization holder mechanism, or the MAH System. Under the MAH System, drug research and development institutions or scientific research personnel in the pilot regions may serve as drug applicants for registration and submit applications for drugs clinical trials and marketing.

In October 2016, the State Council and the Communist Party of China jointly promulgated the Plan for Healthy China 2030 (《"健康中國2030"規劃綱要》), or Healthy China 2030, which aim to strengthen technical innovation by forming a Government-Industry-University-Research cooperation efficient system.

In October 2017, the General Office of the State Council promulgated the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation of Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》), or the Deepening Reform Opinions, which seek to streamline the clinical trial process and shorten the time line. The Deepening Reform Opinions provided for special fast-track approval for new drugs and devices in urgent clinical need, and drugs and devices for rare diseases.

In December 2017, the China Food and Drug Administration promulgated the Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation (《關於鼓勵藥品創新實行優先審評審批的意見》), which further clarified that a fast track clinical trial approval or drug registration pathway will be available to innovative drugs.

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

Drug Regulations

Drug Administration

In order to strengthen drug control and administration and ensure the quality of drugs, the Standing Committee of the National People's Congress, or the SCNPC, promulgated the Drug Administration Law (《藥品管理法》) in 1984, which was latest amended in April 2015. The Implementation Rules for the Drug Administration Law (《藥品管理法實施條例》) was released accordingly by the State Council in 2002, amended on February 6, 2016, which laid out the rules and principals of the Drug Administration Law and provides detailed implementation rules of drugs administration. The Drug Administration Law and the Implementation Rules for the Drug Administration Law have laid out the legal framework for the establishment of pharmaceutical manufacturing enterprises and pharmaceutical trading enterprises and for the administration of pharmaceutical products, including the development and manufacturing of new drugs and medicinal preparations by medical institutions. They also regulate and prescribe a framework for the administration of pharmaceutical manufacturers, pharmaceutical trading companies, and medicinal preparations of medical institutions and the development, research, manufacturing, distribution, packaging, pricing and advertisements of pharmaceutical products. According to the Drug Administration Law and the Implementation Rules for the Drug Administration Law, no pharmaceutical products can be produced in the PRC without a Pharmaceutical Manufacturing Permit. A local pharmaceutical manufacturer must obtain a Pharmaceutical Manufacturing Permit from one of NMPA's provincial level

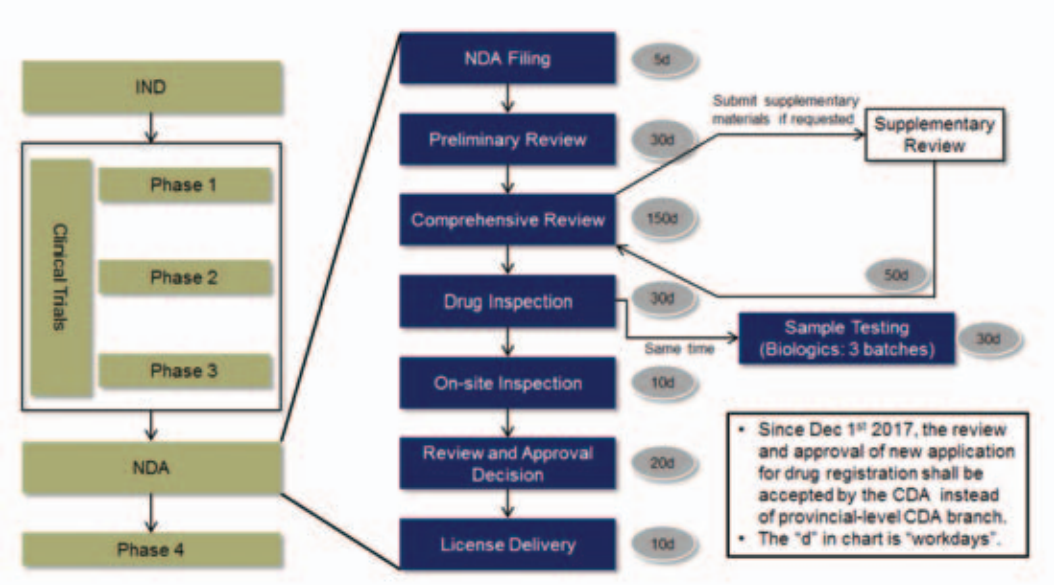
branches in order to commence production of pharmaceuticals. Prior to granting such license, the relevant government authority will inspect the manufacturer's production facilities, and decide whether the sanitary conditions, quality assurance system, management structure and manufacturing equipment have met the standards and criteria.

Drug Registration

In July 2007, the State Food and Drug Administration released the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) which took effect on October 1, 2007. The Administrative Measures for Drug Registration mainly cover: (1) definitions of drug registration applications and regulatory responsibilities of the drug administration; (2) general requirements for drug registration; (3) clinical trials; (4) application for new drug approval, examination and approval of new drugs; (5) supplemental applications and re-registrations of drugs; (6) inspections; (7) registration standards and specifications; (8) time limit; (9) re-examination; and (10) liabilities and other supplementary provisions.

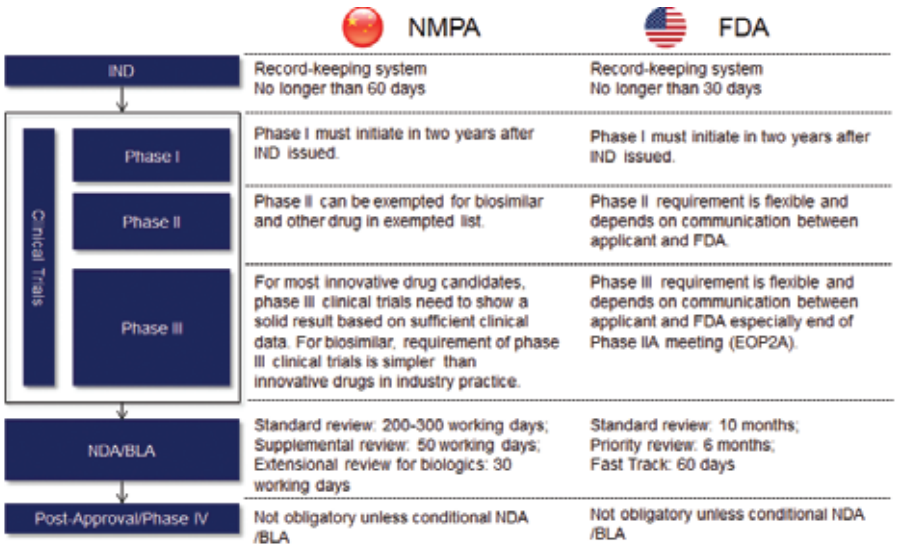
The diagrammatic flow charts below show a general drug registration approval procedures in China and a comparison of such procedures to the drug registration process and timeline in the U.S.. The steps and timelines in the diagram below is only for indicative purposes based on the common practices in the industry of relevant countries, and the actual procedures and timelines for approving a drug registration are varied from case to case.

