PRC REGULATION

We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section summarizes the principal PRC laws, rules and regulations that we believe are relevant to our business and operations.

LAWS AND REGULATIONS RELATING TO DRUGS

Introduction

In 2017, the drug regulatory system entered a new and significant period of reform. The General Office of the State Council and the General Office of the Central Committee of the China Communist Party jointly issued the *Opinion on Deepening the Reform of the Evaluation and Approval System to Encourage Innovation in Drugs and Medical Devices* (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) or the Innovation Opinion in October 2017. The expedited programs and other advantages under this and other recent reforms encourage drug manufacturers to seek marketing approval in China first, manufacture domestically, and develop drugs in high priority disease areas, such as oncology.

To implement the regulatory reform introduced by the Innovation Opinion, the National People's Congress, or the NPC and the National Medical Products Administration, or the NMPA has been revising the fundamental laws, regulations and rules regulating pharmaceutical products and the industry, which include the framework law known as the *PRC Drug Administration Law* (《中華人民共和國藥品管理法》), or DAL. The DAL was promulgated by the Standing Committee of the NPC on September 20, 1984 and latest amended on August 26, 2019 and took effect as of December 1, 2019. The DAL is implemented by a high-level regulation issued by the State Council referred to as the DAL Implementing Regulation. The NMPA has its own set of regulations further implementing the DAL; the primary one governing clinical trial applications, or CTAs, marketing approval, and post-approval amendment and renewal is known as the *Drug Registration Regulation* (《藥品註冊管理辦法》), or DRR. The DRR was promulgated by the NMPA on February 28, 2005 and the latest amended DRR took effect from July 1, 2020. Although the NMPA has issued several notices and proposed regulations in 2018 and 2019 to implement the reforms, the implementing regulations for many of the reforms in the Innovation Opinion have not yet been finalized and issued, and therefore, the details regarding the implementation of the regulatory changes remained uncertain in some respects.

Regulatory Authorities and Recent Government Reorganization

In the PRC, the NMPA is the primary regulatory agency for pharmaceutical products and businesses. The agency was formed from the prior China Food and Drug Administration, or CFDA, in 2018 as part of a government reorganization. Like the CFDA, the NMPA is still the primary drug regulatory agency and implements the same laws, regulations, rules, and guidelines as the CFDA, and it regulates almost all of the key stages of the life-cycle of pharmaceutical products, including nonclinical studies, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution, and pharmacovigilance (i.e., post-marketing safety reporting obligations). The Center for Drug Evaluation, or CDE, which remains under the NMPA, conducts the technical evaluation of each drug and biologic application to assess safety and efficacy.

The NHC (formerly known by the names: the Ministry of Health and National Health and Family Planning Commission), is China's primary healthcare regulatory agency. It is responsible for overseeing the operation of medical institutions, some of which also serve as clinical trial sites. NHC plays a significant role in drug reimbursement.

Regulations on Drug Research and Development

Non-Clinical Research and Animal Testing

The NMPA requires preclinical data to support registration applications for imported and domestic drugs. According to the DRR, nonclinical safety studies must comply with the *Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory Studies of Drugs* (《藥物非臨床研究質量管理規範》), or the GLP. On August 6, 2003, the NMPA promulgated the GLP, which was latest revised on July 27, 2017, to improve the quality of non-clinical research, and began to conduct the Good Laboratories Practice. Pursuant to the *Circular on Administrative Measures for Certification of Good Laboratory Practice for Non-clinical Laboratory* (《關於印發藥物非臨床研究質量管理規範認證管理辦法的通知》) issued by the NMPA on April 16, 2008, the NMPA is responsible for the certification of non-clinical research institutions nationwide and local provincial medical products administrative authorities is in charge of the daily supervision of non-clinical research institution. The NMPA decides whether an institution is qualified for undertaking pharmaceutical non-clinical research by evaluating such institution's organizational administration, its research personnel, its equipment and facilities, and its operation and management of non-clinical pharmaceutical projects. A GLP Certification will be issued by the NMPA if all the relevant requirements are satisfied, which will also be published on the NMPA's website.

Pursuant to the Regulations for the *Administration of Affairs Concerning Experimental Animals* (《實驗動物管理條例》) promulgated by the State Science and Technology Commission on November 14, 1988 and latest amended on March 1, 2017, by the State Council, the *Administrative Measures on Good Practice of Experimental Animals* (《實驗動物質量管理辦法》) jointly promulgated by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision on December 11, 1997, and the *Administrative Measures on the Certificate for Experimental Animals (Trial)* (《實驗動物許可證管理辦法(試行)》) promulgated by the Ministry of Science and Technology and other regulatory authorities on December 5, 2001, using and breeding experimental animals shall be subject to some rules and performing experimentation on animals requires a Certificate for Use of Laboratory Animals.

Clinical Trials Approval

Upon completion of preclinical studies, a sponsor typically needs to conduct clinical trials in China for registering a new drug. The NMPA has taken a number of steps to increase efficiency for approving CTAs, and it has also significantly increased monitoring and enforcement of the *Administrative Regulations of Quality of Drug Clinical Practice* (《藥物臨床試驗質量管理規範》), or the PRC's Good Clinical Practices, or the PRC's GCP, to ensure data integrity. The PRC's GCP was promulgated by CFDA on June 4, 2003 and the latest amended PRC's GCP took effect from July 1, 2020.

All clinical trials conducted in China for new drug registration purposes must be approved and conducted at pharmaceutical clinical trial institutions which shall be under the filing administration. 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)》) (the "**Multi-Center Clinical Trial Guidelines**"), promulgated by the NMPA on January 30, 2015 and effective on 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 DAL, the implementing rules of the DAL and the DRR, execute the GCP, make reference to universal international principles such as the International Council for Harmonization (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 BLA in the PRC, it shall involve at least two countries, including China, and shall satisfy the requirements for clinical trials set forth in the International Multi-Center Clinical Trial Guidelines (Trial) and the DRR.

The NMPA has now adopted a system for clinical trials of new drugs where trials can proceed if after 60 business days, the applicant has not received any objections from the CDE. China is also expanding the number of trial sites by changing from a clinical trial site certification procedure into a notification procedure.

Priority Evaluation and Approval Programs to Encourage Innovation

The NMPA has adopted several expedited review and approval mechanisms since 2009 and created additional expedited programs in recent years that are intended to encourage innovation. Applications for these expedited programs can be submitted together with the registration package or after the registration submission is admitted for review by the CDE. The *Opinions on Encouraging the Prioritized Evaluation and Approval for Drug Innovation* (《關於鼓勵藥品創新實行優先審評審批的意見》) promulgated by the NMPA on December 21, 2017 clarified that fast track CTAs or drug registration pathways will be available to the innovative drugs.

If admitted to one of these expedited programs, an applicant will be entitled to more frequent and timely communication with reviewers at the CDE, expedited review and approval, and more agency resources throughout the review approval process.

NMPA also permits conditional approval of certain medicines based on early phase China clinical trial data or only on foreign approval clinical data. Post-approval the applicant may need to conduct one or more post-market studies. According to *the Opinion on Deepening the Reform of the Evaluation and Approval System to Encourage Innovation in Drugs and Medical Devices* for any drugs or medical devices used for the treatment of severe and life-threatening diseases that cannot be treated in an effective manner and those badly needed for public health, if the early and mid-term indicators in clinical trials show their efficacy and their clinical value is predictable, conditional approval for the marketing of these drugs and medical devices can be granted, and enterprises shall develop the risk control plans to conduct researches according to the requirements.

