Our business operations are primarily in the PRC and subject to regulation by the PRC government. This section provides (i) an introduction of the primary PRC government authorities with jurisdiction over our operations; and (ii) an overview of the laws, regulations and policies with which we must comply.

REGULATORY AUTHORITIES

NMPA and CDE

The National Medical Products Administration ("NMPA"), formerly known as the China Food and Drug Administration (國家食品藥品監督管理總局), is the competent authority for China's pharmaceutical industry. It is responsible for drawing up the laws and regulations relating to pharmaceuticals, vaccines and medical devices, formulating policies and plans, formulating departmental regulations, organizing the formulation and issuance of standards, classifications and management systems for pharmaceutical and medical devices, and supervising their implementation.

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

NHC

The National Health Commission (國家衛生健康委員會) ("NHC") is the primary supervisory unit for public health and family planning, and is mainly responsible for organizing the formulation of national health policies, coordinating and promoting the deepening of the reform of the medical and health system, formulating and organizing the implementation of disease prevention and control planning and national immunization planning, and organizing the formulation of national drug policies and the national system of basic medicines, among other things.

NIFDC

The National Institutes for Food and Drug Control (中國食品藥品檢定研究院) ("NIFDC") is a public institution directly subordinate to NMPA and the statutory authority and the supreme technical arbitration institution for inspecting the quality of pharmaceuticals and biological products in the country, and undertakes the implementation of approval and registration testing, import testing, supervision and inspection, safety evaluation and approval and issuance of biological products in various fields, such as drugs, biological products, medical devices, food, health food, cosmetics, experimental animals, packaging materials, etc., in accordance with the law. It is also in charge of the research, distribution and management of the national standard substances for drugs and medical devices, and the bacterial strains used for production and testing, as well as carrying out the related technical research work.

China CDC

The Chinese Center for Disease Control and Prevention (中國疾病預防控制中心) ("China CDC") is a public institution directly subordinate to the National Disease Control and Prevention Administration (國家疾病預防控制局). It is primarily responsible for carrying out disease prevention and control and responding to public health emergencies, providing technical support and consulting suggestions for the formulation of public health laws, regulations, policies, plans and projects, monitoring infectious diseases, public health emergencies and suspected abnormal reactions to inoculation as well as the monitoring and evaluation of the national health status. It carries out investigations and risk assessments of major public health problems, researches and formulates intervention measures for major public health problems and national immunization plans and organizes their implementation, guides localities in the implementation of national disease prevention and control plans and projects, and provides operational guidance to local disease prevention and control institutions.

NDRC

The National Development and Reform Commission (國家發展和改革委員會) ("NDRC") is a ministerial-level department of the State Council. NDRC is primarily responsible for formulating and organizing the implementation of national economic and social development strategies, medium and long-term development plans and annual plans, participating in the formulation of health development policies, setting up investment projects for technological reforms, providing macro guidance and management of the economic performance of pharmaceutical enterprises, and overseeing the implementation of the relevant policies and regulations. It monitors and forecasts changes in drug prices and puts forward price control objectives and policy recommendations.

MOFCOM

The Ministry of Commerce (商務部) ("MOFCOM") is responsible for providing macro guidance on foreign investment affairs throughout the country, drafting policies, laws, regulations and rules on foreign investment, guiding the approval and filing of foreign investment, and formulating the Special Administrative Measures for Foreign Investment Entry (Negative List) (《外商投資准入特別管理措施(負面清單)》) and the Catalog of Industries Encouraging Foreign Investment (《鼓勵外商投資產業目錄》) with NDRC.

NHSA

The National Healthcare Security Administration (國家醫療保障局) ("NHSA") is mainly responsible for formulating draft laws and regulations, policies, plans and standards for medical insurance, maternity insurance, medical assistance and other medical security systems, organizing the formulation and adjustment of prices and fees for medicines and medical services, and formulating and supervising the implementation of policies on bidding and procurement of medicines and medical consumables.