Drug Registration Approval Procedures in China



Source: Frost & Sullivan

Comparison of Drug Registration Procedures in China and U.S.



Source: Frost & Sullivan

Regulations on the Clinical Trials and Drug Registration Procedure

- Four phases of clinical trials

According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), a clinical development program consists of Phases I, II, III and IV. Phase I refers to the initial clinical pharmacology and safety evaluation studies in humans. Phase II refers to the preliminary evaluation of a drug candidate's therapeutic effectiveness and safety for particular indication(s) in patients, which provides evidence and support for the design of Phase III clinical trials and builds the administered dose regime. Phase III refers to clinical trials undertaken to confirm the therapeutic effectiveness of a drug. Phase III is used to further verify a drug's therapeutic effectiveness and safety on patients with targeted indication(s), to evaluate overall benefit-risk profile of a drug, and ultimately to provide sufficient evidence for the review of drug registration application. Phase IV refers to a new drug's post-market study to assess therapeutic effectiveness and adverse events when the drug is widely used, to evaluate overall benefit-risk profile of the drug when used among the general population or specific groups and to adjust the administered dose, etc.

- Approving authority for IND

According to the Administrative Measures for Drug Registration, upon completion of its pre-clinical research, a research institution must apply for approval of a clinical trial application, or IND approval, before conducting clinical trials. From May 1, 2017, the IND approval can be directly issued by the CDE on behalf of the NMPA. This delegation of authority can shorten the timeline for the application of an IND approval. In July 2018, the NMPA promulgated the Announcement of the China National Medical Products Administration

on Adjusting Evaluation and Approval Procedures for Drug Clinical Trials (《國家藥品監督管理局關於調整藥物臨床試驗審評審批程式的公告》) to further simplify the procedures for the application for an IND approval, according to which if an applicant does not receive any negative or questioning opinions from the CDE within 60 days after the CDE's acceptance of the application and fee, such applicant may proceed with conducting the drug clinical trials in accordance with the plan submitted to the CDE.

- Good Clinical Practices for Pharmaceuticals

To improve the quality of clinical trials, the State Food and Drug Administration promulgated the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) in August 2003. In February 2004, the State Food and Drug Administration issued the Circular on Measures for Determination of Eligibility of Drug Clinical Trials Institutions (Trial) (《藥物臨床試驗機構資格認定辦法(試行)》), providing that the NMPA is responsible for certification of clinical trial institutions, and that the PRC National Health and Family Planning Commission, formerly known as the Ministry of Health, is responsible for certification of clinical trial institutions within its duties. Under the Circular on Measures for Determination of Eligibility of Drug Clinical Trials Institutions (Trial), the NMPA and the PRC National Health and Family Planning Commission decide whether an institution is qualified for undertaking clinical trials for pharmaceuticals based on the evaluation of its organizational management research personnel, equipment and facilities, management structure and its standard operational rules. If all requirements are met, a GCP Certification will be issued by the NMPA and the result will be published on the NMPA's website.

- Drug Clinical Trial Registration

Upon obtaining the approval of IND and before conducting a clinical trial, applicant shall file a registration with the NMPA containing various details with a copy sent to the competent provincial drug regulatory authority. In September 2013, the China Food and Drug Administration published the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗資訊平台的公告》), providing that, instead of the aforementioned registration filed with the NMPA, all clinical trials approved by the NMPA and conducted in China shall complete clinical trial registration and publish trial information through the Drug Clinical Trial Information Platform. The applicant shall complete the trial registration within one month after obtaining the approval of IND in order to obtain the trial's unique registration number and complete registration of certain follow-up information before the first subject's enrollment in the trial. If the registration is not completed within one year after the approval of IND, the applicant shall submit an explanation, and if the first submission is not completed within three years, the approval of IND shall automatically expire.

- New Drug Application

According to the Administrative Measures for Drug Registration, after Phase I, Phase II and Phase III of the clinical trials have been completed, the applicant may apply to NMPA for approval of a new drug application, or NDA, following the procedures as below. Notably, if we plan to manufacture our drug in-house, we must obtain GMP Certification (as described later) for our manufacturing facilities in advance.

- The applicant will first submit its application materials including clinical research report and relevant supporting documents to the drug regulatory authorities at the provincial level and, at the same time, submit raw materials used for the production for the new drug, related research data and product samples to the PRC National Institutes for Food and Drug Control, or the NIFDC.

- The drug regulatory authority at the provincial level will review the relevant documents for formalities and if relevant requirements are satisfied, it will issue a notice of acceptance and, within five days thereafter, start conducting site inspections. The drug regulatory authority at the provincial level will issue a preliminary opinion and collect samples of the new drug (if it is not a biological product) and notify the relevant drug control institute to review the medicine standards.

- The drug regulatory authority at the provincial level will then submit their preliminary opinion, inspection report and applicant's application materials to the Center for Drug Evaluation and notify the applicant of the progress.

- The drug control institute will review the medicine standards and report its opinion to the CDE and send a copy of the opinion to the applicant.

- After receiving the application materials, the CDE will arrange for pharmaceutical, medical or other professionals to conduct a technical review on the application materials and request for supplemental materials and explanations, if necessary. After completion of the technical review and if all the requirements are met, the CDE will report to the Certification Center of the NMPA and notify the applicant that it may apply for a production site inspection within six months thereafter.

- The Certification Center of the NMPA will arrange an on-site inspection of the facilities for the mass production of the new drug within 30 days after receiving the application to confirm the feasibility of the manufacturing process. The Certification Center of the NMPA will also collect one batch of samples (or three batches of samples if the new drug is a biological product) for the relevant drug control institute to examine. The Certification Center of the NMPA will prepare an inspection report within ten days after the production site inspection and submit the report to the CDE.

- The drug control institute will examine the sample(s) under the reviewed medicine standards, prepare a report after completing the examination and submit the report to the CDE. A copy of the report will be available to the applicant; and

- The CDE will form a comprehensive opinion based on the technical opinion previously received, the report on production site inspection and the result of sample examination, and will submit the comprehensive opinion and the application materials to the NMPA.

If all the regulatory requirements for NDA are satisfied, the NMPA will grant a New Drug Certification and a drug registration number (assuming the applicant has a valid Pharmaceutical Manufacturing Permit and the requisite production conditions for the new medicine have been met). All pharmaceutical products produced in China, with certain exceptions, must bear drug registration numbers issued by the NMPA. Drug manufacturing enterprises must obtain the drug registration numbers before manufacturing any drug. A drug registration number issued by the NMPA is valid for five years and the applicant shall apply for renewal six months prior to its expiration date.