The DRR also stipulates that during drug clinical trials, when the drugs are used for treatment of diseases that seriously endanger life and have no effective measure of treatment, and the data of drug clinical trials can prove the efficacy and forecast the clinical value of the drugs, applications for conditional approval may be submitted for drugs falling under this circumstance.

Moreover, on July 7, 2020, NMPA issued the *Announcement of the National Medical Products Administration on Promulgating Three Documents Including the Working Procedures for the Evaluation of Breakthrough Therapy Designation Drugs (Trial)* (《國家藥監局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》), which replaced the Opinion on Encouraging the Prioritized Evaluation and Approval for Drug Innovation, stating that during clinical trials, innovative drugs or improved new drugs that are used to prevent and treat diseases that are severely life-threatening or severely affecting the quality of life and have no effective prevention and treatment or have sufficient evidence showing they have obvious clinical advantages compared with existing treatment methods, etc., such drugs are eligible to apply for the breakthrough therapy designation drugs procedure during Phase I and II clinical trials, no later than the commencement

of Phase III clinical trials. In 2018, NMPA established a conditional approval program for drugs designated by the CDE that have been approved in the US, European Union and Japan within the last 10 years and that meet one of three criteria (1) orphan indications, (2) drugs that treat life threatening illnesses for which there are not effective treatment or preventive methods, and (3) drugs that treat life threatening illnesses and that have a clear clinical advantage over other approved therapies.

Drug Clinical Trial Registration

Pursuant to the DRR, upon obtaining the clinical trial approval and before commencing a clinical trial, the applicant shall file a registration with the NMPA containing various details of the clinical trial, including the clinical study protocol, the name of the principal researcher of the leading institution, names of participating institutions and researchers, an approval letter from the ethics committee, and a sample of the Informed Consent Form, with a copy sent to the competent provincial administration departments where the trial institutions will be located. On September 6, 2013, the NMPA released the *Announcement on Drug Clinical Trial Information Platform* (《關於藥物臨床試驗信息平台的公告》), providing that for all clinical trials approved by the NMPA and conducted in China, instead of the aforementioned registration filed with the NMPA, clinical trial registration shall be completed and trial information shall be published through the Drug Clinical Trial Information Platform. The applicant shall complete trial pre-registration within one month after obtaining the clinical trial approval to obtain the trial's unique registration number and shall complete registration of certain follow-up information before the first subject's enrollment in the trial. If approval of the foregoing pre-registration and registration is not obtained within one year after obtaining the clinical trial approval, the applicant shall submit an explanation, and if the procedure is not completed within three years, the clinical trial approval shall automatically be annulled.

Human Genetic Resources Approval

According to the *Interim Measures for the Administration of Human Genetic Resources* (《人類遺傳資源管理暫行辦法》), promulgated by the Ministry of Science and Technology and the NHC jointly on June 10, 1998, an additional approval is required for any foreign companies or foreign affiliates that conduct trials in China. Prior to beginning a trial, the foreign sponsor and the Chinese clinical trial site are required to obtain approval from the Human Genetic Resources Administration of China, or HGRAC, which is an agency under the Ministry of Science and Technology, to collect any biological samples that contain the genetic material of Chinese human subjects, and to transfer any cross-border transfer of the samples or associated data. Furthermore, one of the key review points for the HGRAC review and approval process is the IP sharing arrangement between Chinese and foreign parties. The parties are required to share patent rights to

inventions arising from the samples. Conducting a clinical trial in China without obtaining the relevant HGRAC preapproval will subject the sponsor and trial site to administrative liability, including confiscation of HGRAC samples and associated data, and administrative fines.

On July 2, 2015, the Ministry of Science and Technology issued the *Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, or Taking Such Resources out of the PRC* (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》), which provides that foreign-invested sponsors that sample and collect human genetic resources in clinical trials shall be required to file with the China Human Genetic Resources Management Office through its online system. On October 26, 2017, the Ministry of Science and Technology issued the *Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources* (《關於優化人類遺傳資源行政審批流程的通知》), which simplified the approval for sampling and collecting human genetic resources for the purpose of commercializing a drug in the PRC. On May 28, 2019, the State Council of PRC issued the *Administration Regulations on Human Genetic Resources* (《人類遺傳資源管理條例》), which became effective on July 1, 2019. The *Administration Regulations on Human Genetic Resources* formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities. Pursuant to the new rule, a new notification system (as opposed to the advance approval approach originally in place) is put in place for clinical trials using China's human genetic resources at clinical institutions without involving the export of human genetic resources outside of China.

Clinical Trial Process and Good Clinical Practices

Typically, drug clinical trials in China have four phases. Phase 1 refers to the initial clinical pharmacology and human safety evaluation studies. Phase 2 refers to the preliminary evaluation of a drug candidate's therapeutic efficacy and safety for target indication(s) in patients. Phase 3 (often the registrational study) refers to clinical trials to further verify the drug candidate's therapeutic efficacy and safety in patients with target indication(s) and ultimately provide sufficient evidence for the review of a drug registration application. Phase 4 refers to a new drug's post-marketing study to assess therapeutic effectiveness and adverse reactions when the drug is widely used to evaluate overall benefit-risk relationships of the drug when used among the general population or specific groups and to adjust the administration dose, etc. The NMPA requires that the different phases of clinical trials in China receive ethics committee approval and comply with the PRC's GCP. The NMPA conducts inspections to assess the PRC's GCP compliance and will cancel the CTA if it finds substantial issues.

On August 6, 2003, the NMPA promulgated the PRC's GCP to improve the quality of clinical trials. According to the latest PRC's GCP which took effect from July 1, 2020, the sponsor shall provide investigators and the clinical trial institution with legal and economic insurance or guarantee relating to the clinical trial, and ensure that such insurance or guarantee is appropriate to the nature and degree of risks of the clinical trial. But the damages caused by the negligence of

investigators or the clinical trial institution are not included. Pursuant to the newly amended DAL, and the *Regulations on the Administration of Drug Clinical Trial Institution* (《藥物臨床試驗機構管理規定》) jointly promulgated by NMPA and NHC on November 29, 2019 and effective from December 1, 2019, drug clinical trial institutions shall be under filing administration. Entities that only conduct analysis of biological samples related to clinical trials of drugs do not need to be filed.

Regulations on New Drug Application (NDA) and Approval

Upon completion of clinical trials, a sponsor may submit clinical trial data to support marketing approval for the drug. For imported drugs, this means issuance of an import license. Again, the applicant must submit evidence of foreign approval, unless it is an innovative drug that has never been approved anywhere in the world.

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 NMPA on March 4, 2016, stipulates the reclassification of drug applications under the DRR and under which, Category I Drugs refer to new drugs that have not been marketed anywhere in the world.

The *Registration Category of Biological Products and the Data Requirements for Declaration* (《生物製品註冊分類及申報資料要求》), issued by NMPA on June 29, 2020, and took effect from July 1, 2020, which replaced the former category of therapeutic biological products and stipulated that the therapeutic biological products should be classified into 3 Categories, and Category I refers to therapeutic biological products that have not been marketed anywhere in the world. Category II refers to improved new therapeutic biological products and Category III refers to therapeutic biological products that have been marketed in China or abroad.