REGULATORY PROVISIONS

Laws and Regulations Relating to Drugs

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) promulgated by the Standing Committee of the NPC in September 1984 and most recently amended on August 26, 2019 and effective since December 1, 2019, and the Implementation Regulations of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》) promulgated by the State Council in August 2002 and most recently amended on November 22, 2024, set forth the legal framework for the establishment and maintenance of pharmaceutical manufacturing enterprises, as well as for the administration of pharmaceutical products.

Pursuant to the Vaccine Administration Law of the People's Republic of China (《中華人民共和國疫苗管理法》) promulgated by the Standing Committee of the NPC on June 29, 2019 and effective since December 1, 2019, vaccines refer to the preventive biological products used for human immunization in order to prevent and control the occurrence and prevalence of diseases. These vaccines include two categories: Class I vaccines are provided by the Chinese government to its citizens free of charge and should be administered in accordance with relevant government regulations. These include vaccines determined in the national immunization program, additional vaccines required by provincial governments in implementing national immunization programs and vaccines used in emergency vaccination or mass vaccination organized by the government at the county level or above, or their respective healthcare departments. Class II vaccines are those voluntarily vaccinated by citizens in China, with the cost paid by the recipient.

The General Office of the State Council promulgated Opinions on Further Enhancing Administration of Circulation and Vaccination of Vaccines (《關於進一步加強疫苗流通和預防接種管理工作的意見》) on January 15, 2017, which requires the strengthening of the management of the whole process of vaccine circulation, including the standardization of centralized procurement of vaccines, the enhancement of vaccine cold-chain distribution management and the strengthening of the whole process of vaccine traceability management.

Non-clinical Research

The Good Laboratory Practices for Nonclinical Drug Research (《藥物非臨床研究質量管理規範》), promulgated by the China Food and Drug Administration on July 27, 2017 and became effective since September 1, 2017, is a code to be followed for activities related to non-clinical safety evaluation studies of drugs, and other preclinical research activities related to drugs for the purpose of registration are also referred to this code.

Pursuant to the Measures for the Certification and Management of Non-clinical Drug Research Quality Management Practices (《藥物非臨床研究質量管理規範認證管理辦法》) promulgated by the State Food and Drug Administration on April 16, 2007, revised on January 19, 2023 and implemented on July 1, 2023, the NMPA is responsible for the examination of materials related to the GLP certification, on-site inspections and comprehensive evaluation, as well as the implementation of the supervision and inspection of the relevant institutions and other work.

Animal Testing

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 (now known as the Ministry of Science and Technology) in November 1988 and recently amended by the State Council in March 2017, the Administration Measures on Good Practice of Experiment-use Animals (《實驗動物質量管理辦法》) promulgated by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision in December 1997, and the Administrative Measures on the Certificate for Experiment-use 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 in December 2001, the use of laboratory animals for scientific research and experiments requires a license.

Clinical Trial

Pursuant to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) promulgated by the State Administration for Market Regulation on January 22, 2020, which became effective on July 1, 2020, drug clinical trials shall be conducted before a drug is listed for registration. If an applicant submits an application for drug clinical trials after completing the pharmacology, pharmacology toxicology and other studies supporting the drug clinical trial, it shall submit relevant research information in accordance with the requirements of the declaration information. The relevant authorities should reach a decision on whether to approve the application for drug clinical trials within sixty days from the date of acceptance, and notify the applicant of the approval results through the CDE website. If the notification is not provided within this timeframe, it is deemed that the applicant is permitted to proceed with the drug clinical trials in accordance with the program.

Pursuant to the Administrative Provisions on Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), promulgated by the NMPA and NHC on November 29, 2019 and effective since December 1, 2019, the commencement of clinical trials of drugs should be carried out in drug clinical trial institutions; drug clinical trial institutions should comply with the conditions stipulated in the "Administrative Provisions on Drug Clinical Trial Institutions" and be filed in the State Drug Supervision and Administration Department.