According to the Administrative Measures for Drug Registration and Notice of Adjustment of Drug Registration Acceptance (《關於調整藥品註冊受理工作的公告》) in November 2017, the time limitation on each stage of review process was changed and the review of the local branch of NMPA on provincial level was cancelled in order to accelerate the NDA review and approval.

- Biosimilars Guideline

In February 2015, the China Food and Drug Administration released the Technical Guideline for the Research, Development and Evaluation of Biosimilars (Tentative) (《生物類似藥研發與評價技術指導原則(試行)》), or the Biosimilars Guideline, which outlines the regulatory framework for biosimilars in China. It sets forth the definition of biosimilars and their reference products, the basic principles for the technical review, the criteria for comparability, and the conditions under which extrapolations of indications would be permissible. According to the Biosimilars Guideline, a biosimilar drug should in principle have the same amino acid sequence as the reference product. Under the Biosimilars Guideline, the NMPA expects a structural and functional characterization of the biosimilar drug when comparing the same to the reference product. The NMPA also adopts a stepwise approach to examine comparability through comparative pharmacology data, non-clinical studies, and clinical studies.

- Anti-PD-1 and Anti-PD-L1 Monoclonal Antibodies NDA

In February 2018, the CDE promulgated the Basic Data Requirements for Anti-PD-1 and Anti-PD-L1 Monoclonal Antibodies NDA (《抗PD-1/PD-L1單抗品種申報上市的資料基本要求》) to regulate the clinical trials for anti-PD-1 and anti-PD-L1 monoclonal antibodies and the relevant regulatory approval procedures. To be more specific, it allows applicants to submit NDAs based on results from single-arm clinical trials with objective response rate, or the ORR, as the major endpoint, and to submit clinical data in stages in the form of rolling applications. It also provides that, before submission of NDAs, sponsors must propose pre-NDA meetings. The CDE decides whether to hold pre-NDA meetings and the form of such meetings according to the specific conditions of the drug candidates. Those sponsors complying with submission requirements can submit NDAs and propose the priority review simultaneously.

Drug Manufacture

- Pharmaceutical Manufacturing Permit

To manufacture pharmaceutical products in China, a pharmaceutical manufacturing enterprise must first obtain a Pharmaceutical Manufacturing Permit issued by the competent pharmaceutical administration authorities at the provincial level. Among other things, such a permit sets forth the permit number, the name, legal representative and registered address of the enterprise, the site and scope of production, issuing institution, date of issuance and effective period.

Each Pharmaceutical Manufacturing Permit issued to a pharmaceutical manufacturing enterprise is effective for a period of five years. Any enterprise holding a Pharmaceutical Manufacturing Permit is subject to review by the relevant regulatory authorities on an annual basis. Such enterprise is required to apply for renewal of such permit within six months prior to its expiry and will be subject to re-assessment by the issuing authorities in accordance with the then effective legal and regulatory requirements for the purposes of such renewal.

- GMP Certificates

The World Health Organization encourages the adoption of good manufacturing practice, or GMP, standards in pharmaceutical production in order to minimize the risks involved in any pharmaceutical production that cannot be eliminated by testing the final products.

A GMP certification certifies that a manufacturer's factory and quality management system have met certain criteria for engaging in the planning and manufacturing of drug products in various aspects, including, among others, institution and staff qualifications, production premises and facilities, equipment, production management, quality controls, production operation, maintenance of sales records and management of customer complaints and adverse event reports. In January 2011, the Ministry of Health, or MOH, issued an updated set of GMP standards (《藥品生產質量管理規範》), also known as the new GMP, to replace the previous version issued in 1998. There are also five annexes to the new GMP issued by the China Food and Drug Administration in February 2011, with detailed requirements for the manufacturing of sterile drugs, APIs, biologics, blood products and traditional Chinese medicines.

Drug Operation

The State Food and Drug Administration promulgated the Measures for the Administration of Pharmaceutical Operation Permit (《藥品經營許可證管理辦法》) on February 4, 2004 and amended on November 17, 2017, which provides the application procedures and requirements for the Pharmaceutical Operation Permit.

Pursuant to the Administrative Measures for the Supervision of Circulation of Pharmaceuticals (《藥品流通監督管理辦法》), promulgated by the State Food and Drug Administration in 2007, pharmaceutical enterprises shall be responsible for the quality of pharmaceuticals they manufacture, operate or use. A pharmaceutical enterprise shall be responsible for its purchase or sale of pharmaceuticals, including activities carried out by its staff on its behalf, and it shall not store or sell, pharmaceuticals at a place other than the

address approved by the pharmaceutical regulatory authority. Where a pharmaceutical enterprise knows or ought to know that any person operates pharmaceutical business without the permits but still supplies such person with pharmaceutical products, the pharmaceutical regulatory authority may give a disciplinary warning to the pharmaceutical enterprise, order such enterprise to rectify the non-compliance and impose a fine of no more than RMB10,000. In the case of a serious violation, such enterprise may be fined in an amount ranging from RMB10,000 to RMB30,000.

According to the Administrative Measures for Certification of Good Supply Practices (《藥品經營質量管理規範認證管理辦法》), promulgated by the State Food and Drug Administration on April 24, 2003, and the Administrative Measures Governing the Good Supply Practice of Pharmaceutical Products (《藥品經營質量管理規範》), promulgated on April 30, 2000 and amended on June 30, 2016, each retail or wholesale supplier of pharmaceutical products is required to obtain a GSP certificate from the NMPA. The GSP certificate is valid for five years and shall be renewed three months prior to its expiration date subject to a re-examination by the relevant authority.

Drug technology transfer regulations

On August 19, 2009, the State Food and Drug Administration promulgated the Administrative Regulations for Technology Transfer Registration of Drugs (《藥品技術轉讓註冊管理規定》) to standardize the registration process of drug related technology transfer, which includes the process of application for, and evaluation, examination, approval and monitoring of, drug related technology transfer. Drug related technology transfer refers to the transfer of drug production technology by the owner to a drug manufacturer and the application for drug registration by the transferee according to the Administrative Regulations for Technology Transfer Registration of Drugs. Drug related technology transfer includes new drug related technology transfer and drug production technology transfer.

Other Drug Related Regulations

- Advertising of Drug Products

Pursuant to the Criteria for Censoring Drug Advertisements (《藥品廣告審查發佈標準》), which were promulgated and came into effect in 2007, an enterprise seeking to advertise its drugs must apply for an advertisement approval code. The valid term of an advertisement approval code for pharmaceuticals is one year. The content of an approved advertisement may not be altered without prior approval. Where any alteration to the advertisement is needed, a new advertisement approval code shall be obtained.