NDA sponsors must submit data derived from domestically manufactured drugs in support of a drug approval. According to the DRR, the applicant may submit an application for drug marketing registration to CDE upon completion of relevant search on pharmacy, pharmacology, toxicology and drug clinical trials, determination of the quality standards of the drug, validation of commercial-scale production processes and preparation for acceptance of verification and inspection conducted by professional technical institution designated by competent NMPA. The CDE will organize pharmaceutical, medial and other technicians to conduct comprehensive review of the safety, efficacy and quality controllability, among others, of the drug according to the application materials submitted by the applicant, the results of the verification and inspection conducted by professional technical institutions, etc. If the comprehensive review conclusion is affirmative, the drug shall be approved for marketing and a drug registration certification will be issued containing the information of the drug approval number, the MAH and the manufacturer, which is effectively the marketing approval allowing the holder to market/commercialize the drug in China.

Pursuant to the *Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment* (《關於改革藥品醫療器械審評審批制度的意見》) promulgated on August 9, 2015, the State Council published the policy for carrying out a pilot plan for the drug marketing authorization holder mechanism.

Regulations on Drug Marketing Authorization Holder

Pursuant to the newly amended DAL and the *Measures for the Supervision and Administration of Drug Production* (《藥品生產監督管理辦法》), which was promulgated on January 22, 2020 and took effect from July 1, 2020, under the drug marketing authorization holder mechanism, an enterprise obtained drug registration certificate and a research and development institution are eligible to be a pharmaceutical marketing authorization holder, and this pharmaceutical marketing authorization holder shall be responsible for non-clinical laboratory studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of the DAL.

The pharmaceutical marketing authorization holder may engage contract manufacturers for manufacturing, provided that the contract manufacturers are licensed and may engage pharmaceutical distribution enterprises with drug distribution license for the distribution activities. Upon the approval of the medical products administrative department under the State Council, a drug marketing authorization holder may transfer the drug marketing license and the transferee shall have the capability of quality management, risk prevention and control, and liability compensation to ensure the safety, effectiveness and quality controllability of drugs, and fulfill the obligations of the drug marketing license holder.

Pursuant to the *Measures for the Supervision and Administration of Drug Production*, a marketing authorization holder who entrusts another party to produce preparations shall apply for the drug production license in accordance with provisions therein.

Regulations on Drug Manufacturing

According to the newly amended DAL and the implementing Measures of the DAL, all facilities that manufacture drugs in China must receive a Drug Manufacturing License with an appropriate "scope of manufacturing" from the local drug regulatory authority. This license must be renewed every five years.

Similarly, to conduct sales, importation, shipping and storage, or distribution activities, a company must obtain a Drug Distribution License with an appropriate "scope of distribution" from the local drug regulatory authority, subject to renewal every five years.

Regulations on Dual Invoicing System

According to the *Notice of Publishing Opinions on Implementing Dual Invoicing System in Drug Procurement Among Public Medical Institutions (For Trial Implementation)* (《印發關於在公立醫療機構藥品採購中推行"兩票制"的實施意見(試行)的通知》) ("**Dual Invoicing System Notice**") which was issued on December 26, 2016, the "dual invoicing system" refers to the system that requires one invoice to be issued from pharmaceutical manufacturers to pharmaceutical distributors and the other invoice to be issued from pharmaceutical distributors to medical institutions. According to the *Dual Invoicing System Notice and the Several Opinions of the General Office of the State Council on Further Reforming and Improving the Policies on Drug Production, Circulation and Use* (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》) issued on January 24, 2017, dual invoicing system will be promoted in pilot provinces (autonomous regions and municipalities directly under the Central Government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis, while other regions are encouraged to implement such system, so that such system can be promoted in full swing nationwide in 2018.

Regulations on Centralized Procurement

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

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

Second, on the basis of the centralized volume-based drug procurement implemented by 4+7 cities, the State organizes relevant regions to form an alliance to carry out the centralized volume-based drug procurement of cross-regional alliances in September 2019. The *Document for Centralized Drug Procurement in the Alliance area (GY-YD2019-1)* (《聯盟地區藥品集中採購文件(GY-YD2019-1)》) was issued by the Joint Procurement Office (聯合採購辦公室) on September 1, 2019. The alliance area includes the provinces and autonomous regions of Shanxi, Inner

Mongolia, Liaoning, Jilin, Heilongjiang, Jiangsu, Zhejiang, Anhui, Jiangxi, Shandong, Henan, Hubei, Hunan, Guangdong, Guangxi, Hainan, Sichuan, Guizhou, Yunnan, Xizang, Shaanxi, Gansu, Qinghai, Ningxia and Xinjiang (including Xinjiang Production and Construction Army Unit), except the 4+7 cities in the alliance area.

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

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

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

Regulations on Importing and Exporting of Goods

Pursuant to the *Customs Law of the PRC* (《中華人民共和國海關法》) which was promulgated by Standing Committee of the National People's Congress, or the SCNPC on January 22, 1987 and became effective as of July 1, 1987, and latest amended on November 4, 2017 and came into force on November 5, 2017, the import of goods throughout the period from the time of arrival in the territory of China to the time of customs clearance, the export of goods throughout the period from the time of declaration to the customs to the time of departure from the territory of China, and the transit, transshipment and through-shipment goods throughout the period from the time of arrival in the territory of China to the time of departure from the territory of China shall be subject to customs control.

Pursuant to the *Foreign Trade Law of the PRC* (《中華人民共和國對外貿易法》) which was promulgated by the SCNPC on May 12, 1994 and became effective as of July 1, 1994, and latest amended and came into force on November 7, 2016, any foreign trade business operator that is engaged in the import and export of goods or technology shall be registered for archival purposes with the administrative authority of foreign trade of the State Council or the institution entrusted thereby, unless it is otherwise provided for by any law, administrative regulation or the foreign trade department of the State Council. Where any foreign trade business operator that fails to file for archival registration according to relevant provisions, the customs may not handle the procedures of customs declarations and release of the import or export goods.

Pursuant to the *Administrative Provisions on the Registration of Customs Declaration Entities of the PRC* (《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 and became effective as of March 13, 2014, and latest amended on May 29, 2018 and came into force on July 1, 2018, the import and export of goods shall be declared by the consignor or consignee itself, or by a customs declaration enterprise entrusted by the consignor or consignee and duly registered with the customs authority. Consignors and consignees of imported and exported goods shall go through customs declaration entity registration formalities with the competent customs departments in accordance with the applicable provisions. After completing the registration formalities with the customs, consignors and consignees of the imported and exported goods may handle their own customs declarations at customs ports or localities where customs supervisory affairs are concentrated within the customs territory of the PRC.

Regulations on New Drug Monitoring Period

According to the Implementing Regulations of the DAL, the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of five years for new drugs approved to be manufactured, commencing from the date of approval, to continually monitor

the safety of those new drugs. During the monitoring period, the NMPA will not approve another manufacturing or importing approval from another applicant for the same type of drug. In March 2020, for better implementation of the DRR, which would take into effect on July 2020, and ensure the smooth transition and connection between the new DRR and the original DRR, the NMPA promulgated *the Announcement on Matters Concerning the Implementation of Drug Registration Regulation* (《國家藥監局關於實施《藥品註冊管理辦法》有關事宜的公告(2020年第46號)》), which kept silent on the transition and connection of monitoring period from original DRR to new DRR. In July 2020, the new DRR took into effect, and the five-year monitoring period was removed accordingly. Furthermore, the CDE issued the *Guidelines for Acceptance and Review of Registration of Biological Products* (《生物製品註冊受理審查指南》) in July 2020, according to the Appendix II of such guidelines, the description of the monitoring period of the same type of therapeutic biological products was also removed.