When conducting a clinical trial, all parties involved must comply with the procedural requirements of the Good Practice for Clinical Trials of Drugs (《藥物臨床試驗質量管理規範》) most recently amended by NMPA and NHC on April 23, 2020 and effective since July 1, 2020, which stipulates the requirements for the procedures of conducting clinical trials, including preclinical trial preparations, trial protocols, protection of the rights and interests of the subjects, the duties of the investigators, sponsors and supervisors, as well as the management of data and statistical analyses.

Approval and Filing of Human Genetic Resources

The Administrative Regulations of the People's Republic of China on the Management of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》) was promulgated by the State Council on May 28, 2019 and became effective on July 1, 2019, and was revised on March 10, 2024 by the State Council. Pursuant to the Regulations, for the purpose of obtaining marketing authorization for relevant medicines and medical devices in China, no approval is required for the use of China's human genetic resources in clinical institutions to conduct international collaborative clinical trials, provided that these materials do not involve the export of human genetic resource materials. However, both the Chinese and international parties involved in the clinical collaboration shall file the types and quantities of human genetic resources to be used and their uses with the competent health authorities of the State Council before conducting clinical trials.

The Biosecurity Law of the People's Republic of China (《中華人民共和國生物安全法》) was promulgated by the Standing Committee of the NPC on October 17, 2020 and became effective on April 15, 2021, and was most recently amended on April 26, 2024. This law clarifies the State's sovereignty over human genetic and biological resources in the country.

Drug Registration

Pursuant to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), an applicant shall upon completion of pharmacy, pharmacology and toxicology and clinical trial of drugs etc. to support registration of drug marketing, determination of quality standards, verification of commercial scale manufacturing process, and preparation to undergo examination and inspection for drug registration, submit an application for drug marketing authorization. The CDE is responsible for reviewing for accepted drug marketing authorization applications. Where the application is cleared after comprehensive review, the drug shall be approved for marketing and a drug registration certificate shall be issued. An applicant who has obtained a drug registration certificate shall be a drug marketing authorization holder ("MAH").

Drug Manufacturing

Pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》), drug registration applicants must obtain a drug manufacturing certificate to undertake drug manufacturing. Those without a drug manufacturing license are not allowed to manufacture drugs.

Pursuant to the Administrative Measures on Supervision of Pharmaceutical Manufacturing (《藥品生產監督管理辦法》) promulgated by the State Administration of Market Regulation on January 22, 2020 and effective since July 1, 2020, a drug manufacturing certificate shall be valid for five years, and the holder of a drug manufacturing license shall apply to the original issuing authorities for reissuance of a drug manufacturing certificate at least six months prior to the expiration of the validity period.

The Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》), most recently amended on January 17, 2011 and effective since March 1, 2011, comprises a set of detailed standard guidelines governing the manufacture of drugs, including institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, raw material management, maintenance of sales records and manner of handling customer complaints.

Lot Release of Vaccines

Pursuant to the Measures for the Administration of Lot Release of Biological Products (《生物製品批簽發管理辦法》) promulgated on December 13, 2002 and most recently amended on December 11, 2020 and effective since March 1, 2021, the vaccine products with marketing approval shall be subject to document review and sample inspection by drug lot release institutions designated by the NMPA and shall pass the biological product lot release approval before the marketing and sales of each batch of products. The NMPA has established a unified information platform for the lot release of biological products. This platform publishes information about the lot release institutions, any adjustments made, major issue resolution decisions, and provides applicants with access to query the progress and conclusion of lot releases. Additionally, it promptly publishes information on products that have passed lot release for public inquiry.

Circulation of Vaccines

According to the Opinions on Further Enhancing Administration of Circulation and Vaccination of Vaccines (《關於進一步加強疫苗流通和預防接種管理工作的意見》), vaccines should be procured online in accordance with the principles of transparency, competition and fair dealing.