- Insert Sheet and Labels of Products

According to the Measures for the Administration of the Insert Sheets and Labels of Drugs (《藥品説明書和標籤管理規定》) effective on June 1, 2006, the insert sheets and labels of drugs should be reviewed and approved by the NMPA. A drug insert sheet should include

the scientific data, conclusions and information concerning drug safety and efficacy in order to direct the safe and rational use of drugs. The inner label of a drug should bear information such as the drug's name, indication and function, strength, dose and usage, production date, batch number, expiration date and drug manufacturer; and the outer label of a drug should indicate information such as the drug's name, ingredients, description, indication or function, strength, dose and usage and adverse event.

- Packaging of Drug Products

According to the Measures for the Administration of Drug Packaging (《藥品包裝管理辦法》) effective in 1988, drug packaging must comply with the national and professional standards. If no national or professional standards are available, an enterprise can formulate its own standards and put into implementation after obtaining the approval of the food and drug administration bureau at provincial level. Such enterprise must reapply with the relevant authorities if it needs to change its own packaging standards. Pharmaceuticals that have not developed or received approval for, packing standards must not be sold or traded its drugs in China (except for drugs for the military).

Animal Testing Permits

According to the Regulations for the Administration of Affairs Concerning Laboratory Animals (《實驗動物管理條例》) promulgated by the State Science and Technology Commission in November 1988 as latest amended in March 2017, and Administrative Measures on the Certificate for Animal Experimentation (Trial) (《實驗動物許可證管理辦法(試行)》) promulgated by the State Science and Technology Commission and other regulatory authorities in 2001, performing experimentation on animals requires a certificate for use of laboratory animals.

Coverage and Reimbursement

Historically, Chinese patients paid most of their health-care expenses by themselves, which has limited the growth of sales of more expensive pharmaceutical products. However, in recent years the number of people whose medical expenses are reimbursable by government and commercial insurance schemes has increased. The PRC government has announced a plan to give every person in China access to basic healthcare by 2020.

Reimbursement under 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 in 1998, under which all employers in urban areas are required to enroll their employees in the basic medical insurance program and the insurance premium is jointly contributed by the employers and employees. 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 in the pilot districts who are not employed may voluntarily participate in the urban resident basic medical insurance scheme. In addition, in January 2016, the Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents (《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 rural migrant workers and persons in flexible employment arrangements who participate in the basic medical insurance for urban employees.

Participants of the national medical insurance program and their employers, if any, are required to contribute to the insurance program on a monthly basis. Program participants are eligible for full or partial reimbursement of the costs of medicines included in the National Reimbursement Drug List (《國家基本醫療保險藥品目錄》), or the NRDL.

National list of essential drugs

In 2009, MOH and other eight regulatory authorities in China issued the Measures on the Administration of the National List of Essential Drugs (《國家基本藥物目錄管理辦法》) 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 the use of fairly priced essential medicines in China and ensure that the general public in China has equal access to the drugs contained in the National Essential Drugs. MOH promulgated the National List of Essential Drugs (Catalog for the Basic Healthcare Institutions) on August 18, 2009, and promulgated the amended National List of Essential Drugs on March 13, 2013. According to these regulations, basic healthcare institutions funded by government, which primarily include state-level hospitals, state-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed on the National List of Essential Drugs. The drugs listed on the National List of Essential Drugs shall be purchased through centralized tender process and shall be subject to the price control by the NDRC. Remedial drugs in the National List of Essential Drugs are all listed in the NRDL and the entire amount of the purchase price of such drugs is entitled to reimbursement.

Commercial insurance

On October 25, 2016, the State Council and Central Committee of the Communist Party of China jointly issued the Development Plan and Guidelines for Healthy China 2030 (《"健康中國"2030規劃綱要》) or the Plan. According to the Plan, China will establish a multi-level medical security system built around basic medical insurance, with other forms of insurance supplementary to the basic medical insurance, including serious illness insurance for urban and rural residents, commercial health insurance and medical assistance. Furthermore, the Plan encourages enterprises and individuals to participate in commercial health insurance and various forms of supplementary insurance. The evolving medical insurance system makes innovative drugs more affordable and available to Chinese people, which creates greater opportunities to drug manufacturers that focus on the research and development of innovative drugs, such as high-cost anti-cancer therapeutics.

Price controls

Instead of direct price controls which were historically used in China but abolished in June 2016, the government regulates drug prices mainly by establishing a centralized procurement mechanism, improving medical insurance reimbursement standards and strengthening regulation of medical and pricing practices as discussed below.

Centralized procurement and tenders

The Guiding Opinions concerning the Urban Medical and Health Care System Reform (《關於城鎮醫藥衛生體制改革的指導意見》), promulgated in 2000, aim to regulate the procurement process of pharmaceutical products by medical institutions. The MOH and other relevant government authorities have promulgated a series of regulations and rules in order to implement the tender requirements. According to the Notice on Issuing Certain Regulations on the Trial Implementation of Centralized Tender Procurement of Drugs by Medical Institutions (《醫療機構藥品集中招標採購試點工作若干規定的通知》) promulgated in 2000 and the Notice on Further Improvement on the Implementation of Centralized Tender Procurement of Drugs by Medical Institutions (《關於進一步做好醫療機構藥品集中招標採購工作的通知》) promulgated in 2001, medical institutions established by government or state-owned enterprises are required to implement centralized tender procurement of drugs.

The centralized tender process takes the form of public tender operated and organized by provincial or municipal government authorities. The centralized tender process is generally conducted once a year in the relevant provinces or cities in China. The bids are assessed by a committee composed of pharmaceutical and medical experts who are randomly selected from a pool 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 of the manufacturer, after-sale services and innovation. Only pharmaceuticals that have won in the centralized tender process may be purchased by public medical institutions funded by the government or state-owned enterprise in the relevant region.

Insurance reform

The Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents (《關於整合城鄉居民基本醫療保險制度的意見》) issued by the State Council on January 3, 2016, call for 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 rural migrant workers and persons in flexible employment arrangement who participate in the basic medical insurance for urban employees.

According to the Main Tasks of Healthcare System Reform in 2016 (《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 key tasks of the medical insurance reform are: (1) to advance the establishment of

the mechanisms of stable and sustainable financing and security level adjustment, (2) to advance the integration of the basic medical insurance systems for urban and rural residents, (3) to consolidate and improve the system for serious illness insurance for urban and rural residents, (4) to reform medical insurance payment methods, and (5) to advance the development of commercial health insurance.

The Human Resources and Social Security Departments issued the Guiding Opinions on Actively Promoting the Coordinated Healthcare, Medical Insurance and Pharmaceutical Reforms (《關於積極推動醫療、醫保、醫藥聯動改革的指導意見》) on June 29, 2016, which state that reform will focus on exploring and leveraging the fundamental role of medical insurance through further integration of medical insurance systems in all aspects, deepening the reform of the payment methods for medical insurance and promoting innovation in the medical insurance management system.