Regulations on Post-Marketing Surveillance

Pursuant to the newly amended DAL, the drug marketing authorization holder shall be responsible for the monitoring, reporting and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of the DAL. Marketing authorization holders, pharmaceutical manufacturer, pharmaceutical distributors and medical institutions shall regularly inspect the quality, efficacy and adverse reactions of drugs manufactured, distributed and used by them. Cases of suspected adverse reactions shall be promptly reported to the drug administrative authorities and the competent health administrative authority. The drug marketing authorization holder shall forthwith stop selling, notify the relevant pharmaceutical distributors and medical institutions to stop sales and use, recall sold drugs, promptly announce recall information if the drugs have quality issues or other safety hazards.

China became a member of the International Council for Harmonization (ICH) in 2017, and on January 25, 2018, the NMPA promulgated the *Announcement on the Application of the Secondary Guidelines of International Council on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use* (《關於適用國際人用藥品註冊技術協調會二級指導原則的公告》), which took effective on February 1, 2018 and stipulated that in order to promote the international integration of drug registration technical standards, accelerate drug review and approval, and strengthen drug life-cycle management, the "*E2D: Post-Approval Safety Date Management: Definitions and Standards for Expedited Reporting*" (《E2D: 上市後安全數據的管理; 快速報告的定義和標準》) shall be applicable to the reporting adverse drug reactions after marketing since July 1, 2018. The "*M1 MedDRA Terminology*" (《M1: 監管活動醫學詞典 (MedDRA)》) and "*E2B(R3): Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs) E2B(R3) Data Elements and Message Specification*" (《E2B(R3): 臨床安全

數據的管理：個例安全報告傳輸的數據元素》) would be applicable to reporting adverse drug reactions after marketing since July 1, 2019, however, such guidelines shall be applicable since July 1, 2022.

Regulations on Human Cell Therapy

China has a dual-track regulatory approval pathway for conducting T-cell therapy clinical trials. One is approval as health care clinical study which is managed by NHC (the "**NHC Pathway**"). The other pathway is to register as biological drug which requires IND, registrational clinical trial and NDA approval by CDE/NMPA prior to commercialization.

The NHC Pathway

On March 2, 2009, the NHC published the *Management Measures for Clinical Application of Medical Technology* (《醫療技術臨床應用管理辦法》), which came into effect on May 1, 2009 and prescribed that cell immunotherapy belongs to the Category III medical technology of which the Clinical Application shall be subject to the additional provisions of the NHC. On May 1, 2009, the NHC published the *First List of Category III Medical Technologies Allowed for Clinical Application* (《首批允許臨床應用的第三類醫療技術目錄》) which prescribed cell immunotherapy technology as a Category III medical technology allowed for clinical application.

On June 29, 2015, the National Health and Family Planning Commission (the "**NHFP**") published the *Notice on Cancellation of the Category III Medical Technology Entry Approval* (《關於取消第三類醫療技術臨床應用准入審批有關工作的通知》), or the Notice, which cancelled the approval of the Category III medical technology clinical application. The Notice further provided that the cell immunotherapy (including T-cell therapy) technology shall be regulated as clinical study, instead of medical technology. Since then, any T-Cell therapy shall be governed by the *Measures for the Management of Clinical Study Projects Carried Out by Medical Institution* (《醫療衛生機構開展臨床研究項目管理辦法》), and shall got the approval from the Institutional Review Board, or the IRB.

In May 2016, after the Wei Zexi Incident, the relevant regulatory authorities stopped all clinical application of cellular immunotherapy, and re-announced that cellular immunotherapy technology should be regulated under the scope of clinical study.

In March 2019, a *Draft Somatic Cell Therapy Clinical Research and the Transformation Application Management Measures (Trial)* (《體細胞治療臨床研究和轉化應用管理辦法(試行) (徵求意見稿)》) was released by NHC in March 2019, which stipulated, among others, that after filing with NHC, hospitals may use somatic cell therapy treatment and charge patients. However, as of the Latest Practicable Date, such measures do not come into effect, and any medical institutions or

biotech companies which choose the NHC Pathway to conduct T-cell therapy shall be regulated as clinical study within medical institutions and NHC Pathway shall not be utilized for the purpose of commercialization.

Regulated as Medicines by NMPA and CDE

Pursuant to the DRR, human cell therapy and its products belong to biological products and the application for biological products shall be submitted as the process of new drug application.

On November 30, 2017, the NMPA promulgated the *Notice of Guidelines for Acceptance and Examination of Drug Registration (Trial)* (《關於發佈藥品註冊受理審查指南(試行)的通告》), the application of clinical trials of therapeutic biological products and the production and listing application of therapeutic biological products shall be subject to the provisions thereof. On December 18, 2017, the NMPA promulgated the *Technical Guiding Principles for Research and Evaluation of Cell Therapy Products (Trial)* (《細胞治療產品研究與評價技術指導原則(試行)》), or the Technical Guiding Principles for Cell Therapy Products, which sets out the guidelines for medical study, non-clinical research and clinical research of cell therapy products.

As for the medical study of cell therapy, the general principle is that the medical studies and quality control of cell therapy shall take the fact that cells are capable of living in a body, multiplying and/or differentiating into consideration. At the same time, cell therapy products should meet the general requirements of drug quality management, and the whole production process of clinical samples should meet the basic principles and relevant requirements of the *Good Manufacturing Practice for Drugs* (《藥品生產質量管理規範》), or the GMP Regulations, published by the Ministry of Health on December 28, 1992 and further amended on January 17, 2011.

According to the Technical Guiding Principles for Cell Therapy Products, the non-clinical research shall follow the following principles:

(i) the research and evaluation of different products should follow the principle of a "case by case analysis" while at the same time, the Guidelines for the Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals (《生物技術藥品的臨床前安全性評價》) issued by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (人用藥品註冊技術要求國際協調會) provide reference for the evaluation of non-clinical research of cell therapy products;

(ii) non-clinical study evaluation trials should use cell therapy products intended for clinical trials whenever possible. The production process and quality control of a subject used in a non-clinical trial shall be consistent with that of the subject to be used in a clinical trial (if not, the subject shall be explained and its effect on the prediction of human response shall be assessed);

(iii) non-clinical study evaluation should be conducted by selecting suitable species of animals whose biological response to cell therapy products is close to or similar to the expected human response. In some cases, alternatives to animal sources may also be used for evaluation;

(iv) in non-clinical study evaluation, the administration of cell therapy products should be able to maximise the simulation of the proposed clinical administration. If clinical administration cannot be simulated in animal studies, alternative administration methods should be identified in pre-clinical studies and their scientific and rational nature should be clarified; and

(v) subject analysis data should be provided.

As for clinical trials, the Technical Guiding Principles for Cell Therapy Products stipulate that when cell therapy products enter clinical trials, they should follow the requirements of the GCP. In principle, the research contents of clinical trials should include clinical safety evaluation, pharmacokinetics study, pharmacodynamics study, dose exploration study and confirmatory clinical trials. According to the product nature of different cell therapy products, the specific test design can be adjusted as appropriate.