The procurement of Class II vaccines shall be organized by provincial CDCs through provincial public resources trading platforms. The price of vaccines shall be set reasonably and independently by the vaccine MAH, and the price level, price difference rate and profit rate of vaccines shall be kept within a reasonable range. A vaccine MAH shall, as agreed upon in the procurement contract, deliver vaccines to the relevant CDC or the points of vaccination ("POV") designated thereby.

Storage and Transportation of Vaccines

Pursuant to the Vaccine Administration Law of the People's Republic of China (《中華人民共和國疫苗管理法》), the vaccine MAHs and CDCs that distribute vaccines themselves shall have the conditions for cold chain storage and transport of vaccines or may entrust eligible vaccine distribution entities to distribute vaccines. The whole process of storage and transport of vaccines shall be subject to prescribed temperatures, and the cold chain storage and transport shall meet the relevant requirements, and the temperature shall be regularly monitored and recorded.

According to the Distributing Regulations on Administration of Vaccine Storage and Transportation (《疫苗儲存和運輸管理規範》) promulgated by the NMPA and NHC on December 15, 2017, vaccine manufacturers are required to equip full-time staff for vaccine management, establish a management system for vaccine storage and transportation, maintain cold-chain facilities and equipments for the storage and transportation of vaccines in order to ensure the quality of vaccines, and are required to store and transport vaccines in accordance with the instructions for the use of vaccines, the working rules for vaccines and other relevant regulations on vaccine storage and transportation temperature.

Administration of Vaccines after Marketing

Pursuant to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), the MAH shall proactively conduct drug post-marketing research, further confirm the safety, effectiveness and quality control of the drug, and strengthen continuous management of marketed drug.

Pursuant to the Vaccine Administration Law, the vaccine MAH shall establish and improve the quality management system for the whole life cycle of a vaccine, formulate and implement the risk management plan after the vaccine is marketed, carry out studies after the vaccine is marketed, and further confirm the safety, effectiveness and quality controllability of the vaccine. With respect to a vaccine for which the requirements for further study are put forward when the application for registration of the vaccine is approved, the vaccine MAH shall complete the study within the prescribed time limit. If it fails to complete the study within the time limit or is unable to prove that the benefits outweigh the risks, the NMPA shall deal with the matter in accordance with law until its drug registration certificate is nullified.

The vaccine MAH shall continuously update the instructions and labels based on the research conducted after the vaccine is marketed and Monitoring Program for Adverse Events Following Immunization ("AEFI") and shall apply for approval or filing in accordance with the provisions. The NMPA shall, in a timely manner, release the updated contents of the vaccine instructions and labels on its website.

Laws and Regulations Relating to Environmental Protection and Fire Prevention

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 and most recently amended on April 24,2014 and effective since January 1, 2015, the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》), promulgated by the SCNPC on October 28, 2002 and most recently amended on December 29, 2018, and the Administrative Regulations on the Environmental Protection of Construction Project (《建設項目環境保護管理條例》), promulgated by the State Council on November 29, 1998 and most recently amended on July 16, 2017 and effective since October 1, 2017, the State shall implement classified administration of environmental impact assessment for construction projects in accordance with the degree of environmental impacts of construction projects; and the construction entity shall produce environmental impact reports and environmental impact statements or complete environmental impact registration forms pursuant to the laws and regulations.

Pursuant to the Administrative Measures for Pollutant Discharge Licensing (《排污許可管理辦法》) promulgated on April 1, 2024 and effective since July 1, 2024 by the Ministry of Ecological Environment (生態環境部), as well as the Regulation on Pollutant Discharge Permit Administration (《排污許可管理條例》) promulgated by the State Council on January 24, 2021, the enterprises, public institutions and other producers and operators shall be subject to the key management, simplified management of pollutant discharge licensing and pollutant discharge registration management according to the quantity of pollutants generated and discharged, the impact on the environment and other factors. Entities subject to pollutant discharge licensing administration in accordance with the law shall apply for a pollutant discharge permit in accordance with the law and discharge pollutants as stipulated in the pollutant discharge permit. No pollutants may be discharged without such permit. The period of validity of a pollutant discharge permit is five years. Should a pollutant discharging entity need to continue discharging pollutants upon the expiration of the permit, it must apply to the approving department 60 days before the expiration of the pollutant discharge permit.