According to the Notice on the Issuance of the 13th Five-year Plan on Strengthening the Reform of Healthcare System (《國務院關於印發"十三五"深化醫藥衛生體制改革規劃的通知》) issued by the State Council on December 27, 2016, one of the guiding principles is to insist on the reform of the coordinated development among healthcare, medical insurance and pharmaceutical systems. The reform intends to establish a complete policy structure in healthcare by 2017, including perfecting the graded diagnosis and treatment system, establishing and improving the comprehensive supervision and modern hospital management systems, improving the universal medical insurance system, perfecting drug production and distribution policies and strengthening systems of public health service, medical service, medical insurance, drug supply, supervision and management throughout the healthcare industry.

OTHER SIGNIFICANT LAWS AND REGULATIONS OF THE PRC AFFECTING OUR BUSINESS

Foreign Investment

Investment in the PRC conducted by foreign investors and foreign-owned enterprises shall comply with the Guidance Catalogue of Industries for Foreign Investment (《外商投資產業指導目錄》) (the "Catalogue"), which was newly amended and promulgated by the Ministry of Commerce of the People's Republic of China (the "MOFCOM") and National Development and Reform Commission (the "NDRC") on June 28, 2017. The Catalogue, as amended, became effective on July 28, 2017 and contains specific provisions guiding market access of foreign capital, stipulating in detail the areas of entry pertaining to the categories of encouraged foreign-invested industries, restricted foreign-invested industries and prohibited foreign-invested industries. Restricted category projects are subject to higher-level government approvals. Furthermore, foreign investors are not allowed to invest in companies engaged in industries that are listed in the prohibited category. Any industry not listed in the Catalogue is a permitted industry, and is generally open to foreign investment unless specifically prohibited or restricted by the PRC laws and regulations. The industry in which our PRC subsidiaries are primarily engaged does not fall into the category of restricted or prohibited foreign-invested industries.

The establishment procedures, examination and approval procedures, registered capital requirement, foreign exchange restriction, accounting practices, taxation and labour matters of a wholly foreign-owned enterprise are governed by the Wholly Foreign-owned Enterprise Law of the PRC (《中華人民共和國外資企業法》) (the "Wholly Foreign-owned Enterprise Law"), which was promulgated on April 12, 1986 and amended on October 31, 2000, and the Implementation Regulations of the Wholly Foreign-owned Enterprise Law (《中華人民共和國外資企業法實施細則》), which was promulgated on December 12, 1990, newly amended on February 19, 2014, and became effective on March 1, 2014. Pursuant to the Provisional Administrative Measures on Establishment and Modifications (Filing) for Foreign Investment Enterprises (《外商投資企業設立及變更備案管理暫行辦法》) promulgated by MOFCOM on October 8, 2016 and amended on July 30, 2017, establishment and modifications of foreign-invested enterprises not subject to the approval under the special entry management measures shall be filed with the competent commercial authorities.

On August 8, 2006, six PRC regulatory agencies, namely, MOFCOM, the State-owned Assets Supervision and Administration Commission, the State Administration of Taxation (the "SAT"), the State Administration for Industry and Commerce, the China Securities Regulatory Commission, and the SAFE, jointly adopted the Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (《關於外國投資者併購境內企業的規定》) (the "M&A Rules"), which became effective on September 8, 2006 and were amended by MOFCOM on June 22, 2009. The M&A Rules require, among others, that a foreign investor acquiring the equity interest in a non-foreign invested PRC enterprise or purchasing and operating the asset of such enterprise by establishing a foreign invested enterprise shall comply with relevant foreign investment industry policies and shall be subject to approval by MOFCOM or its local competent authorities.

Product Liability

According to the Product Quality Law of the PRC (《中華人民共和國產品質量法》), the "Product Quality Law"), promulgated by the SCNPC on February 22, 1993 and amended on July 8, 2000 and August 27, 2009, the General Rules of the Civil Law of the PRC (《中華人民共和國民法總則》) promulgated on March 15, 2017 and the General Principles of the Civil Law of the PRC (《中華人民共和國民法通則》), manufacturers shall be liable for the quality of products produced by them and sellers shall take measures to ensure the quality of the products sold by them. A manufacturer shall be liable to compensate for any bodily injury or property damage, other than the defective product itself, resulting from the defects in the product unless the manufacturer is able to prove that: (1) the product has never been circulated; (2) the defects causing injuries or damage did not exist at the time when the product was circulated; or (3) the science and technology at the time when the product was circulated were at a level incapable of detecting the defects. A seller shall be liable to compensate for any bodily injury or property damage of others caused by the defects in the product sold by the seller if such defects are attributable to the seller. A seller shall pay compensation if it fails to indicate neither the manufacturer nor 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.

Tort Law

Pursuant to the Tort Liability Law of the PRC (《中華人民共和國侵權責任法》), promulgated by the SCNPC on December 26, 2009 and became effective on July 1, 2010, manufacturers shall assume tort liability where the defects in relevant products cause damage to others. Sellers shall assume tort liability where the defects in relevant products causing damage to others which are attributable to the sellers. The aggrieved party may claim for compensation from the manufacturer or the seller of the relevant product in which the defects have caused damage.

Commercial Bribery

Pharmaceutical companies involved in a criminal investigation or administrative proceedings related to bribery are listed in the Adverse Records of Commercial Briberies by its provincial health and family planning administrative department. Pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry which became effective on March 1, 2014, provincial health and family planning administrative departments formulate the implementing measures for establishment of Adverse Records of Commercial Briberies. If a pharmaceutical company is listed in the Adverse Records of Commercial Briberies for the first time, its production is not required to be purchased by public medical institutions. A pharmaceutical company will not be penalized by the relevant PRC government authorities merely by virtue of having contractual relationships with distributors or third party promoters who are engaged in bribery activities, so long as such pharmaceutical company and its employees are not utilizing the distributors or third party promoters for the implementation of, or acting in conjunction with them in, the prohibited bribery activities. In addition, a pharmaceutical company is under no legal obligation to monitor the operating activities of its distributors and third party promoters, and will not be subject to penalties or sanctions by relevant PRC government authorities as a result of failure to monitor their operating activities.

Labor and Social Warfare

Pursuant to the PRC Labor Law (《中華人民共和國勞動法》), which was promulgated by the SCNPC on July 5, 1994 and became effective on January 1, 1995 and subsequently amended on August 27, 2009, the PRC Labor Contract Law (《中華人民共和國勞動合同法》), which was promulgated by the SCNPC on June 29, 2007 and subsequently amended on December 28, 2012 and became effective on July 1, 2013, and the Implementing Regulations of the 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 by the State Council and became effective on September 18, 2008, labor contracts in written form shall be executed to establish labor relationships between employers and employees. Wages shall not be lower than local minimum wage. The employer must establish a system for labor safety and sanitation, strictly abide by national 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 national rules, and carry out regular health examination for employees engaged in work involving occupational hazards.