On 13 March 2018, the CDE promulgated the Key Considerations in Applying for Clinical Trials of Cell Therapy Products for Pharmaceutical Research and Application Data (細胞治療產品申請臨床試驗藥學研究和申報資料的考慮要點) to encourage the innovation of cell therapy products in view of the urgent need of clinical drug use. The document provides guidance on the preparation of pharmaceutical research and application materials in the application phase of clinical trials, according to which, on the basis of following the requirements of technical guidelines for carrying out relevant research, the applicant should pay special attention to the certain considerations of pharmaceutical research and application materials, including production of raw materials, production process, quality studies, and stability studies. On the basis of the Technical Guiding Principles for Cell Therapy Products, on 18 October 2019, the CDE promulgated the Pharmaceutical Research Questions and Answers for Application of Cell Therapy Products for Clinical Trials (Issue One) (細胞治療產品申報臨床試驗藥學研究問題與解答(第一期)) to provide reference for applicants on the common problems in the review and communication of CTA application data of cell therapy products. On July 6, 2020, CDE published the draft of the

Technical Guidelines for Clinical Trials of Immunocell Therapy Products (《免疫細胞治療產品臨床試驗技術指導原則(徵求意見稿)》), the draft guidelines provide necessary technical guidance for the overall planning, design, implementation, and data analysis of cellular immune treatment (including CAR-T) products to carry out clinical trials, to reduce certain risks of the participating subjects in clinical trials and to regulate the evaluation method of the safety and effectiveness of such treatment. The draft guidelines are not mandatory and, as of the Latest Practicable Date, have not been implemented.

Given the uniqueness of CAR-T and human cell therapies and that the regulatory pathway for such therapies is still evolving, standardization for CAR-T therapies is difficult to achieve and therefore approval would be assessed on a case-by-case basis.

LAWS AND REGULATIONS RELATING TO NATIONAL MEDICAL INSURANCE PROGRAM

The national medical insurance program was adopted pursuant to the *Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program* (《關於建立城鎮職工基本醫療保險制度的決定》) issued by the State Council on December 14, 1998, under which all employers in urban cities are required to enroll their employees in the Urban Employee Basic Medical Insurance Program and the insurance premium is jointly contributed by the employers and employees. In 2015, the PRC government announced the *Outline for the Planning of the National Medical and Health Service System (2015-2020)* (《全國醫療衛生服務體系規劃綱要(2015-2020年)》) which aims to establish a basic medical and health care system that covers both rural and urban citizens by 2020.

The Notice Regarding the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《關於印發城鎮職工基本醫療保險用藥範圍管理暫行辦法的通知》) issued on May 12, 1999, provides that a pharmaceutical product listed in the National Reimbursement Drug List, or the NRDL, must be clinically needed, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements: (1) it is set forth in the Pharmacopeia (the prevailing version) of the PRC; (2) it meets the standards promulgated by the NMPA; and (3) if imported, it is approved by the NMPA for import.

According to the *Notice Regarding the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee* (《關於印發城鎮職工基本醫療保險用藥範圍管理暫行辦法的通知》), the PRC Ministry of Labor and Social Security, together with other government authorities, has the power to determine the medicines included in the NRDL, which is divided into two parts, Part A and Part B. Provincial governments are required to include all Part A medicines listed on the NRDL in their provincial catalogue, but

have the discretion to adjust upwards or downwards by no more than 15% from the number of Part B medicines listed in the NRDL. However, such aforementioned mechanism has been changed since the issuance of the *Notice of MHRSS and the NHSA on the Issuance of the NRDL* (《國家醫保局、人力資源社會保障部關於印發〈國家基本醫療保險、工傷保險和生育保險藥品目錄〉的通知》) on August 20, 2019 which became effective on January 1, 2020. Such Notice regulates that all localities shall strictly implement the NRDL and are not allowed to make a catalogue or add drugs in the NRDL, or adjust the limited payment scope of drugs in the NRDL.

Patients purchasing medicines included in Part A of the NRDL are entitled to reimbursement in accordance with the regulations in respect of basic medical insurance. Patients purchasing medicines included in Part B of the NRDL are required to pay a certain percentage of the purchase price and the remainder of the purchase price shall be reimbursed in accordance with the regulations in respect of basic medical insurance.

LAWS AND REGULATIONS RELATING TO PRODUCT LIABILITY

The *Product Quality Law of the PRC* (《中華人民共和國產品質量法》), or the Product Quality Law, promulgated by the Standing Committee of the NPC on February 22, 1993 and latest amended on December 29, 2018, is the principal governing law relating to the supervision and administration of product quality. According to the Product Quality Law, 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 for compensating for any bodily injuries or property damages, 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 distributed; (2) the defects causing injuries or damages did not exist at the time when the product was distributed; or (3) the science and technology at the time when the product was distributed was at a level incapable of detecting the defects. A seller shall be liable for compensating for any bodily injuries or property damages of others caused by the defects in the product if such defects are attributable to the seller. A seller shall pay compensation if it fails to indicate either the manufacturer or 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.

Pursuant to the *General Principles of the Civil Law of the PRC* (《中華人民共和國民法通則》) promulgated by the NPC on April 12, 1986 and latest amended on August 27, 2009, both manufacturers and sellers shall be held liable where the defective products result in property damages or bodily injuries to others. Pursuant to the *Tort Liability Law of the PRC* (《中華人民共和國侵權責任法》) promulgated by the Standing Committee of the NPC on December 26, 2009 and effective from July 1, 2010, manufacturers shall assume tort liabilities where the defects in

products cause damages to others. Sellers shall assume tort liabilities where the defects in products that have caused damages to others are attributable to the sellers. The aggrieved party may claim for compensation from the manufacturer or the seller of the defected product that has caused damage.

On May 28, 2020, the *Civil Code of the PRC* (《中華人民共和國民法典》) was adopted by the third session of the 13th NPC, which will become effective on January 1, 2021 and simultaneously replace the current effective *Tort Liability Law of the PRC*, according to which, a patient may make a claim against the drug marketing authorization holder, a medical institution or producer for any damage arising from defects of drugs.

LAWS AND REGULATIONS RELATING TO INTELLECTUAL PROPERTY PROTECTIONS

Patents

Pursuant to the *PRC Patent Law* (《中華人民共和國專利法》), most recently amended in December 2008, and its implementation rules, most recently amended in January 2010, patents in China fall into three categories: invention, utility model and design. An invention patent is granted to a new technical solution proposed in respect of a product or method or an improvement of a product or method. A utility model is granted to a new technical solution that is practicable for application and proposed in respect of the shape, structure (or a combination of both) of a product. A design patent is granted to a new design of a certain product in shape, pattern (or a combination of both) and in color, shape and pattern combinations aesthetically suitable for industrial application. Under the *PRC Patent Law*, the term of patent protection starts from the date of application. Patents relating to invention are effective for twenty years, and utility model and design patents are effective for ten years from the date of application. The PRC Patent Law adopts the principle of "first-to-file" system, which provides that where more than one person files a patent application for the same invention, a patent will be granted to the person who first files the application.

Existing patents can be narrowed, invalidated 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 *PRC 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 three years from the date of application.

The *PRC Patent Law* provides that, for an invention or utility model completed in China, any applicant (not limited to Chinese companies and individuals), before filing a patent application outside of China, must first submit it to the SIPO for a confidential examination. Failure to comply with this requirement will result in the denial of any Chinese patent for the relevant invention. This added requirement of confidential examination by the SIPO has raised concerns by foreign companies that conduct research and development activities in China or outsource research and development activities to service providers in China.