Pursuant to Categorized Management Catalog of Pollutant Discharge Permits for Stationary Sources of Pollution (2019 Edition) (《固定污染源排污許可分類管理名錄(2019年版)》) issued on December 20, 2019 by the Ministry of Ecological Environment, the State implements key management, simplified management and registration-based management of pollutant discharge permits according to factors such as the quantity of pollutants generated and discharged and the degree of impact on the environment. Pollutant discharging entities subject to registration-based management are not required to apply for a pollutant discharge permit.

Laws and Regulations Relating to Data Compliance

The Cybersecurity Law of the People's Republic of China (《中華人民共和國網絡安全法》), promulgated by the Standing Committee of the NPC on November 7, 2016 and effective since June 1, 2017, requires network operators to adopt technical and other necessary measures to ensure security of personal data and safeguard against information leakage, damage or loss.

On June 10, 2021, the Standing Committee of the NPC promulgated the Data Security Law of the People's Republic of China (《中華人民共和國數據安全法》) which became effective on September 1, 2021. The Data Security Law provides that "data" refers to any recording of information by electronic or other means and "data processing" includes the collection, storage, use, processing, transmission, availability and disclosure of data, etc. Data processors shall establish and improve the whole-process data security management rules, organize and implement data security training as well as take appropriate technical measures and other necessary measures to protect data security.

On December 28, 2021, the Cyberspace Administration of China, together with other government departments, promulgated the Measures for the Cybersecurity Review (《網絡安全審查辦法》), which became effective on February 15, 2022. Pursuant to the Measures, the online platform operators possessing personal information of more than one million users who are applying for foreign listing, must make declaration for cybersecurity review with the Office of Cybersecurity Review.

Pursuant to the Civil Code of the People's Republic of China (《中華人民共和國民法典》), which was promulgated by the NPC on May 8, 2020 and became effective on January 1, 2021, the personal information of an individual shall be protected. Any organization or individual must legally obtain the personal information of any person when necessary and ensure its safety, and shall not illegally collect, use, process or transmit such personal information, or illegally buy or sell, provide or make public such personal information. A natural person has the privacy right and provisions on the privacy right shall apply to the private information included in personal information.

The Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), promulgated by the Standing Committee of the NPC on August 20, 2021 and effective since November 1, 2021, stipulates the scope of personal information and establishes rules for processing personal information onshore and offshore. The Law sets forth certain specific personal information protection requirements, including but not limited to detailed inform and consent requirements in various contexts, enhanced and categorized obligations of personal information processors, and additional limitations and rules on the processing of personal information.

Laws and Regulations Relating to Product Liability

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

Pursuant to the Civil Code of the People's Republic of China (《中華人民共和國民法典》), where a patient suffers damage due to defects in drugs, disinfectants or medical equipment, or receipt of transfusion of unqualified blood, the patient may seek compensation from the drug MAH, manufacturer, blood supply institution or medical institution.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》) was promulgated on October 31, 1993 and most recently amended on October 25, 2013 and came into effect on March 15, 2014 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with the law when they manufacture or sell goods and/or provide services to customers. All business operators must pay high attention to protecting customers' privacy and must strictly keep confidential any consumer information they obtain during their business operations.

Laws and Regulations Relating to Intellectual Property

Patent

The Patent Law of the People's Republic of China (《中華人民共和國專利法》) was most recently revised on October 17, 2020 and became effective on June 1, 2021. The duration of patent rights for an invention shall be 20 years and the duration of patent rights for a utility model shall be 10 years, commencing from the filing date. Following the grant of patent rights for an invention or a utility model, unless otherwise stipulated in this Law, no organization or individual shall implement the patent without a specific license from the patentee; they shall not manufacture, use, offer to sell, sell or import such patented products for manufacturing and business purposes, nor use the patented method and use, offer to sell, sell or import products obtained directly according to the patented method. Implementation of a patent without licensing of the patentee shall constitute an infringement of patent rights. Disputes arising therefrom shall be negotiated and resolved by the parties concerned. Where the parties concerned are not willing to negotiate or the negotiation is unsuccessful, the patentee or an interested party may file a lawsuit with a people's court, or request the patent administrative authority to handle the matter.