Social insurance

According to the Regulation of Insurance for Labor Injury (《工傷保險條例》) implemented on January 1, 2004 and amended in 2010, the Provisional Measures for Maternity Insurance of Employees of Corporations (《企業職工生育保險試行辦法》) implemented on January 1, 1995, the Decisions on the Establishment of a Unified Program for Basic Old-Aged Pension Insurance of the State Council (《國務院關於建立統一的企業職工基本養老保險制度的決定》) promulgated on July 16, 1997, the Decisions on the Establishment of the Medical Insurance Program for Urban Workers of the State Council (《國務院關於建立城鎮職工基本醫療保險制度的決定》) promulgated on December 14, 1998, the Unemployment Insurance Measures (《失業保險條例》) promulgated on January 22, 1999 and the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) implemented on July 1, 2011, enterprises are obliged to provide their employees in the PRC with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, labor injury insurance and medical insurance. These payments are made to local administrative authorities and any employer that fails to contribute may be fined and ordered to make up within a prescribed time limit.

Housing fund

In accordance with the Regulations on the Management of Housing Funds (《住房公積金管理條例》) which was promulgated by the State Council in 1999 and amended in 2002, enterprises must register at the competent managing center for housing funds and complete procedures for opening accounts for the deposit of employees' housing funds. Enterprises are also required to pay and deposit housing funds on behalf of their employees in full and in a timely manner.

Employee stock incentive plan

In February 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (《關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》), or the Stock Option Rules, which replaced the Application Procedures of Foreign Exchange Administration for Domestic Individuals Participating in Employee Stock Ownership Plans or Stock Option Plans of Overseas Publicly Listed Companies (《境內個人參與境外上市公司員工持股計劃和認股期權計劃等外匯管理操作規程》) issued by the SAFE on March 28, 2007. In accordance with the Stock Option Rules and relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period no less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with the SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are PRC citizens or who reside in China for a continuous period no less than one year and who participate in our stock incentive plan will be subject to such regulation. In addition, the SAT has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in the PRC who exercise share options, or whose restricted shares vest, will be subject

to PRC individual income tax, or the IIT. The PRC subsidiaries of an overseas listed company have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their share options or restricted shares, failure of which may subject such PRC subsidiaries to sanctions imposed by the tax authorities or other PRC government authorities.

Taxation

Income Tax

On March 16, 2007, the National People's Congress promulgated the Law on Enterprise Income Tax (《中華人民共和國企業所得税法》) which was amended on February 24, 2017, and on December 6, 2007, and the State Council enacted the Regulations for the Implementation of the Law on Enterprise Income Tax (《中華人民共和國企業所得税法實施條例》) (collectively, the "EIT Law"). According to the EIT Law, taxpayers consist of resident enterprises and non-resident enterprises. Resident enterprises are defined as enterprises that are established in China in accordance with PRC laws, or that are established in accordance with the laws of foreign countries but whose actual or de facto control is administered from within the PRC.

Non-resident enterprises are defined as enterprises that are set up in accordance with the laws of foreign countries and whose actual administration is conducted outside the PRC, but have established institutions or premises in the PRC, or have no such established institutions or premises but have income generated from inside the PRC. Under the EIT Law and relevant implementing regulations, a uniform corporate income tax rate of 25% is applicable. However, if non-resident enterprises have not formed permanent establishments or premises in the PRC, or if they have formed permanent establishment institutions or premises in the PRC but there is no actual relationship between the relevant income derived in the PRC and the established institutions or premises set up by them, the enterprise income tax is, in that case, set at the rate of 10% for their income sourced from inside the PRC.

Enterprises that are recognized as high and new technology enterprises in accordance with the Notice of the Ministry of Science, the Ministry of Finance (the "MOF") and the SAT on Amending and Issuing the Administrative Measures for the Determination of High and New Tech Enterprises (《科技部、財政部、國家税務總局關於修訂印發<高新技術企業認定管理辦法>的通知》) are entitled to enjoy the preferential enterprise income tax rate of 15%. The validity period of the high and new technology enterprise qualification shall be three years.

The Notice Regarding the Determination of Chinese-Controlled Offshore Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies (《關於境外註冊中資控股企業依據實際管理機構標準實施居民企業認定有關問題的通知》) promulgated by the SAT on April 22, 2009 and amended on January 29, 2014 sets out the standards and procedures for determining whether the "de facto management body" of an enterprise registered outside of the PRC and controlled by PRC enterprises or PRC enterprise groups is located within the PRC.

The EIT Law provides that an income tax rate of 10% will normally be applicable to dividends payable to investors that are "non-resident enterprises", and gains derived by such investors, which (a) do not have an establishment or place of business in the PRC or (b) have an establishment or place of business in the PRC, but the relevant income is not effectively connected with the establishment or place of business to the extent such dividends and gains are derived from sources within the PRC. Such income tax on the dividends may be reduced pursuant to a tax treaty between China and the jurisdictions in which our non-PRC shareholders reside. Pursuant to an Arrangement Between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion With Respect to Tax on Income (《內地和香港特別行政區關於對所得避免雙重徵税和防止偷漏税的安排》) (the "Double Tax Avoidance Arrangement"), and other applicable PRC laws, if a Hong Kong resident enterprise is determined by the competent PRC tax authority to have satisfied the relevant conditions and requirements under such Double Tax Avoidance Arrangement and other applicable laws, the 10% withholding tax on the dividends the Hong Kong resident enterprise receives from a PRC resident enterprise may be reduced to 5% upon receiving approval from in-charge tax authority. However, based on the Notice on Certain Issues with Respect to the Enforcement of Dividend Provisions in Tax Treaties (《關於執行税收協定股息條款有關問題的通知》) (the "Notice No. 81") issued on February 20, 2009 by the SAT, if the relevant PRC tax authorities determine, in their discretion, that a company benefits from such reduced income tax rate due to a structure or arrangement that is primarily tax-driven, such PRC tax authorities may adjust the preferential tax treatment; and based on the Announcement on Certain Issues with Respect to the "Beneficial Owner" in Tax Treaties (《國家税務總局關於税收協定中"受益所有人"有關問題的公告》) issued on February 3, 2018 and effective on April 1, 2018, if an applicant's business activities do not constitute substantive business activities, it could result in the negative determination of the applicant's status as a "beneficial owner" and consequently, the applicant could be precluded from enjoying the above-mentioned reduced income tax rate of 5% under the Double Tax Avoidance Arrangement.

Intellectual Property

China has made substantial efforts to adopt comprehensive legislation governing intellectual property rights, including patents, trademarks, copyrights and domain names.