The Amendment to the PRC Patent Law (second Draft) was issued on July 3, 2020, under which the patent protection was further enhanced, but has not yet been implemented.

Trade Secrets

According to the *PRC Anti-Unfair Competition Law* (《中華人民共和國反不正當競爭法》), the term "trade secrets" refers to technical and business information that is unknown to the public, has utility and may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Trade secret requirements under the current framework in China is still under development and not robust.

Under the *PRC Anti-Unfair Competition Law*, which was promulgated on September 2, 1993 and was latest amended on April 23, 2019, business persons are prohibited from infringing others' trade secrets by: (1) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (2) disclosing, using, or allowing another person to use a trade secret acquired from the right holder by any means as specified in the item (1) above; (3) disclosing, using, or allowing another person to use a trade secret in its possession, in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; (4) abetting a person, or tempting, or aiding a person into or in acquiring, disclosing, using, or allowing another person to use the trade secret of the right holder in violation of his or her non-disclosure obligation or the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known that an employee or former employee of the right owner of trade secrets or any other entity or individual conducts any of the illegal acts listed above, but still accepts, publishes, uses or allows any other to use such secrets,

this practice will be deemed as an infringement of trade secrets. A party whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties in the amount of RMB100,000 to RMB1,000,000, and where the circumstance is serious, the fine will be RMB500,000 to RMB5,000,000. Alternatively, persons whose trade secrets are being misappropriated may file lawsuits in a Chinese court for loss and damages incurred due to the misappropriation.

The measures to protect trade secrets include oral or written non-disclosure agreements or other reasonable measures to require the employees of, or persons in business contact with, legal owners or holders to keep trade secrets confidential. Once the legal owners or holders have asked others to keep trade secrets confidential and have adopted reasonable protection measures, the requested persons bear the responsibility for keeping the trade secrets confidential.

Trademarks

Pursuant to the *Trademark Law of the PRC* (《中華人民共和國商標法》) promulgated by the Standing Committee of the NPC on August 23, 1982 and latest amended on April 23, 2019 and became effective from November 1, 2019, the period of validity for a registered trademark is ten years, commencing from the date of registration. The registrant shall go through the formalities for renewal within twelve months prior to the expiry date of the trademark if continued use is intended. Where the registrant fails to do so, a grace period of six months may be granted. The validity period for each renewal of registration is ten years commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be canceled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided according to the law.

Copyright

Pursuant to the *Copyright Law of the PRC* (《中華人民共和國著作權法》), effective in June 1, 1991 and latest amended on February 26, 2010, copyrights include personal rights such as the right of publication and that of attribution as well as property rights such as the rights of production and distribution. Reproducing, distributing, performing, projecting, broadcasting or compiling a work or communicating the same to the public via an information network without permission from the owner of the copyright therein, unless otherwise provided in the *Copyright Law of the PRC*, constitutes infringements of copyrights. The infringer must, according to the circumstances of the case, undertake to cease the infringement, take remedial action, and offer an apology or pay damages.

Pursuant to the *Computer Software Copyright Protection Regulations* (《計算機軟件保護條例》) promulgated on December 20, 2001 and latest amended on January 30, 2013, a software copyright owner may complete registration formalities with a software registration authority recognized by the State Council's copyright administrative department. A software copyright owner may authorize others to exercise that copyright, and is entitled to receive remuneration.

Domain names

Domain names are protected under the *Administrative Measures on the Internet Domain Names* (《互聯網域名管理辦法》) issued by the Ministry of Industry and Information Technology, or the MIIT, on August 24, 2017 and effective from November 1, 2017. The MIIT is the main regulatory authority responsible for the administration of PRC internet domain names. Domain name registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

LAWS AND REGULATIONS RELATING TO FOREIGN INVESTMENT

Investment activities in China by foreign investors are principally governed by the *Guidance Catalogue of Industries for Foreign Investment* (《外商投資產業指導目錄》), or the Catalogue, which was promulgated and is amended from time to time by the Ministry of Commerce, or the MOFCOM and National Development and Reform Commission, or the NDRC. Pursuant to the *Catalogue of Industries for Encouraging Foreign Investment (2019)* (《鼓勵外商投資產業目錄(2019年版)》), or the 2019 Catalogue, which came to effect from July 30, 2019 *Special Administrative Measures (Negative List) for the Access of Foreign Investment in Pilot Free Trade Zones (2020)* (《自由貿易試驗區外商投資准入特別管理措施(負面清單) (2020年版)》), or the Negative List in Pilot Free Trade Zones and *Special Administrative Measures (Negative List) for the Access of Foreign Investment (2020)* (《外商投資准入特別管理措施(負面清單) (2020年版)》), or the Negative List (2020), all of which shall come into effect on July 23, 2020, industries are divided into two categories: encouraged industries and the industries within the Negative List. The Negative List is further divided into two sub-categories: restricted industries and prohibited industries. Foreign investors are not allowed to invest in industries in the prohibited category. According to the Negative List (2020), the development and application of technologies of human stem cell and gene diagnosis and therapy remains as prohibited areas for foreign investment.

On March 15, 2019, the NPC approved the *Foreign Investment Law of the PRC* (《外商投資法》), or the Foreign Investment Law, which became effective on January 1, 2020 and replaced the three old rules on foreign investment in China, namely, the *PRC Equity Joint Venture Law* (《中外合資經營企業法》), the *PRC Cooperation Joint Venture Law* (《中外合作經營企業法》) and the *Wholly Foreign-Owned Enterprise Law* (《外資企業法》), together with their implementation rules and ancillary regulations. The *Foreign Investment Law* establishes the basic framework for the

access to, and the promotion, protection and administration of foreign investments in view of investment protection and fair competition. According to the *Foreign Investment Law*, "foreign investment" refers to investment activities directly or indirectly conducted by one or more natural persons, business entities, or other organizations of a foreign country (collectively referred to as "foreign investor") within China, and "investment activities" include the following activities: (i) a foreign investor, individually or together with other investors, establishes a foreign-invested enterprise within China; (ii) a foreign investor acquires stock shares, equity shares, shares in assets, or other similar rights and interests of an enterprise within China; (iii) a foreign investor, individually or together with other investors, invests in a new construction project within China; and (iv) investments in other means as provided by the laws, administrative regulations or the State Council. The *Foreign Investment Law* grants foreign invested entities the same treatment as PRC domestic entities, except for those foreign invested entities that operate in industries deemed to be either "restricted" or "prohibited" in the Negative List.

On December 26, 2019, the State Council promulgated the *Implementation Rules to the Foreign Investment Law* (《外商投資法實施條例》), which became effective on January 1, 2020. The implementation rules further clarified that the state encourages and promotes foreign investment, protects the lawful rights and interests of foreign investors, regulates foreign investment administration, continues to optimize foreign investment environment, and advances a higher-level opening.

On December 30, 2019, the MOFCOM and the SAMR jointly promulgated *Measures for Information Reporting on Foreign Investment* (《外商投資信息報告辦法》), which became effective on January 1, 2020. Pursuant to the Measures for Information Reporting on Foreign Investment, where a foreign investor carries out investment activities in China, the foreign investor or the foreign-invested enterprise shall submit the investment information to the competent commerce department.