Trademark

The Trademark Law of the People's Republic of China (《中華人民共和國商標法》) was most recently revised on April 23, 2019 and became effective on November 1, 2019. A registered trademark shall be valid for 10 years, commencing from the date of registration. Upon expiry of the validity period of a registered trademark, where the trademark registrant intends to continue using the trademark, it shall complete renewal formalities pursuant to the provisions within the 12-month period before the expiry date. The validity period of each renewal shall be 10 years. In case of infringement of the exclusive rights of use of registered trademarks, the trademark registrant or a stakeholder may file a lawsuit with a People's Court or request that the administration for industry and commerce to handle the dispute.

Copyright

The Copyright Law of the People's Republic of China (《中華人民共和國著作權法》) was most recently amended on November 11, 2020 and became effective on June 1, 2021. For the purpose of this Law, works shall refer to original intellectual achievements in the fields of literature, art and science which can be expressed in a certain form, including fine arts and computer software, among others. Chinese citizens, legal persons or organizations without legal personality enjoy copyright over their works, regardless of whether they have been published.

Domain Names

The Administrative Measures on the Internet Domain Names (《互聯網域名管理辦法》) was promulgated by the Ministry of Industry and Information Technology (工業和信息化部) ("MIIT") on August 24, 2017 and became effective on November 1, 2017. The MIIT is the primary regulatory authority responsible for the administration of internet domain names in the PRC. Domain names registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration. Communications administrative bureaus at provincial levels shall conduct supervision and administration of the domain name services within their respective administrative jurisdictions.

Laws and Regulations Relating to Labor Protection

Pursuant to Labor Contract Law of the People's Republic of China (Revision 2012)《中華人民共和國劳動合同法(2012修正)》, an employer shall be deemed to have established a labor relationship with a worker with effect from the date of commencement of work. Employers shall establish and improve upon labor rules and system pursuant to the law to ensure workers' entitlement to labor rights and performance of labor obligations. A secondment employer shall provide the corresponding working conditions and labor protection, and promptly pay labor remuneration in full amount.

Pursuant to Social Security Law of the People's Republic of China (Revision 2018) (《中華人民共和國社會保險法(2018修正)》), the State shall establish social security systems such as basic pension insurance, basic medical insurance, work injury insurance, unemployment insurance, family planning insurance, among others, and the employer shall complete social security registration with the social security agency for its employee within 30 days from the date of recruitment; where an employer failed to promptly contribute social security premiums in full amount, the social security premiums collection agency shall order the employer to make or supplement contributions within a stipulated period.

Pursuant to Regulations on the Housing Provident Fund (Revision 2019) (《住房公積金管理條例(2019修訂)》), when employing a new employee, the employer shall make registration of contribution with the housing provident fund management center within 30 days from the date of the employment and shall go through the formalities of opening or transferring housing provident fund accounts on behalf of the employee. Where an employer is overdue in contributing to, or underpays, the housing provident fund, the housing provident fund management center shall order it to make the contribution within a prescribed time limit; where the contribution has not been made after the expiration of the time limit, an application may be made to a people's court for compulsory enforcement.