Patents

Pursuant to the Patent Law of the PRC (《中華人民共和國專利法》, the "Patent Law"), promulgated by the SCNPC on March 12, 1984, as latest amended on December 27, 2008, and effective from October 1, 2009 and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), promulgated by the State Council on June 15, 2001 and latest amended on January 9, 2010, there are three types of patent in the PRC: invention patent, utility model patent and design patent. The protection period is 20 years for invention patent and 10 years for utility model patent and design patent, commencing from their respective application dates. Any individual or entity that utilizes a patent or conducts any other activity in infringement of a patent without prior authorization of the patentee shall pay

compensation to the patentee and is subject to a fine imposed by relevant administrative authorities and, if constituting a crime, shall be held criminally liable in accordance with the law. In the event that a patent is owned by two or more co-owners without an agreement regarding the distribution of revenue generated from the exploitation of any co-owner of the patent, such revenue shall be distributed among all the co-owners.

Existing patents can become narrowed, invalid or unenforceable due to a variety of grounds, including lack of novelty, creativity, and deficiencies in patent application. In China, a patent must have novelty, creativity and practical applicability. Under the Patent Law, novelty means that before a patent application is filed, no identical invention or utility model has been publicly disclosed in any publication in China or overseas or has been publicly used or made known to the public by any other means, whether in or outside of China, nor has any other person filed with the patent authority an application that describes an identical invention or utility model and is recorded in patent application documents or patent documents published after the filing date. Creativity means that, compared with existing technology, an invention has prominent substantial features and represents notable progress, and a utility model has substantial features and represents any progress. Practical applicability means an invention or utility model can be manufactured or used and may produce positive results. Patents in China are filed with the State Intellectual Property Office, or SIPO. Normally, the SIPO publishes an application for an invention patent within 18 months after the filing date, which may be shortened at the request of applicant. The applicant must apply to the SIPO for a substantive examination within 3 years from the date of application.

Medical patent compulsory license

According to the Patent Law, for the purpose of public health, the SIPO may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which PRC has acceded.

Trademarks

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》, the "Trademark Law"), promulgated by the SCNPC on August 23, 1982, as latest amended on August 30, 2013 and effective from May 1, 2014, the period of validity for a registered trademark is 10 years, commencing from the date of registration. Upon expiry of the period of validity, the registrant shall go through the formalities for renewal within 12 months prior to the date of expiry as required if the registrant needs to continue to use the trademark. Where the registrant fails to do so, a grace period of 6 months may be granted. The period of validity for each renewal of registration is 10 years, commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be canceled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided according to law.

Domain Names

Pursuant to the Administrative Measures for Internet Domain Names (《互聯網絡域名管理辦法》) promulgated by the Ministry of Information Industry on August 24, 2017 and effective from November 1, 2017, "domain name" shall refer to the character mark of hierarchical structure, which identifies and locates a computer on the internet and corresponds to the Internet protocol (IP) address of such computer. The principle of "first come, first served" applies to domain name registration service. After completing the domain name registration, the applicant will become the holder of the registered domain name. Furthermore, the holder shall pay operation fees for registered domain names on schedule. If the domain name holder fails to pay corresponding fees as required, the original domain name registry shall deregister the relevant domain name and notify the holder of deregistration in written forms.

Environmental Protection

Construction Project Environment Protection

The main PRC environmental protection laws and regulations applicable to us include the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) (the "Environmental Protection Law"), which was promulgated by the SCNPC on December 26, 1989 and whose amendments were made on April 24, 2014 and became effective as from January 1, 2015, the Appraising of Environmental Impacts Law of the PRC (《中華人民共和國環境影響評價法》) (the "Appraising of Environmental Impacts Law") promulgated by the SCNPC on October 28, 2002 and amended on July 2, 2016 with effect from September 1, 2016, the Regulations on Administration of Construction Project Environmental Protection (《建設項目環境保護管理條例》) promulgated by the State Council on November 29, 1998 and amended on July 16, 2017 with effect from October 1, 2017, the Rules on the Administration of Acceptance Inspection of Construction Project Environmental Protection (《建設項目竣工環境保護驗收管理辦法》) (the "Rules on Acceptance Inspection") promulgated on December 27, 2001 and amended on December 22, 2010, the Rules on the Administration of Filing of Environmental Impact Registration Form of the Construction Project (《建設項目環境影響登記表備案管理辦法》) promulgated by the Ministry of Environmental Protection on November 16, 2016 with effect from January 1, 2017 and other relevant laws and regulations.

In accordance with the Appraising of Environmental Impacts Law and the Regulations on Administration of Construction Project Environmental Protection, the development of each construction project is subject to the environmental impact assessment which assesses the pollution the construction project is likely to produce and its impact on the environment and stipulates the preventive and curative measures. The environmental impact report and environmental impact statement of a construction project shall be submitted to the relevant environmental protection authorities for examination and approval and the State implements the record-filing administration over the environmental impact registration forms. In accordance with the Rules on Acceptance Inspection, after completion of the project, the construction entity shall also apply to the relevant environmental protection authorities for

checks and acceptance of the corresponding environmental protection facilities. The said construction project may be put into operation or use only after the completion of the said checks and acceptance procedures.

Water Pollution

According to the Law of the PRC on Prevention and Control of Water Pollution (《中華人民共和國水污染防治法》) effective on November 1, 1984 and amended on May 15, 1996 and February 28, 2008 respectively, construction, renovation and expansion projects and other upper-water facilities that directly or indirectly discharge pollutants to water are subject to environmental impact assessment. In addition, water pollution prevention facilities are required to be designed, constructed and put into operation simultaneously with the main part of the project. No construction projects may be put into operation until the relevant environmental protection administrative authorities inspect and accept their water pollution prevention facilities.

Pollutant Discharge

The Environmental Protection Law of the PRC stipulates that the government shall implement the pollutant emission license administration system. Pollutant discharge by enterprises, public institutions and other producers and business operators is subject to relevant pollutant emission license. The Environmental Protection Law of the PRC requires any entity operating a facility that produces pollutants or other hazardous materials to adopt environmental protection measures in its operations, and to establish an environmental protection responsibility management system. Effective measures to control and properly dispose of waste gas, waste water, waste residue, dust or other waste materials shall be adopted. Any entity operating a facility that discharges pollutants shall report to and register with the competent authority pursuant to applicable regulations. According to the Environmental Protection Law of the PRC, in the event that an entity discharges pollutants in violation of the pollutant discharge standards or volume control requirement, the entity would be subject to administrative penalties, including order to suspend business for rectification, and even order to terminate or close down business under severe circumstances.

Hazardous Chemicals

Regulation on Safety Administration of Hazardous Chemicals (《危險化學品安全管理條例》) (the "Hazardous Chemicals Regulation") was promulgated by the State Council on January 26, 2002 and amended on March 2, 2011 and December 7, 2013. The Hazardous Chemicals Regulation provides regulatory requirements on the safe production, storage, use, operation and transportation of hazardous chemicals. The PRC government exerts strict control over, and adopts an examination and approval system of, the manufacture and storage of hazardous chemicals.