M&A Rules

According to the *Provisions on the Merger or Acquisition of Domestic Enterprises by Foreign Investors* (《關於外國投資者並購境內企業的規定》), or the M&A Rules, which was jointly issued by the MOFCOM, the State-owned Assets Supervision and Administration Commission of the State Council, the State Administration of Taxation of the PRC, or the SAT, the State Administration for Industry and Commerce, China Securities Regulatory Commission, or the CSRC and State Administration of Foreign Exchange, or the SAFE, on August 8, 2006 and latest amended by the MOFCOM on June 22, 2009, application shall be made for examination and approval of the acquisition of any company in China affiliating to a domestic company, enterprise or natural person, which is made in the name of an oversea company established or controlled by such domestic company, enterprise or natural person.

LAWS AND REGULATIONS RELATING TO FOREIGN EXCHANGE

The *PRC Foreign Exchange Administration Regulations* (《中華人民共和國外匯管理條例》) promulgated by the State Council on January 29, 1996, which was latest amended on August 5, 2008, are the principal regulations governing foreign currency exchange in China. Under the *PRC foreign exchange regulations*, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, may be made in foreign currencies without prior approval from the SAFE, by complying with certain procedural requirements. In contrast, approval from or registration with appropriate government authorities or designated banks is required when RMB is to be converted into a foreign currency and remitted out of China to pay capital expenses such as the repayment of foreign currency-denominated loans.

Under current regulations, the capital of a foreign-invested enterprise and capital in RMB obtained by the foreign-invested enterprise from foreign exchange settlement must not be used for the following purposes: directly or indirectly used for the payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations; directly or indirectly used for investment in securities, unless otherwise provided by relevant laws and regulations; extending loans to non-related parties, unless permitted by the scope of business; and/or paying the expenses related to the purchase of real estate that is not for self-use, except for the real estate enterprises.

In 2017, new regulations were adopted which, among other things, relax the policy restriction on foreign exchange inflow to further enhance trade and investment facilitation and tighten genuineness and compliance verification of cross-border transactions and cross-border capital flows.

In 2019, SAFE promulgated *Notice by the State Administration of Foreign Exchange of Further Facilitating Cross-border Trade and Investment* (《關於進一步促進跨境貿易投資便利化的通知》), or the SAFE Circular 28, which cancelled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. If a non-investing foreign-funded enterprise makes domestic equity investment with capital funds obtained from foreign exchange settlement, the investee shall undergo registration formalities for accepting domestic reinvestment and open the "capital account — account for settled foreign exchange to be paid" to receive the corresponding funds according to relevant provisions.

SAFE Circular 37

In July 2014, SAFE promulgated the *Notice of the State Administration of Foreign Exchange on Issues concerning Foreign Exchange Administration of the Overseas Investment and Financing and the Round-tripping Investment Made by Domestic Residents through Special-Purpose Companies* (《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》), or the SAFE Circular 37, which replaces the *Notice of the State Administration of Foreign Exchange on Relevant Issues concerning Foreign Exchange Administration for Domestic Residents to Engage in Financing and in Return Investment via Overseas Special Purpose Companies* (《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》), or the SAFE Circular 75. SAFE Circular 37 requires PRC residents, including PRC individuals and PRC corporate entities, to register with SAFE or its local branches in connection with their direct or indirect offshore investment activities. SAFE Circular 37 is applicable to our Shareholders who are PRC residents and may be applicable to any offshore acquisitions that we may make in the future.

Under SAFE Circular 37, PRC residents who make, or have prior to the implementation of SAFE Circular 37 made, direct or indirect investments in offshore special purpose vehicles, or SPVs, are required to register such investments with SAFE or its local branches. In addition, any PRC resident who is a direct or indirect shareholder of an SPV, is required to update its registration with the local branch of SAFE with respect to that SPV, to reflect any change of basic information or material events. If any PRC resident shareholder of such SPV fails to make the required registration or to update the registration, the subsidiary of such SPV in China may be prohibited from distributing its profits or the proceeds from any capital reduction, share transfer or liquidation to the SPV, and the SPV may also be prohibited from making additional capital contributions into its subsidiaries in China.

Regulations Relating to Employee Stock Incentive Plan

On February 15, 2012, the SAFE promulgated the *Notice of the State Administration of Foreign Exchange on Issues concerning the Foreign Exchange Administration of Domestic Individuals' Participation in Equity Incentive Plans of Overseas 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畫外匯管理有關問題的通知》), or the Stock Option Rules. 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 of not 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 of not 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. If the employees fail to pay, or the PRC subsidiaries fail to withhold, their IIT according to relevant laws, rules and regulations, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC government authorities.

LAWS AND REGULATIONS RELATING TO DIVIDEND DISTRIBUTIONS

The principal laws, rules and regulations governing dividend distributions by foreign-invested enterprises in the PRC are the *PRC Company Law* (《中華人民共和國公司法》), promulgated in 1993 and latest amended in 2018 and the *Foreign Investment Law* and its Implementing Regulations. Under these requirements, foreign-invested enterprises may pay dividends only out of their accumulated profit, if any, as determined in accordance with PRC accounting standards and regulations. A PRC company is required to allocate at least 10% of their respective accumulated after-tax profits each year, if any, to fund certain capital reserve funds until the aggregate amount of these reserve funds have reached 50% of the registered capital of the enterprises. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year.

LAWS AND REGULATIONS RELATING TO EMPLOYMENT, SOCIAL SECURITY AND HOUSE FUNDS

Labor Law, Labor Contract Law and its Implementation Regulations

Pursuant to the *PRC Labor Law* (《中華人民共和國勞動法》) promulgated by the Standing Committee of the NPC on July 5, 1994 and latest amended on December 29, 2018 and the *PRC Labor Contract Law* (《中華人民共和國勞動合同法》) promulgated by the Standing Committee of the NPC on June 29, 2007 and latest amended on December 28, 2012, employers must execute written labor contracts with full-time employees. All employers must comply with local minimum wage standards. Employers must establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions. Violations of the *PRC Labor Contract Law* and the *PRC Labor Law* may result in the imposition of fines and other administrative and criminal liability in the case of serious violations.

Regulations on Social Insurance and Housing Provident Funds

In addition, according to the *PRC Social Insurance Law* (《中華人民共和國社會保險法》) promulgated on October 28, 2010 by the Standing Committee of the NPC and latest amended on December 29, 2018, the *Interim Regulations on the Collection and Payment of Social Security Funds* (《社會保險費徵繳暫行條例》) promulgated by the State Council on January 22, 1999 and latest amended on March 24, 2019, and the *Regulations on the Administration of Housing Provident Funds* (《住房公積金管理條例》) promulgated by the State Council on April 3, 1999 and latest amended on March 24, 2019, employers like our PRC subsidiary in China must provide employees with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, work-related injury insurance, medical insurance and housing funds. These payments are made to local administrative authorities, and any employer who fails to contribute may be fined and ordered to pay the deficit amount within a stipulated time limit.

LAWS AND REGULATIONS RELATING TO TAXATION

Regulations on Enterprise Income Tax

Pursuant to the *PRC Enterprise Income Tax Law* (《中華人民共和國企業所得税法》) effective as of January 1, 2008 and latest amended on December 29, 2018, the income tax rate for both domestic and foreign-invested enterprises is 25% with certain exceptions. To clarify certain provisions in the *PRC Enterprise Income Tax Law*, the State Council promulgated the *Implementation Rules of the Enterprise Income Tax Law* (《中華人民共和國企業所得税法實施條例》) on December 6, 2007, which was latest amended and became effective on April 23, 2019. Under the *PRC Enterprise Income Tax Law* and the *Implementation Rules of the PRC Enterprise Income Tax Law*, enterprises are classified as either "resident enterprises" or "non-resident enterprises." Aside from enterprises established within the PRC, enterprises established outside of China whose "de facto management bodies" are located in China are considered "resident enterprises" and are subject to the uniform 25% enterprise income tax rate for their global income. In addition, the *PRC Enterprise Income Tax Law* provides that a non-resident enterprise refers to an entity established under foreign law whose "de facto management bodies" are not within the PRC, but has an establishment or place of business in the PRC, or does not have an establishment or place of business in the PRC but has income sourced within the PRC.