Laws and Regulations Relating to Taxation

Enterprise Income Tax ("EIT")

In accordance with the PRC Enterprise Income Tax Law (《中華人民共和國企業所得税法》) promulgated on March 16, 2007 and most recently amended on December 29, 2018, and the Regulation on the Implementation of Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得税法實施條例》) promulgated on December 6, 2007 and most recently amended on November 22, 2024, enterprises are classified as either "resident enterprises" or "non-resident enterprises". The "resident enterprises" are defined as enterprises set up in the PRC under the PRC laws or set up according to the foreign country/region's law whereas whose actual or de facto control is administered from within the PRC. Enterprises established under the foreign country/region's law with "de facto management bodies" outside the PRC, but have set up institutions or establishments in the PRC or, without institutions or establishments set up in the PRC, have income originating from the PRC, shall be considered as "non-resident enterprises". A resident enterprise shall pay EIT on its income originating from both inside and outside the PRC at an EIT rate of 25%. A non-resident enterprise that has establishments or places of business in the PRC shall pay EIT on its income originating from the PRC obtained by such establishments or places of business, and on its income which is derived outside PRC but has an actual connection with such establishments or places of business, at the EIT rate of 25%. A non-resident enterprise that does not have an establishment or place of business in the PRC, or it has an establishment or place of business in the PRC but the income has no actual connection with such establishment or place of business, shall pay EIT on its passive income derived from the PRC at a reduced EIT rate of 10%.

Value-added Tax ("VAT")

Pursuant t to Provisional Regulations on Value-added Tax of the PRC (《中華人民共和國增值税暫行條例》) promulgated by the State Council on December 13, 1993, most recently amended on November 19, 2017, and the Detailed Rules for the Implementation of the Provisional Regulations of the People's Republic of China on Value-added Tax (《中華人民共和國增值税暫行條例實施細則》) promulgated on December 18, 2008 and revised on October 28, 2011, organizations and individuals engaging in the sale of goods, or the provision of processing, repair and assembly services; the sale of services, intangible assets, immovable properties; and the importation of goods in the PRC shall be taxpayers of VAT, and shall pay VAT pursuant to these Regulations. The amount of VAT payable is calculated as "output VAT" minus "input VAT". Pursuant to the VAT Regulations, the rate of VAT is 17% for those engaging in the sale of goods or labor services or tangible personal property leasing services or importation of goods except as otherwise provided by the VAT Regulations. The tax rate of VAT is 11% for the sales of the service of transportation, posting, basic telecommunications, construction and leasing real estate, the sale of real estate and the transfer of land use right, or sell or import the goods listed in the VAT Regulations.

Pursuant to the Notice of the Ministry of Finance and the State Administration of Taxation on the Adjustment of the VAT Rates (《財政部、國家税務總局關於調整增值税税率的通知》), which was promulgated on April 4, 2018 and became effective on May 1, 2018, the tax rates for taxpayers who have engaged in the act of VAT-taxable sales or who have imported goods to which the tax rates of 17% and 11% were originally applicable have been adjusted to 16% and 10%, respectively.

On March 20, 2019, Ministry of Finance, SAT and General Administration of Customs jointly issued the Announcement on Policies for Deepening the VAT Reform (《關於深化增值税改革有關政策的公告》) (effective on April 1, 2019.), or Circular 39, according to which for general VAT payers' sales activities or imports that are subject to VAT at a current applicable rate of 16% or 10%, the applicable VAT rate is adjusted to 13% or 9%, respectively.

Laws and Regulations Relating to Foreign Exchange

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

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

According to the Notice of SAFE on Reforming and Standardizing Capital Account Foreign Exchange Settlement Administration Policies (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) issued by SAFE on June 9, 2016, it has been specified clearly in the relevant policies that, for the capital account foreign exchange income subject to voluntary foreign exchange settlement (including the repatriation of the proceeds from overseas listing), the domestic institutions may conduct the foreign exchange settlement at the banks according to their operation needs. The proportion of the capital account foreign exchange income subject to voluntary foreign exchange settlement was tentatively set as 100%, provided that SAFE may adjust the aforesaid proportion according to the international payment balance status in good time.

Laws and Regulations Relating to Overseas Securities Offering and Listing

The Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) was promulgated by the CSRC on February 17, 2023, and became effective on March 31, 2023. Pursuant to the Measures, domestic companies seek to offer or list securities overseas, both directly and indirectly, shall complete the filing procedures and report relevant information to the CSRC.