An enterprise that stores and uses hazardous chemicals is required to appoint a qualified institution to conduct safety evaluation of its safety production conditions once every three years and to prepare the safety evaluation report accordingly. Such report shall set out the

rectification measures and plans for problem solution as to the safety production. The safety evaluation report and the implementation of the rectification measure shall be filed with the safety supervision regulatory authority.

Overseas Investment

Pursuant to the Administrative Measures for the Outbound Investment of Enterprises (《企業境外投資管理辦法》), which was promulgated by the NDRC on December 26, 2017 and became effective on March 1, 2018, the State adopts approval administration and filing administration for overseas investment projects respectively according to different circumstances. An overseas investment project that involves any sensitive country or region or any sensitive industry is to be approved by the NDRC. Under the circumstances, with regard to an overseas investment project that has the Chinese party's investment amount of not less than USD300 million, the NDRC is in charge of the record-filing.

Pursuant to the Measures on the Administration of Overseas Investment (《境外投資管理辦法》), promulgated by the Ministry of Commerce on September 6, 2014 and became effective on October 6, 2014, overseas investments refer to possessing of non-financial enterprises abroad or acquisition of the ownership of, control over, business management right of, or other rights and interests of existing overseas non-financial enterprises by enterprises established in the PRC through newly establishment or mergers and acquisitions or other methods. Other than the overseas investments involving sensitive countries, regions or sensitive industries which are subject to approval, all other overseas investments are subject to filing administration.

Foreign Exchange

The principal regulations governing foreign currency exchange in China are the Foreign Exchange Administration Regulations of the 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, became effective on April 1, 1996 and was subsequently amended on January 14, 1997 and August 5, 2008 and the Regulations on the Administration of Foreign Exchange Settlement, Sale and Payment (《結匯、售匯及付匯管理規定》) which was promulgated by PBOC on June 20, 1996 and became effective on July 1, 1996. Pursuant to these regulations and other PRC rules and regulations on currency conversion, Renminbi is freely convertible for payments of current account items, such as trade and service-related foreign exchange transactions and dividend payments, but not freely convertible for capital account items, such as direct investment, loan or investment in securities outside China unless prior approval of the SAFE or its local counterpart is obtained.

Foreign invested enterprises are permitted to convert their after tax dividends into foreign exchange and to remit such foreign exchange out of their foreign exchange bank accounts in the PRC. However, foreign exchange transactions involving overseas direct investment or investment and exchange in securities, derivative products abroad are subject to registration with SAFE and approval from or filing with the relevant PRC government authorities (if necessary).

SAFE promulgated the Notice on Reforming the Administration of Foreign Exchange Settlement of Capital of Foreign invested Enterprises (《關於改革外商投資企業外匯資本金結匯管理方式的通知》) ("SAFE Circular 19") on March 30, 2015, further expanding the extent of convertibility under direct investment. SAFE Circular 19 stipulates that the use of capital funds and exchange settlement funds by foreign-invested enterprises shall be subject to foreign exchange management regulations, and implement negative list management.

On June 9, 2016, the SAFE promulgated the Circular on Reforming and Regulating Policies on the Management of the Settlement of Foreign Exchange of Capital Accounts (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) (the "SAFE Circular 16"). The SAFE Circular 16 unifies the Discretional Foreign Exchange Settlement for all the domestic institutions. The Discretional Foreign Exchange Settlement refers to the foreign exchange capital in the capital account which has been confirmed by the relevant policies subject to the Discretional Foreign Exchange Settlement (including foreign exchange capital, foreign loans and funds remitted from the proceeds from the overseas listing) can be settled at the banks based on the actual operational needs of the domestic institutions. The proportion of Discretional Foreign Exchange Settlement of the foreign exchange capital is temporarily determined as 100%. Violations of SAFE Circular 19 or SAFE Circular 16 could result in administrative penalties in accordance with the Regulations of the People's Republic of China on Foreign Exchange Control and relevant provisions.

Furthermore, SAFE Circular 16 stipulates that the use of foreign exchange incomes of capital accounts by foreign-invested enterprises shall follow the principles of authenticity and self-use within the business scope of enterprises. The foreign exchange incomes of capital accounts and capital in Renminbi obtained by the FIE from foreign exchange settlement shall not be used for the following purposes: (i) directly or indirectly used for the payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations; (ii) directly or indirectly used for investment in securities or financial schemes other than bank guaranteed products unless otherwise provided by relevant laws and regulations; (iii) used for granting loans to non-connected enterprises, unless otherwise permitted by its business scope; and (iv) used for the construction or purchase of real estate that is not for self-use (except for the real estate enterprises).

SAFE Circular 37

On October 21, 2005, SAFE promulgated the Circular Concerning Relevant Issues on the Foreign Exchange Administration of Raising Funds through Overseas Special Purpose Vehicle and Investing Back in China by Domestic Residents (《關於境內居民通過境外特殊目的公司融資及返程投資外匯管理有關問題的通知》), which became effective on November 1, 2005 (the "Circular No. 75"). The notice requires PRC domestic resident natural persons to register or file with the local SAFE branch in the following circumstances: (i) before establishing or controlling any company outside the PRC for the purpose of capital financing, (ii) after contributing their assets or shares of a domestic enterprise into overseas special purpose vehicles, or raising funds overseas after such contributions, and (iii) after any major change in the share capital of the special purpose vehicle without any round-trip investment being made.

On July 4, 2014, SAFE promulgated the Circular Concerning Relevant Issues on the Foreign Exchange Administration of Offshore Investing and Financing and Round-Trip Investing by Domestic Residents through Special Purpose Vehicles (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) (the "Circular No. 37"), for the purpose of simplifying the approval process, and for the promotion of the cross-border investment. The Circular No. 37 supersedes the Circular No. 75 and revises and regulates the relevant matters involving foreign exchange registration for round-trip investment. Under the Circular No. 37, in the event the change of basic information of the registered offshore special purpose vehicle such as the individual shareholder, name, operation term, etc., or if there is a capital increase, decrease, equity transfer or swap, merge, spin-off or other amendment of the material items, the domestic resident shall complete the change of foreign exchange registration formality for offshore investment. In addition, according the procedural guideline as attached to the Circular No. 37, the principle of review has been changed to "the domestic individual resident is only register the SPV directly established or controlled (first level)". At the same time, the SAFE has issued the Operation Guidance for the Issues Concerning Foreign Exchange Administration over Round-trip Investment (《返程投資外匯管理所涉業務操作指引》) with respect to the procedures for SAFE registration under the Circular No. 37, which became effective on July 4, 2014 as an attachment to Circular No. 37.

Under the relevant rules, failure to comply with the registration procedures set forth in the Circular No. 37 may result in restrictions being imposed on the foreign exchange activities of the relevant onshore company, including the payment of dividends and other distributions to its offshore parent or affiliate, and may also subject relevant PRC residents to penalties under PRC foreign exchange administration regulations. PRC residents who hold any shares in the company from time to time are required to register with the SAFE in connection with their investments in the company.