The *Implementation Rules of the PRC Enterprise Income Tax Law* provide that since January 1, 2008, an income tax rate of 10% shall normally be applicable to dividends declared to non-PRC resident enterprise investors that do not have an establishment or place of business in the PRC, or 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. The income tax on the dividends may be reduced pursuant to a tax treaty between China and the jurisdictions in which the non-PRC shareholders reside.

According to the *Notice of the State Administration of Taxation on Delivering the Table of Negotiated Dividends and Interest Rates to Lower Levels* (《關於下發協定股息税率情況一覽表的通知》) issued on January 29, 2008, latest revised on February 29, 2008, and the *Arrangement between Mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with Respect to Taxes on Income* (《內地和香港特別行政區關於對所得避免雙重徵税和防止偷漏税的安排》), or Double Tax Avoidance Arrangement, the withholding tax rate in respect of the payment of dividends by a PRC enterprise to a Hong Kong enterprise may be reduced to 5% from a standard rate of 10% if the Hong Kong enterprise directly holds at least 25% of the PRC enterprise and certain other conditions are met, including: (i) the Hong Kong enterprise must directly own the required percentage of equity interests and voting rights in the PRC resident enterprise; and (ii) the Hong Kong enterprise must have directly owned such required percentage in the PRC resident enterprise throughout the 12

months prior to receiving the dividends. However, based on the Circular on Certain Issues with *Respect to the Enforcement of Dividend Provisions in Tax Treaties* (《關於執行税收協定股息條款有關問題的通知》) 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* (《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 from 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.

Regulations on Value Added Tax

Pursuant to the *Provisional Regulations of the PRC on Value-added Tax* (《中華人民共和國增值税暫行條例》), promulgated by the State Council on November 19, 2017, *the Detailed Rules for the Implementation of the Provisional Regulations of the PRC on Value-added Tax* (《中華人民共和國增值税暫行條例實施細則》), promulgated by the Ministry of Finance and the SAT on December 15, 2008 and latest amended and came into effect on November 1, 2011 (collectively, the "VAT Law"), all enterprises and individuals engaged in the sale of goods, the provision of processing, repairing and replacement of services, and the importation of goods within the territory of the PRC must pay value added tax ("VAT"). On November 19, 2017, the State Council promulgated *The Decisions on Abolition of the Provisional Regulations of the PRC on Business Tax and Revision of 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〉的決定》), or Order 691. According to the VAT Law and Order 691, all enterprises and individuals engaged in the sale of goods, the provision of processing, repairing and replacement of services, sales of services, intangible assets, real property and the importation of goods within the territory of the PRC must pay VAT. The VAT tax rates generally applicable are simplified as 17%, 11%, 6% and 0%, and the VAT tax rate applicable to the small-scale taxpayers is 3%. The *Notice of the Ministry of Finance and the State Administration of Taxation on Adjusting Value-added Tax Rates* (《財政部、國家税務總局關於調整增值税税率的通知》), or the Notice, was promulgated on April 4, 2018 and came into effect on May 1, 2018. According to the Notice, the VAT tax rates of 17% and 11% are changed to 16% and 10%, respectively. On March 20, 2019, the Ministry of Finance, State Taxation Administration and General Administration of Customs jointly promulgated the *Announcement on Policies for Deeping the VAT Reform* (《關於深化增值税改革有關政策的公告》), or Notice 39, which came into effect on April 1, 2019. Notice 39 further changes the VAT tax rates of 16% and 10% to 13% and 9% respectively.

LAWS AND REGULATIONS RELATING TO ENVIRONMENT PROTECTION

Pursuant to the *Environmental Protection Law of the PRC* (《中華人民共和國環境保護法》) promulgated by the SCNPC, on December 26, 1989, latest amended on April 24, 2014 and effective on January 1, 2015, any entity which discharges or will discharge pollutants during course of operations or other activities must implement effective environmental protection safeguards and procedures to control and properly treat waste gas, waste water, waste residue, dust, malodorous gases, radioactive substances, noise vibrations, electromagnetic radiation and other hazards produced during such activities. According to the provisions of the *Environmental Protection Law*, in addition to other relevant laws and regulations of the PRC, the Ministry of Environmental Protection and its local counterparts take charge of administering and supervising said environmental protection matters.

Pursuant to the *Environmental Protection Law*, the environmental impact statement on any construction project must assess the pollution that the project is likely to produce and its impact on the environment, and stipulate preventive and curative measures; the statement shall be submitted to the competent administrative department of environmental protection for approval. Installations for the prevention and control of pollution in construction projects must be designed, built and commissioned together with the principal part of the project.

Permission to commence production at or utilize any construction project shall not be granted until its installations for the prevention and control of pollution have been examined and confirmed to meet applicable standards by the appropriate administrative department of environmental protection that examined and approved the environmental impact statement. Installations for the prevention and control of pollution shall not be dismantled or left idle without authorization. Where it is absolutely necessary to dismantle any such installation or leave it idle, prior approval shall be obtained from the competent local administrative department of environmental protection.

Pursuant to the *Law of the People's Republic of China on Environment Impact Assessment* (《中華人民共和國環境影響評價法》), which was issued on October 28, 2002 and latest amended on December 29, 2018, the State implements a classification-based management on the environmental impact assessment, or EIA, of construction projects according to the impact of the construction projects on the environment. Construction units shall prepare Environmental Impact Report, or EIR, or Environmental Impact Statement, or EIS, or fill out the Environmental Impact Registration Form, or EIRF.

LAWS AND REGULATIONS RELATING TO FIRE PROTECTION

Fire Protection Design Approval and Filing

The *Fire Prevention Law of the PRC* (《中華人民共和國消防法》), or the Fire Prevention Law, was adopted on April 29, 1998 and latest amended on April 23, 2019. According to the Fire Prevention Law and other relevant laws and regulations of the PRC, the emergency management authority of the State Council and its local counterparts at or above county level shall monitor and administer the fire prevention affairs. The fire and rescue department of such a people's government are responsible for implementation. The Fire Prevention Law provides that the fire prevention design or construction of a construction project must conform to the national fire prevention technical standards (as the case may be). According to *Provisions on the Supervision and Administration of Fire Protection of Construction Projects* (《建設工程消防監督管理規定》), or the Fire Protection Supervision Provisions, issued on April 30, 2009 and voided on June 1, 2020, for those construction projects with more than 500 square meters, the construction entity shall apply to the fire prevention department of a public security authority for fire protection design approval. For the construction projects other than the conditions foregoing, the construction entity shall, within seven days of obtaining the construction permit of the project, submit the fire protection filing for fire protection design through the website of the fire prevention department of the public security authority at the provincial level or at the service office of the fire prevention department of the public security authority. For a construction project whose investment is less than RMB300,000 or whose construction area is less than 300 square meters, the fire protection design approval or filing is not required.